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A Strategic Framework for Start-Up Medical Device Manufacturing Companies in South Africa

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11 September 2019

DECLARATION

University of the Witwatersrand, Johannesburg

School of Mechanical, Industrial and Aeronautical Engineering

SENATE PLAGIARISM POLICY

Declaration by Students

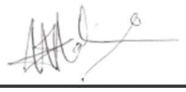
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ABSTRACT

An exploratory, qualitative study was conducted to establish the reasons why local medical device manufacturing firms are not starting up in South Africa. The South African medical device industry is growing at Compound Annual Growth Rate of 7.74%, while the number of medical device importers are increasing at a higher rate than the number of medical device manufacturers.

Semi-structured interviews were conducted with local medical device manufacturers to understand the market environment(s) companies operate in, the competitive environment(s) companies operate in as well as elements of strategy implemented within these companies. A deductive content analysis, comparative analysis and participant observation was conducted to achieve the objectives of this study.

A trend of stable company growth was identified across all medical device manufacturers. Local manufacturers were faced with highest competition from importers and distributors, including multinational companies. The most severe problems experienced by local manufacturers included irregularities and inconsistencies in the regulatory framework governing medical devices; the unreliability of raw material suppliers locally; importers and import duty structures; private sector penetration and the unavailability of funding and incentives.

The competitive forces with the highest impact on medical device manufacturers in South Africa were the barriers to entry and competitive rivalry in the market. Formalized strategies, however, were not key to the success of medical device companies. Success factors of local medical device manufacturers included brand representation, quality of products, reduced product costs through import substitutions, product innovation, being first to market and the level of after sales technical support.

Recommendations were made for medical device manufacturers to mitigate any potential problems that may be faced immediately by the company as well as for medical device regulations and future policy development in the industry. Included in this, is suggestion for regulations to be aligned to other successfully implemented regulatory frameworks across the world.

The study concluded with scope for future research which included developing marketing strategies to enhance brand representation; investigating problems with the medical device regulatory framework; as well as investigating the relationship between local manufacturers and the private healthcare sector in South Africa.

TABLE OF CONTENTS

Declaration ii

Abstract iii

Table of Contents iv

List of Figures x

List of Tables xi

Nomenclature xii

CHAPTER 1 Introduction 1

1.1 Research Background and Context 1

1.2 Problem Statement 4

1.3 Critical Research Question 5

1.4 Research Objectives 5

1.5 Research Method Summary 5

1.6 Research Scope 6

1.7 Research Limitations 6

1.8 Chapter Outline 6

CHAPTER 2 Literature Review 9

2.1 Competitive Forces in the Marketplace 9

2.1.1 The Threat of New Entrants 9

2.1.2 The Bargaining Power of Suppliers or Customers 10

2.1.3 The Threat of Substitute Products or Services 10

2.1.4 Jockeying for Position Among Current Competitors 11

2.1.5 Complementors and Competitors 11
2.1.6 Microforces within Competitive Forces 11
2.2 The Delta Model 15
2.3 Blue Ocean Strategy 18
2.4 Porter's 5 Forces vs The Delta Model vs Blue Ocean Strategy 20
2.5 The South African Market Environment 21
2.5.1 The Internal Environment 21
2.5.1.1 Company Demographics 21
2.5.1.2 Characteristics of the Entrepreneur 21
2.5.1.3 Entrepreneur Demographics 22
2.5.1.4 Previous Experience 22
2.5.2 The External Environment 23
2.5.2.1 Economic Factors 23
2.5.2.2 Policy-Institutional Factors 24
2.5.2.3 Socio-Cultural Factors 24
2.5.2.4 Market Opportunity Factors 25
2.5.3 Obstacles to Growth in South African SME's 26
2.6 The Medical Device Manufacturing Industry 26
2.7 Previous Research Conducted 28
2.8 Summary of Literature 29
CHAPTER 3 Research Method 30
3.1 Research Design 30
3.1.1 Drafting the Interview 31

3.1.2 Piloting the Questions 32
3.1.3 Selecting Interviewees 32
3.1.4 Conducting the Interviews 34
3.1.4.1 Interviews 34
3.1.4.2 Participant Observations 35
3.2 Data Collection and Analysis Procedures 36
3.2.1 Preparation 37
3.2.2 Organization 37
3.2.3 Reporting 38
3.3 Reliability and Validity 38
CHAPTER 4 Data Analysis and Results 41
4.1 Participant Overview 41
4.2 Deductive Content Analysis 42
4.2.1 The Business Environment 43
4.2.1.1 Founding Member Background 43
4.2.1.2 Company Operations 43
4.2.1.3 Raw Materials and Importation 44
4.2.2 The Market Environment 45
4.2.2.1 Competition 45
4.2.2.2 Obstacles to Growth 46
4.2.2.3 Regulatory Affairs 48
4.2.3 Strategic Objectives 49
4.2.3.1 Value Proposition 49
4.2.3.2 Overall Business Strategies 49

4.2.3.3 Survival Strategies 50
4.2.3.4 Growth Strategies 51
4.3 Comparative Analysis 52
4.3.1 Success Factors of SME's in South Africa 52
4.3.2 Obstacles to Growth in the South African Medical Device Industry 57
4.3.3 Strategic Frameworks 58
4.3.3.1 Porter's 5 Forces 59
4.4 Participant Observer Reflection 63
4.4.1 The Market Environment 64
4.4.2 The Regulatory Atmosphere 65
CHAPTER 5 Discussion 67
5.1 Competitive Forces 67
5.1.1 Medical Device Manufacturer Founding Members 68
5.1.2 Company Growth 68
5.1.3 Market Conditions 69
5.1.4 Raw Materials 69
5.1.5 Competition 70
5.1.6 The Regulatory Environment 71
5.1.7 Cash Flow 72
5.1.8 The Private Sector 72
5.1.9 Funding and Incentives 73
5.2 Internal and External Success Factors of South African SME's 73
5.2.1 Company Demographics 73
5.2.2 Economic Factors 73

5.2.3 Policy-Institutional Factors 74
5.2.4 Socio-Cultural Factors 74
5.2.5 Market Opportunity Factors 74
5.2.6 Obstacles to Growth 74
5.3 Strategy and Company Strategic Objectives 75
5.4 Participant Observations 78
5.5 Reliability and Validity 78
5.5.1 Triangulation 78
5.5.2 Low Inference Descriptors 79
5.5.3 Reflexivity 79
5.5.4 Participant Feedback 79
5.5.5 Dependability 79
5.5.6 Transferability 80
CHAPTER 6 Conclusions and Recommendations 81
6.1 Conclusions 81
6.2 Recommendations 82
6.3 Scope for Future Research 84
References 85
Appendices xiii
Appendix A – Interview Questions xiv
Appendix B – Purposeful Sampling Strategies xv
Appendix C – Ethics Documentation xvi

Appendix D – Interview Data xviii

Appendix E – Signed Documents and Researcher Notes xxv

Company A xxv

Company B xxviii

Company C xxxi

Company D xxxiv

Company E xxxvii

Company F xl

Appendix F – Participant Feedback xliii

Company D xliii

Company E xliii

Company F xliii

LIST OF FIGURES

Figure 1.1: South African Medical Devices Forecasted Growth & Sales (South African Medical Device Industry Association, 2014) 1

Figure 1.2: CAGR of Medical Device Imports and Export Quantities from 2013- 2018 (Deloitte & Touche; Department of Trade & Industry, 2014) 2

Figure 2.1: Porter's 5 Forces with Interdependencies (Grundy, 2006) 12

Figure 2.2: Bargaining Power of Customers - Micro Forces (Grundy, 2006) 13

Figure 2.3: Barriers to Entry - Micro Forces (Grundy, 2006) 13

Figure 2.4: Competitive Rivalry - Micro Forces (Grundy, 2006) 14

Figure 2.5: Substitute Products/Services - Micro Forces (Grundy, 2006) 14

Figure 2.6: Bargaining Power of Suppliers - Micro Forces (Grundy, 2006) 15

Figure 2.7: The Delta Model Strategic Positions (Hax & Wilde, 2003) 16

Figure 2.8: The Delta Model's Integrative Framework (Hax & Wilde, 2003) 17

LIST OF TABLES

Table 0.1: List of Abbreviations xii

Table 1.1: South African Medical Device Market Estimated Statistics (Department of Commerce USA, 2017) 2

Table 1.2: Forecasted National Healthcare Expenditure (R '000) (UNICEF, 2017) 3

Table 2.1: Comparative Matrix of 3 Strategic Approaches (Jussani, et al., 2010) 20

Table 4.1: Participant Information 42

Table 4.2: Company Sizes by Year Established 44

Table 4.3: Obstacles to Growth 47

Table 4.4: Issues in the Regulatory Environment 48

Table 4.5: Elements of Strategy Incorporated into Companies 50

Table 4.6: Company Survival Strategies 51

Table 4.7: Company Growth Strategies 52

Table 4.8: Comparative Analysis of SME Success Factors 53

Table 4.9: Competitive Forces Experienced in the Medical Device Industry Compared to Theoretical Forces 59

Table 4.10: Competitive Rivalry Microforces and South African Medical Device Manufacturers 61

Table 4.11: Entry Barrier Microforces and South African Medical Device Manufacturers 62

Table 4.12: The Delta Model and South African Medical Device Manufacturers 63

Table C.0.1: Raw Interview Data xviii

NOMENCLATURE

Table 0.1: List of Abbreviations

BB-BEE	Broad Based Black Economic Empowerment
CAGR	Compound Annual Growth Rate
CE	Conformité Européenne
DTI	Department of Trade and Industry
FDA	Food and Drug Administration
ISO13485	Medical Device Quality Management System for Regulatory Purposes
MCC	Medicines Control Council
MDMSA	Medical Device Manufacturers of South Africa
MRI	Magnetic Resonance Imaging
SABS	South African Bureau of Standards
SAHPRA	South African Health Products Regulatory Authority
SAMED	South African Medical Technology Industry Association
SME	Small to Medium Enterprises

CHAPTER 1 INTRODUCTION

1.1 Research Background and Context

The South African medical device industry is forecasted to grow at a Compound Annual Growth Rate (CAGR) of 7.74% between 2014 and 2018. (Deloitte & Touche; Department of Trade & Industry, 2014). However, this industry still remains underdeveloped as 90% of the US$1.2 billion market value is still imported. (South African Medical Technology Industry Association, 2014; Deloitte & Touche; Department of Trade & Industry, 2014)

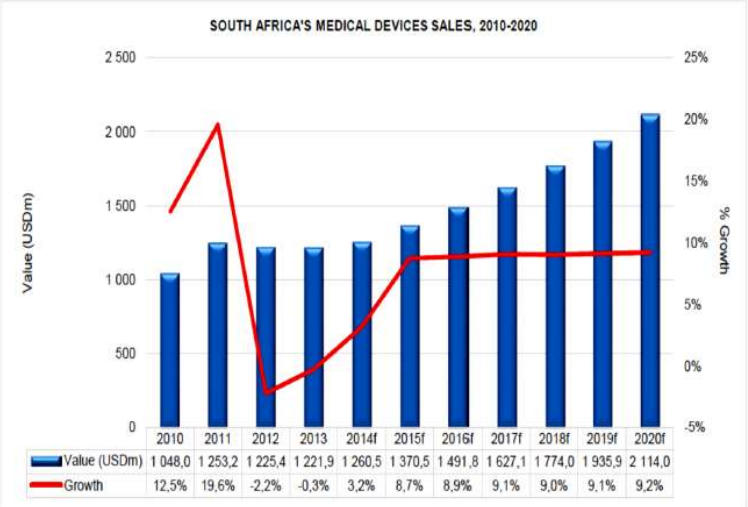


Figure 1.1: South African Medical Devices Forecasted Growth & Sales (South African Medical Device Industry Association, 2014)

The South African Medical Technology Industry Association (2014) forecasted the percentage growth of medical device sales in South Africa from 2014 to 2020 to be a minimum of 8.7%. *(Figure 1.1)* The percentage growth of medical devices imported into South Africa, however, were forecasted to grow at a CAGR of 12.65% from 2013 to 2018. *(Figure 1.2)*

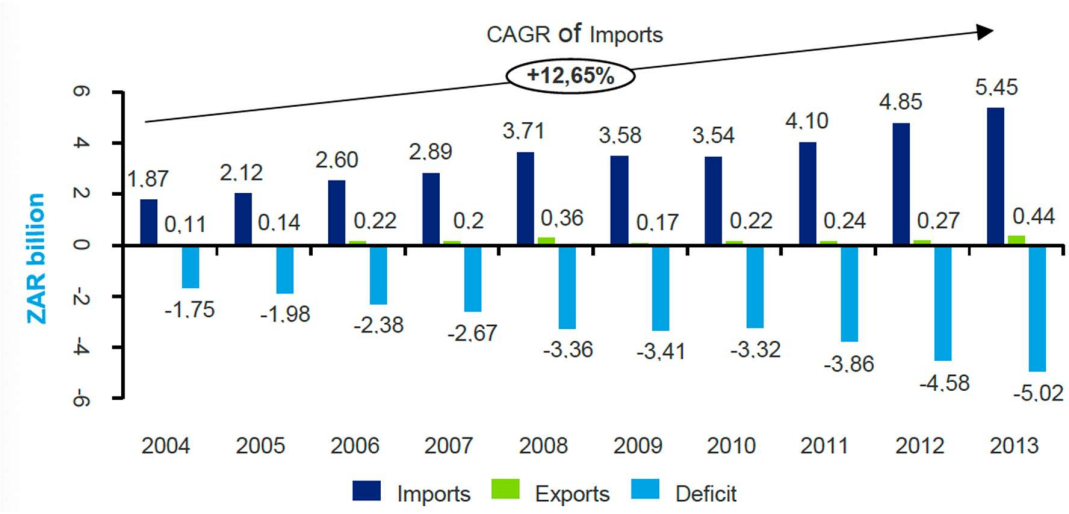


Figure 1.2: CAGR of Medical Device Imports and Export Quantities from 2013- 2018 (Deloitte & Touche; Department of Trade & Industry, 2014)

According to the Department of Commerce, USA (2017), the 2016 South African medical device market size was estimated at US$1.1 billion and was forecasted to grow approximately 41.5% in two years to 2018. (*Table 1.1*) Although the market size shows significant growth, the relative proportion of goods manufactured locally is forecasted to halve in two years. The sales of medical devices are however forecasted to continue growing rapidly until 2020. (*Figure 1.1*) Increasing local manufacturing has become a priority amongst government and Department of Trade and Industry strategic objectives. (The Department of Trade & Industry, 2018)

Table 1.1: South African Medical Device Market Estimated Statistics (Department of Commerce USA, 2017)

Year	**2016**	**2018 (estimated)**
Total Market Size (US$ million)	1102.3	1560.8
Total Local Manufacture (US$ million)	177.1	210.95
Total Imports (US$ million)	1038.2	933
% Imports to Market Size	94.1	59.8

Goals of the Department of Trade and Industry include facilitating the transformation of South Africa's economy to promote industrial development, investment, competitiveness and employment creation. (The Department of Trade and Industry, 2014) In addition to this,

strategic focus areas include chemicals, plastic fabrication and pharmaceuticals which include medical devices. (The Department of Trade and Industry, 2018)

South Africa's provincial government healthcare expenditure for people who do not have medical cover in the year 2015/2016 was R150 billion, which translated to R3 332 per capita. (StatsSA, 2017) Healthcare was the fourth largest item of government expenditure, 11%. (StatsSA, 2017) *Table 1.2* describes the increases in South African National healthcare expenditure as forecasted from 2017/2018 to 2019/2020 where MTEF refers to the Medium Term Expenditure Framework, a transparent planning and budget formulation process used by government departments. (National Treasury, 2018)

Table 1.2: Forecasted National Healthcare Expenditure (R '000) (UNICEF, 2017)

Description	2016/2017	2017/2018 MTEF	2018/2019 MTEF	2019/2020 MTEF
Administration	462	513	548	583
National Health Insurance, Health Planning and Systems Enablement	589	735	993	1047
HIV and AIDS, Tuberculosis and Maternal and Child Health	15 980	18 278	20 746	22 909
Primary Health Care Services	257	264	293	315
Hospitals, Tertiary Health Services and Human Resource Development	19 514	21 108	22 301	23 641
Health Regulation and Compliance Management	1 707	1 727	1 787	1 890
Total	38 507	42 626	46 667	50 385

1.2 Problem Statement

In order to achieve the strategic objectives set out by the Department of Trade and Industry, it is vital to increase South Africa's medical device manufacturing capacity. Despite governmental efforts to increase local manufacturing capacity in South Africa through grant schemes, funding schemes, exports and other incentives, the proportion of local manufacturers of medical devices to the total market size is decreasing. (*Table 1.1*)

The South African medical device industry is a highly competitive industry and small manufacturers are faced with multiple challenges that cause the companies to stagnate or fail. (Deloitte & Touche; Department of Trade & Industry, 2014) Although this is a growing industry in South Africa, there are diminishing numbers of new local manufacturing firms. (Deloitte & Touche; Department of Trade & Industry, 2014) Furthermore, the competitive forces experienced by firms in the medical device manufacturing industry largely determines the skills required for start-up companies to survive and be sustainable. (Maresova & Kuca, 2014)

Upon start-up, firms have to deal with numerous competitive forces, including multiple barriers to entry. These barriers include high capital investment, high research and development costs, legal restrictions and the regulatory atmosphere. (Maresova & Kuca, 2014) Competing with industry leaders is the most significant challenge for local start-up manufacturers. These manufacturers rely on protectionist trade barriers or some sort of other governmental support to survive. As a result, they either become subordinate partners to the bigger multinationals, or simply sell out and leave the industry. (Dawar & Frost, 1999)

No previous research has been conducted on the challenges faced by start-up local manufacturing firms within the South African medical device industry, which limited the data available. Consequently, there have been no directive frameworks developed for companies that wish to start-up in this industry. Research has been conducted to develop a strategy for South Africa's medical device industry including strategies for state-business relations, regulations and manufacturing incentives. (Deloitte & Touche; Department of Trade & Industry, 2014) Many of these strategies have since been implemented within the medical device industry in South Africa, but local companies have remained reluctant to enter this market.

The reluctance of local manufacturers could be attributed to several factors including the lack of directive or strategic frameworks, the regulatory atmosphere and other competitive forces

that may be experienced within the industry. In order to increase South Africa's manufacturing capacity within the medical device industry, it is important to understand the contributing factors to firms' reluctance to enter this market.

1.3 Critical Research Question

Why is there a lack of local manufacturers starting up in the South African medical device industry?

1.4 Research Objectives

- Develop a framework for the analyses of the competitive forces experienced by companies in the South African medical device manufacturing industry.
- Establish reasons that new companies are not starting up within the industry.
- Make recommendations including elements of strategy that may be used for a strategic framework to be developed to increase access into the South African medical device manufacturing industry.

1.5 Research Method Summary

This research consisted of qualitative research which was conducted through semi-structured interviews with South African medical device manufacturers. These interviews allowed the researcher to gain a deeper understanding of the competitive forces experienced by companies in the manufacturing industry, the limitations within the industry, the largest obstacles to growth faced, and key success factors in the firm's survival and growth.

Six interviews were conducted and all data obtained from interview participants were used in this research. Participants were sampled using a combination of extreme or deviant case sampling, critical case sampling, criterion sampling, chain sampling and maximum variation sampling was used.

Interview transcripts were subject to deductive content analysis and comparative analysis. (Hseif & Shannon, 2005) A deductive content analysis approach was used to conceptually support or extend existing frameworks. A comparative analysis was conducted where the similarities and differences of interview data and theoretical frameworks were discussed. The researcher, an active participant in the medical device industry, also provided a participant observer account of the South African medical device industry.

Multiple techniques were used to guarantee the reliability and validity of the study which are mentioned in *Section 3.3*.

1.6 Research Scope

This research was limited to local medical device manufacturers in South Africa. The definition of a local manufacturer in South Africa is any natural or legal person responsible for the design, manufacture, packaging or labelling of a medical device before it is placed on the market in the manufacturer's name; regardless if operations are conducted by a legal person or a third party. (Medicines Control Council, 2015)

1.7 Research Limitations

This study was limited to medical device manufacturing companies founded and grown in South Africa and addressed challenges faced by South African SME's in the marketplace.

The limitations included:

- The limited data available in South Africa for local manufacturing from government entities such as the South African Revenue Service and South African Customs.
    - The lack of import data available for medical devices in South Africa from 2014-2018.
    - The lack of local manufacturing capacities and data for the period 2014-2018.
- The limited spread of research participants due to local manufacturing only accounting for 10% of the medical device market size in South Africa (South African Medical Technology Industry Association, 2014) Specialised and complex medical devices remain imported into South Africa.
- Geographic locations of South African manufacturers only include three major metropoles, Durban, Cape Town and Johannesburg.

South African medical device industry data from 2014-2018 was unavailable as no previous study was conducted during that period.

1.8 Chapter Outline

This research was structured as follows:

Chapter 1 Introduction	This Chapter contextualises the study, provides background information of the area of research and introduces the research question and objectives of the study.
Chapter 2 Literature Review	This Chapter contains a comprehensive literature review of competitive forces in industry, strategic frameworks used for strategy development and strategy implementation, the South African medical device industry, problems faced by South African start-ups and South African SME's and previous research conducted in the industry.
Chapter 3 Research Methodology	This Chapter expands on the research methodology used in this qualitative study, justifies the research method, describes how data will be presented, and discussestechniques used to justify the reliability and validity of the study.
Chapter 4 Data Analysis and Results	This Chapter presents all results of semi-structured interviews conducted using a deductive content analysis, comparative analysis and participant observer reflection.
Chapter 5 Discussion	This Chapter discusses the results of the research presented in *CHAPTER 4* in terms of the research question, research objectives and literature reviewed in *CHAPTER 2*.
Chapter 6 Conclusions, Recommendations and Scope for Future Work	This Chapter draws conclusions of the research and makes recommendations for implementation of strategy in start-up medical device manufacturing companies, regulations and future policy development as well as scope for future work.

Appendix A Interview Question	This Appendix contains interview questions used to conduct semi-structured interviews with research participants.
Appendix B Ethics Documentation	This Appendix contains a Letter of Participation distributed to potential participants and a Letter of Consent presented to participants.
Appendix C Interview Data	This Appendix contains interview categorized interview data obtained from all research participants.
Appendix D Signed Documents and Researcher Notes	This Appendix contains signed Letters of Consent from all participants as well as censored researcher notes scribed during interviews.
Appendix E Participant Feedback	This Appendix contains censored communication of participants' feedback received with respect to interview transcripts.

CHAPTER 2 LITERATURE REVIEW

This literature review explores market forces and competitive forces present in South African industry, and strategic frameworks used for strategy development and strategy implementation are established. This chapter also includes theoretical frameworks for competitive forces; forces faced by South African SME's, success factors of South African SME's, and previous research conducted in the South African medical device industry.

2.1 Competitive Forces in the Marketplace

Porter (1979) argued that the essence of business strategy formulation lies in the ability to cope with competition in the marketplace. The state of competition is identified by five basic forces: the threat of new entrants, the bargaining power of suppliers, the threat of substitute products or services, the bargaining power of customers and jockeying for position among current competitors. (Porter, 1979)

2.1.1 The Threat of New Entrants

The threat of new entrants can be defined as the threat posed by new entrants into the market, to existing competitors. The seriousness of this threat is dependent on the barriers to entry present and on the reaction that the new entrant may expect from existing competitors. If there are a number of barriers to entry and there is rapid retaliation from existing competitors, the entrant will not pose as a threat. (Porter, 2008) Barriers to entry include:

- Economies of scale which is defined as the most efficient level of production where the average costs are at a minimum. It deters entry by forcing a potential new entrant to begin on a large scale or face a cost disadvantage. (Porter, 1979)
- Product Differentiation which is defined as the unique qualities of a product used to gain a competitive advantage. This deters entry by forcing the potential entrant to spend heavily to overcome customer loyalty. Brand identification creates the barrier. (Porter, 1979)
- Capital Requirements – If a large capital investment is required to compete, a barrier to entry is created. Capital intensive industries limits the number of entrants. (Porter, 1979)
- Cost Disadvantages Independent of Size – Long existing competitors have access to resources such as proprietary technology, access to raw materials, government subsidies, assets purchased at pre-inflation pricing. The learning curve, and experience curve are also barriers to entry. (Porter, 1979)

- Access to Distribution Channels – New entrants must secure distribution channels for their product or service. The more limited the wholesale and retail distribution channels are, the stronger the barrier to entry. (Porter, 1979)
- Government Policy – Government may limit or foreclose entry to certain industries through licenses and access to raw materials. (Porter, 1979)

2.1.2 The Bargaining Power of Suppliers or Customers

The bargaining power of suppliers or customers is dependent on a number of characteristics of its market situation as well as the relative importance of sales or purchases to the industry compared with the overall business. (Porter, 2008) The bargaining power of suppliers can be defined as the pressure a group of suppliers applies on an industry which directly affects the buyer or customer and their ability to be profitable. (Porter, 1979) Supplier groups are regarded as powerful if:

- It dominated by an oligopoly, and are more concentrated than the industry it sells to. (Porter, 1979)
- Its product is differentiated, and has built up switching costs where switching costs are the costs associated with changing suppliers. (Porter, 1979)
- It poses a threat of forward integration into the industry's business. (Porter, 1979)
- The industry is not an important customer of the supplier group. (Porter, 1979)

The bargaining power of buyers can be described as the pressure applies on suppliers to better product quality, reduce prices and increase customer service. Buyer groups are powerful if:

- It is concentrated and buys in large volumes. (Porter, 1979)
- Products purchased from suppliers are standard or undifferentiated. (Porter, 1979)
- It earns less profits, and will therefore seek more favourable pricing. (Porter, 1979)
- The suppliers' product is not important to the quality of the buyer's product or services. (Porter, 1979)
- The supplier does not save the buyer money. (Porter, 1979)
- The buyers pose a threat of backward integration into the supplier's product. (Porter, 1979)

2.1.3 The Threat of Substitute Products or Services

The threat of a substitute product or service severely limits an industry's ability to be profitable. It is important for industries to find ways of upgrading product quality and means of

differentiation. The more attractive the price-performance trade-off is, the lower the industry profit potential. (Porter, 1979)

Most effective substitute products include those focussed on improving the price-performance trade-off with the industry's product; and those that are produced by industries earning high profits. Substitutes play a large role in industry if their developments cause price reductions and performance improvements. (Porter, 2008)

2.1.4 Jockeying for Position Among Current Competitors

Competitive rivalry in an industry is experienced through price competition, product differentiation, advertising and product introduction. Intense rivalry exists in the form of jockeying for position in an industry and can be related to the following factors:

- Multiple competitors that are approximately the same in size and power.
- The product or service is not differentiable and lacks switching costs.
- Industry growth is slow, precipitating fights for market share.
- Fixed costs are high or the product is perishable.
- Rivals are diverse in strategies and origins.

(Porter, 1979)

2.1.5 Complementors and Competitors

A complementor, what is commonly referred to as an extension of Porter's (1979) 5 Forces Model, refers to products or services that are compatible with what is sold in the industry, and only influences the competitive structure of the industry. (Brandenburger & Nalebuff, 1996)

A company is your complementor if customers value your product more when they are in possession of that other product than when they have the original product alone. (Brandenburger & Nalebuff, 1996)

The effect on profitability in an industry is dependent on how reliant products or services are on the complementor. Complementary goods do not directly increase or decrease the competitive rivalry of an industry. (Porter, 2008)

2.1.6 Microforces within Competitive Forces

Grundy (2006) argued that Porter's 5 Forces model focusses on industries at a macro level and neglects microeconomic theory. Grundy (2006) provided a critique of Porter's 5 Forces model

and thereafter developed it further with other strategic analysis tools which deal with the external environment and with each other.

Porter's 5 Forces are highly interdependent and need to be understood further as a wider, interacting system rather than a self-contained unit. *Figure 2.1* below describes key interdependencies between Porter's 5 competitive forces.

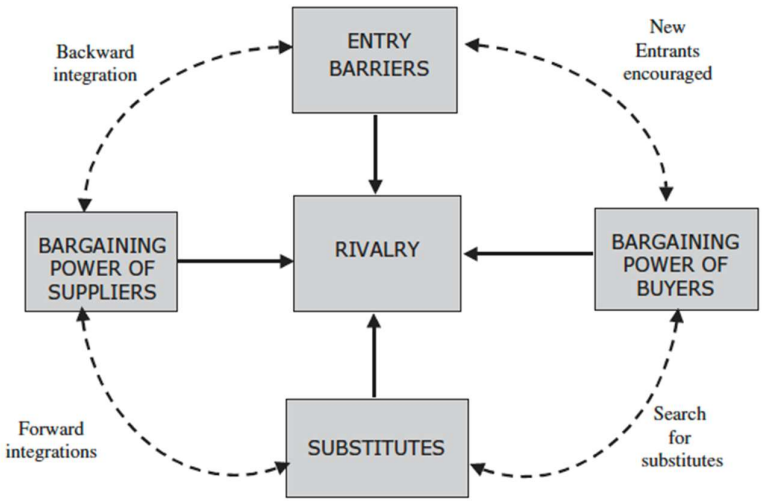


Figure 2.1: Porter's 5 Forces with Interdependencies (Grundy, 2006)

Between 'Bargaining Power of Buyers' and 'Entry Barriers,' buyers may actively encourage new entrants, thus reducing entry barriers. Between 'Bargaining Power of Buyers' and 'Substitutes,' buyers may actively search for substitutes, encouraging other buyers to act similarly. Between 'Entry Barriers' and 'Bargaining Power of Suppliers,' new entrants may seek to enter the market by backward integration, either by acquiring suppliers or via alliances. Between 'Bargaining Power of Suppliers' and 'Substitutes,' suppliers may seek to leapfrog existing industry competitors by marketing and selling substitutes. (Grundy, 2006)

The five competitive forces shown in *Figure 2.1* are then further broken down into viable frameworks to understand how they work at a micro level even for individual business transactions.

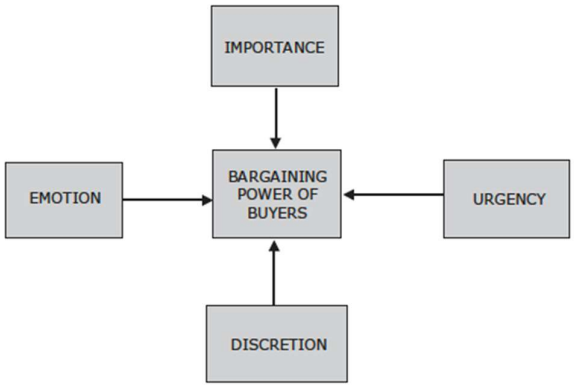


Figure 2.2: Bargaining Power of Customers - Micro Forces (Grundy, 2006)

The bargaining power of buyers can be understood as a function of: importance in terms of value added, urgency in terms of lead time to consumption, discretion and emotion. (Grundy, 2006)

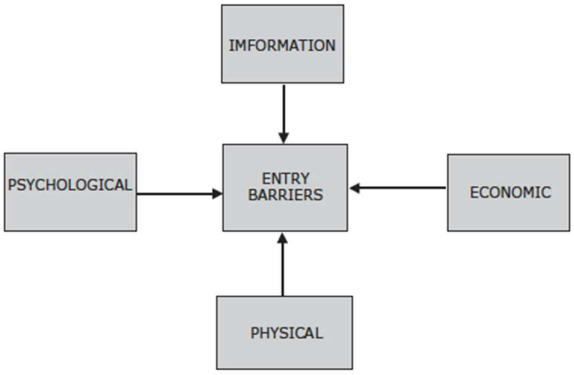


Figure 2.3: Barriers to Entry - Micro Forces (Grundy, 2006)

The barriers to entry can be broken down into:

- Information – is it possible to gain knowledge of tacit competences?
- Economic – what are the costs to enter the industry?
- Physical – is it possible to gain access to customers and/or resources?
- Psychological – is this industry a comfortable industry to remain in?

(Grundy, 2006)

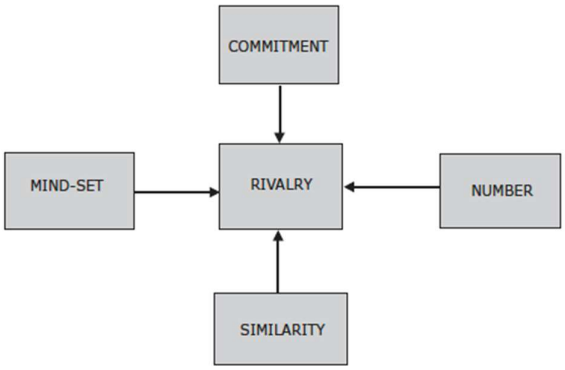


Figure 2.4: Competitive Rivalry - Micro Forces (Grundy, 2006)

Competitive rivalry can be thought of as a function of commitment to the market; the number of players in the market; their similarities or differences with one another; and their strategies and market position. (Grundy, 2006)

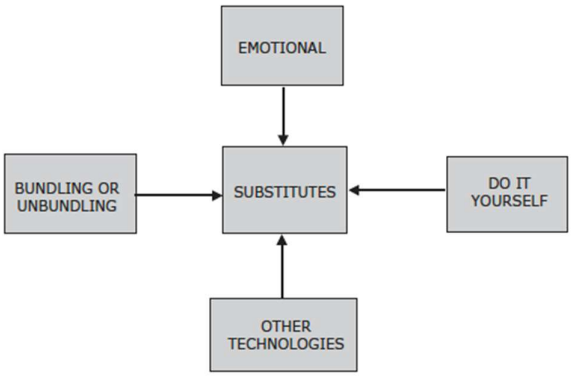


Figure 2.5: Substitute Products/Services - Micro Forces (Grundy, 2006)

Substitutes can be further broken down into the following:

- Emotional – is the purchase of the substitute emotional and to what extent?
- Do it yourself – in-sourcing activities to reduce costs.
- Other technologies – considering other means of achieving the same results.
- Bundling or unbundling – the customer's ability to do something as part of something else, or to take a package offer and capture value by breaking up value-adding activities into their smaller components.

(Grundy, 2006)

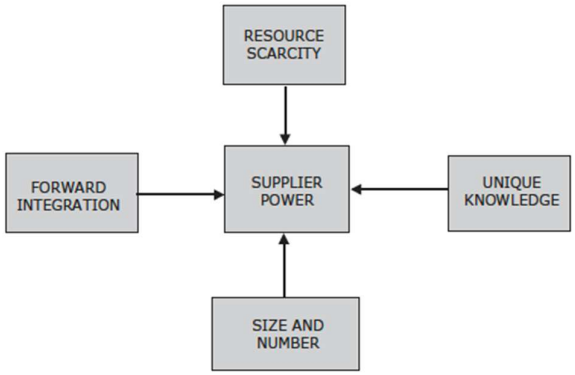


Figure 2.6: Bargaining Power of Suppliers - Micro Forces (Grundy, 2006)

The bargaining power of suppliers can be defined as a function of:

- Resource scarcity – when resources are scarce (permanently), supplier power is promoted.
- Unique knowledge – if the supplier has any unique capabilities, their power will increase.
- Size and Number – if there are a small number of large suppliers, their power is increased.
- Forward integration – if a supplier is capable of integrating forward in the value chain, their power is increased.

(Grundy, 2006)

2.2 The Delta Model

Classic strategic frameworks emphasise a product orientated strategy. Competitors are put up against each other where the outcome is determined by the better product. (Hax & Wilde, 2003) As a result, most companies are product-centred.

The Delta Model provides three distinct strategic positions:

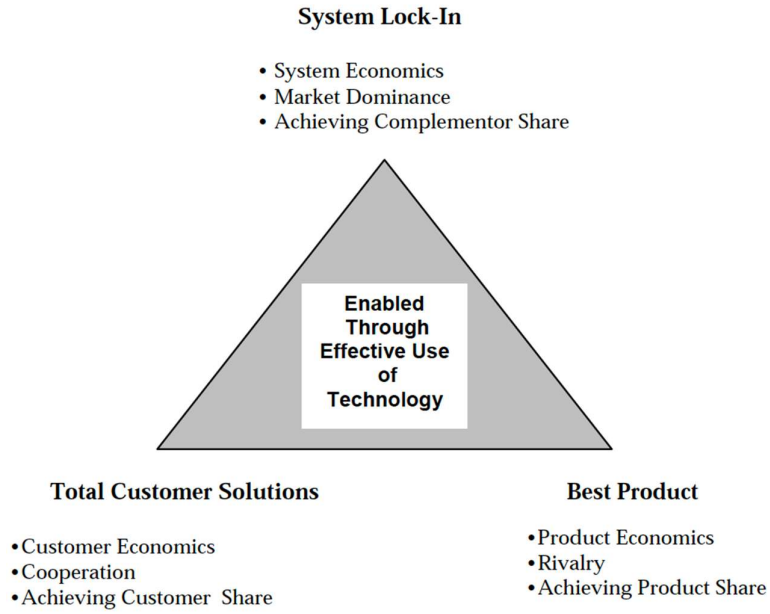


Figure 2.7: The Delta Model Strategic Positions (Hax & Wilde, 2003)

On the right hand side of the triangle (*Figure 2.7*), is the positioning 'Best Product.' It explains that the way companies retain customers is through the inherent characteristics of the product itself. (Hax & Wilde, 2003) The driving forces of this position are to develop an efficient supply chain as well as the internal capabilities for new product development. (Hax & Wilde, 2003)

Total customer solutions represents solutions consisting of customized products and services that represent unique value to individual customers. It is not the internal development capabilities that carry the innovation initiatives in the firm, but rather developmental efforts with customers that are central to this strategy's success. (Hax & Wilde, 2003)

System lock-in describes the most demanding strategic choice and addresses the full network as the relevant scope. It also focusses on gaining complementors' share as the main objective while focussing on the system economics as the driving force. This situation allows dominance in the market and assures a customer lock-in and a competitor lock-out. (Hax & Wilde, 2003)

The Delta Model provides an integrative strategic framework as in *Figure 2.8* below:

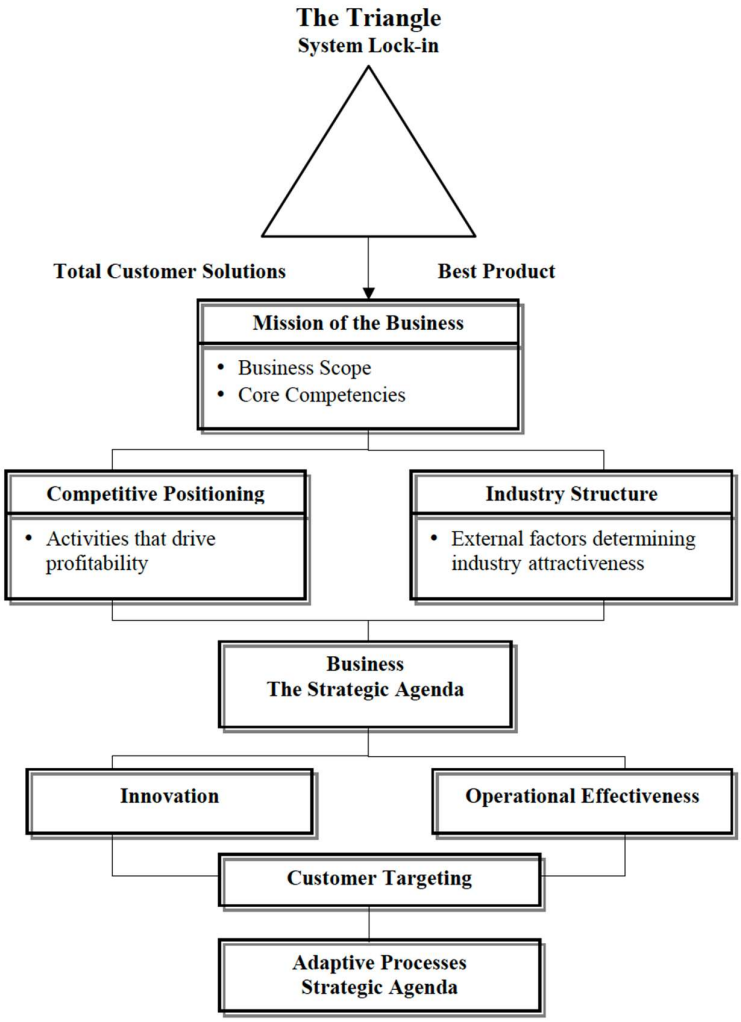


Figure 2.8: The Delta Model's Integrative Framework (Hax & Wilde, 2003)

This mission of the business affirms the strategic option chosen in the strategic positioning triangle in *Figure 2.7*. It includes defining the business scope and where to compete as well as the core competencies of the business which determines the resources and capabilities required. (Hax & Wilde, 2003)

An analysis of the industry structure determines the significant external forces, their trends and their impacts on the business. The Delta Model extends the industry analysis from the business' industry to include the industries of complementors as well as key customers. (Hax & Wilde, 2003)

Following the industry analysis, a competitive position must be established after understanding the opportunities and threats presented. The Delta Model focusses on the extended value chain to define a company's competitive position. (Hax & Wilde, 2003) This includes not just the

business' internal value chain, but also the value chain of all relevant external parties. The value chain describes all activities which bring a product or service from conception, through all phases of production, to the deliver to consumer and disposal after final use. (Kaplinsky & Morris, 2000)

The strategic agenda may then be developed after the relevant background of the business has been established. The agenda should include action-driven tasks set out to achieve the business objectives and define each task clearly to communicate it through the entire organization through indicators and targets. The agenda is subject to continuous revisions and must be communicated throughout the organization. (Hax & Wilde, 2003)

The adaptive processes delve deeper than the strategic agenda into details of the task execution. This then guarantees the alignment of strategy and execution in a direct and explicit manner. (Hax & Wilde, 2003) Every adaptive process produces its own strategic agenda which shares similar characteristics to the business agenda but is more localized and detailed. (Hax & Wilde, 2003

The strategic agenda of the adaptive processes is where business capabilities are addressed. The broader core competencies defined in the business mission move towards the skills required for operational effectiveness, customer targeting and innovation processes. (Hax & Wilde, 2003 This perspective allows the core competencies to support the development of the strategic positioning of the business and identifies resources, skills and capabilities required for implementation. (Hax & Wilde, 2003)

2.3 Blue Ocean Strategy

Kim and Mauborgne (2005) argued that industries are constantly evolving and products eventually become economically obsolete and stop generating profit. This suggests that the traditional business environment, which saw most strategic approaches developed in the twentieth-century, is disappearing at an increasing pace.

Kim and Mauborgne (2005) described the normal life of a firm with its commercial and technological routine, as 'Red Ocean.' Firms experience strong competition, pricing problems and other market related issues. The 'Blue Ocean' strategy originates from the analysis of this 'Red Ocean.' Rather than the regular competitive battles, 'Blue Ocean' pursues unique market spaces, untapped by competitors and where firms can grow. It can be defined as a continual search for value innovation. (Kim & Mauborgne, 2005)

Value innovation occurs where firms have a favourable impact on its cost structure and value proposition to buyers. The economies are achieved through elimination and reduction of competitors within the industry. Value is increased by improving and creating attributes not yet offered by the industry. (Kim & Mauborgne, 2005)

Blue Ocean Strategy highlights six principles for firms to find their 'Blue Ocean:'

1. Reconstruct Market Frontiers – This is the first step in Blue Ocean Strategy to eliminate competitors in the market. It involves successfully identifying new, 'Blue Ocean,' opportunities. It can be done by examining alternative industries, strategic groups within industries, the buyer chain, buyer characteristics and offerings of supplementary, or complementary products and services.
2. Focus on the Big Picture – This entails aligning the strategic planning process to focus on the bigger picture and apply these ideas to a value evaluation system to develop a Blue Ocean Strategy. This approach allows people within firms to open their eyes to 'Blue Ocean,' so that it is easily understood and implemented.
3. Reach Beyond Existing Demand – This approach allows firms to concentrate on noncustomers as well as customers. It focusses on building commonalities in what buyers value as opposed to searching for customer differences. This allows firms to reach beyond existing customers that may not have existed before.
4. Getting the Strategic Sequence Right – This allows for the correct sequence for developing and validating Blue Ocean ideas to assess their business validity. This reduces business model risk significantly. The sequence that firms should follow in Blue Ocean Strategy is: Buyer utility, Price, Cost and Adoption. In other words, is there exceptional buyer utility in the business idea, is the price accessible to mass buyers, will the profit and target cost be attained at the strategic price, and what adoption hurdles are expected in actualizing the business idea.
5. Overcoming Formal Barriers – Firms experience barriers between planning and execution which must be overcome quickly, and economically. The four fundamental hurdles experienced are: cognitive, resource limitation, motivation and organizational policies. To overcome these hurdles, firms must win the support of employees and challenge conventional strategic thinking.
6. Build Execution into the Chosen Strategy – Firms should integrate execution into strategy-making from the start. Management must develop trust and commitment from all levels of employment as well as inspire voluntary co-operation from all. This

minimizes management risk of lack of trust, cooperation and sabotage. The presence of fair processes are essential in execution of the chosen strategy.

(Kim & Mauborgne, 2005; Jussani, et al., 2010)

2.4 Porter's 5 Forces vs The Delta Model vs Blue Ocean Strategy

Jussani, et al. (2010) produced a set of analysis criteria for evaluation and comparison of the abovementioned strategic approaches: objectives, internal analysis, macro-environment and future scenarios. *Table 2.1* below shows the four criteria, with each strategic approach being related to the criterion observed.

Table 2.1: Comparative Matrix of 3 Strategic Approaches (Jussani, et al., 2010)

Criterion	**Porter's 5 Forces**	**The Delta Model**	**Blue Ocean Strategy**
Objectives	To find the best generic strategic position in the market.	To find new sources of profitability.	Value innovation
Internal Analysis	5 Forces analysis.	The trade-off between costs and product differentiation.	Rebuilding market frontiers.
Macro-environment	5 Forces analysis.	To align strategic options with company activities.	Focus on the bigger picture, not on numbers.
Future Scenarios	Identify new opportunities.	To be responsive in an uncertain environment.	To create new, uncontested market space.

In this study, Porter's 5 Forces, The Delta Model and Blue Ocean Strategy were all used to evaluate the elements of strategy implemented in South African medical device manufacturers as well as the importance of each strategy in the medical device industry.

2.5 The South African Market Environment

South African small to medium enterprises have one of the highest failure rates in the world. Five of seven new small businesses in South Africa fail within their first year. (Leboea, 2017) To understand the obstacles that Small to Medium Enterprises (SME's) in South Africa face, as well as the success factors of South African SME's, Olawale & Garwe (2010) and Kunene (2008) separated the business environment into an internal and external environment respectively.

2.5.1 The Internal Environment

The internal environment consists of finance, managerial competency of the owner, location, investment in technology, cost of production and networking. (Olawale & Garwe, 2010) Kunene (2008) described the internal environment to include company demographics, entrepreneur demographics, previous experience and characteristics of the entrepreneur.

2.5.1.1 Company Demographics

Company demographics are factors that may influence firm survival and include:

- The size of firm: Being a small SME negatively correlates with survival rates which are as a result of the limited resources that SME's experience.
- The age of firm: New SME's face a greater risk of survival than old firms as they do not have the access to experience, reputation or the legitimacy of old firms.
- The product and its competitiveness: Sustainable competitive advantage is an important factor in a firm's survival and is achieved through competitive strategies such as product differentiation. (Kunene, 2008)

2.5.1.2 Characteristics of the Entrepreneur

The lack of managerial skills and competencies are the biggest reasons why new firms fail. (Olawale & Garwe, 2010) The lack of education and training has reduced management capacity in South African SME's. (Herrington & Wood, 2009) Managerial skills and competencies were linked to the characteristics of the entrepreneur described by Leboea (2017) which included:

- Initiative: The business depends on the entrepreneurs actions. Therefore, initiative is crucial.
- Self-efficacy: The belief in one's ability to organize the necessary resources, skills and competencies to effectively execute actions and a certain level of achievement on a task.

- Ability to gather resources: The ability to gather and control resources are necessary to start, run and grow a business.
- Adapting to change: When the business environment destabilizes, adaptation and flexibility become important strategies for business success.
- Risk taking propensity: Dealing with risk, taking calculated risks, being realistic when analysing opportunities and spreading one's risk are key factors which impact positively on entrepreneurship.
- Opportunity alertness: The ability to isolate, quantify and refine an opportunity from a set of ideas is a key factor which impacts positively on entrepreneurship.
- Problem solving
- Decision making
- Ability to learn
- Accountability
- Time management skills
- Negotiation skills

2.5.1.3 Entrepreneur Demographics

Kunene (2008) described entrepreneur demographics as one of the most influential factors related to SME performance and competitiveness. These factors included:

- Gender: Women have been associated with lower levels of human capital and have had fewer opportunities to develop the relevant experience required for any industry.
- Role models: Parents are a strong influence on entrepreneurial activity. Entrepreneurs that have descended from entrepreneurs possess an advantage over those that do not.
- Education: Education is a means through which knowledge can be gained. A firms capacity to compete is related to knowledge, skills, problem-solving ability, discipline, motivation, self-confidence and the ability to identify opportunities and gather resources required.

2.5.1.4 Previous Experience

The quality of an entrepreneur is directly proportional to the entrepreneur's previous experience. (Kunene, 2008) The learning process involved allows entrepreneurs to identify opportunities, reduce initial inefficiencies and improve capacity. Previous experience factors included:

- Work experience: The ability to learn from experience is a key factor in influencing the entrepreneurial process. Most new firms are started by people who have worked in other jobs that have given them the ability to identify opportunity and the technical ability to product the product or identify a service. People lacking work experience have fewer capabilities and may find it more difficult to develop a business idea.
- Business ownership experience: Entrepreneurial experience can translate into valuable knowledge through direct experience. SME's that start business without business ownership experience must go through the cost of gaining entrepreneurial experience while implementing the idea.
- Industry-specific experience: Experience in the same industry as the one which the entrepreneur starts up in increases the probability of survival and high performance. It is an essential way of responding to perceived market needs, gaining important contacts and insights about the industry.

2.5.2 The External Environment

Beck (2007) described the external environment, or systematic factors as economic variables and markets, crime and corruption and labour, infrastructure and regulations. Kunene (2008) further categorized external factors into economic factors, policy-institutional factors, socio-cultural factors, market opportunity factors and performance related factors.

2.5.2.1 Economic Factors

Economic factors in the South African market environment has a direct impact on the attractiveness of different strategies. These factors include fiscal policies, monetary policies, inflation, interest rates as well as foreign exchange rates. (Olawale & Garwe, 2010) These factors influence supply and demand of goods and services, and therefore influence the growth of new small to medium enterprises. (Olawale & Garwe, 2010) Kunene (2008) stated that the success of a new venture depends on the state of the national economy at the time that the business is launched and further expanded on economic factors which included:

- The enterprise density of 2% in South Africa allows companies to actively expand and serves as a disincentive for companies to leave. Enterprise density is defined as the number of firms in a given population at a given time and refers to the percentage of existing and possible entrepreneurs.
- SME development is affected by Value Added Tax and corporate taxes. Tax rates that are high reduce the profit incentive.

- Dealing with change and being comfortable with being uncomfortable is important characteristic of businesspeople.
- A positive business environment provides SME's with opportunities, threats, and information and access to role models which are factors in determining SME's success. Governments play a critical role in providing a business environment that supports and promotes a vibrant entrepreneurial culture.

2.5.2.2 Policy-Institutional Factors

South Africa's business sector is the largest organized group suffering from crime and violence. A report released by Standard Bank and Fujitsu Siemens Computer (2009) concluded that businesses are not actively pursuing different growth avenues as they are too focussed on operational matters because of the high crime rate. Corruption in the public sector as well as the private sector are also growing in South Africa (Leboea, 2017) Gaviria (2002) argued that the reason why small to medium enterprises engage in corruption is because of the lack of bargaining power and influence to turn down unofficial payments and other attempts of corruption. (Leboea, 2017) described other policy-institutional factors including the political climate and legal requirements of doing business which included:

- Macro-economic policies, legislation, frameworks, regulations and laws could hinder entrepreneurship. Appropriate trade, labour, investment and tax policies and regulations can provide an environment that sustains and enables entrepreneurship. A hostile environment with legal and regulatory constraints can hinder entrepreneurship and increase the cost of doing business.
- In South Africa, the cost of compliance with legislation is high and is seen as a threat to entrepreneurship.
- Lack of public sector support has a negative impact on SME's to grow businesses beyond the initial incubation and early survival phase.

2.5.2.3 Socio-Cultural Factors

Small to medium enterprises require suitably skilled and suitably motivated labour to sustain growth. South African SME's find it both difficult and expensive to find skilled labour. (Leboea, 2017) The quality of infrastructure also determines an SME's ability to grow. Electricity supply does not meet the demand in South Africa and therefore companies experience power cuts. Additionally, the cost of regulations may be another barrier to entry as SME's must still obtain registration licenses as well as pay taxes. (Leboea, 2017) Investment

in technology and keeping up with information technology is important for all firms. With the rising costs of inputs like electricity and petroleum, it is necessary for firms to reduce waste and determine the most efficient means of production. (Olawale & Garwe, 2010) Additional socio-cultural factors outlined by (Leboea, 2017) included:

- The availability of capital and funding for business development enables entrepreneurs to put ideas into practice, be competitive, to survive in unfavourable conditions and to grow.
- Access to economic resources such as bankers, suppliers, lawyers, training and other resources required in the total value chain is important for SME success.

2.5.2.4 Market Opportunity Factors

Location is a factor that can impact the growth opportunities of new firms. The geographical proximity to critical buyers or suppliers enables firms to easily identify new growth opportunities within the market. (Olawale & Garwe, 2010) Networking can also positively impact on the growth of South African SME's as well as their access to finance. Networking increases a firm's legitimacy which also positively influences the firm's access to finance. (Ngoc, et al., 2009) Other market opportunity factors outlined by Kunene (2008) included:

- Market conditions: The life cycle that an industry is in can promote or inhibit entrepreneurship. Industry complexities and weaknesses can inhibit growth. High growth potential of an industry is an important factor in entrepreneurship. Choosing a market segment with high growth potential is a factor that influences SME success. Having knowledge of opportunities in particular markets has a positive impact on entrepreneurship.
- Demand for supply: The demand for SME's in an industry is a determining factor in the success of SME's. Low, insufficient or unsteady demand for products or services limits SME growth.
- Competition: Competitive concentration and strategies of competitors has an impact on SME's. An analysis of the role of competitors and counter-competition intelligence is crucial for the survival of SME's.
- Access to markets: Stable access to markets and the ability to overcome barriers to entry are crucial for enhancing SME success. Limited access to profitable markets inhibits entrepreneurship.

2.5.3 Obstacles to Growth in South African SME's

Olawale and Garwe (2010) conducted an empirical study, which consists of primary research and data collection through questionnaires, to determine the most significant obstacles to growth experienced by South African SME's:

1. Lack of access to finance
2. Lack of collateral
3. Crime
4. Lack of owner's equity contribution
5. Bad credit record
6. Insufficient government support
7. High production costs
8. Inadequate market research
9. Lack of information technology
10. Corruption

2.6 The Medical Device Manufacturing Industry

The global medical device industry is characterized by high barriers to entry. These include capital intensive research and development, regulatory restrictions and the inability of smaller manufacturers to compete with larger multinationals. (Maresova & Kuca, 2014)

In order for a medical device to be a viable substitute, it should perform the same function as the current product. The threat of substitutes can be described as a medium force as although there is intent to substitute certain products, demand for these products are still growing. (Maresova & Kuca, 2014)

Buyer power can also be described as a medium force in the medical device industry which is becoming more consolidated and medical reimbursement policies are evolving. Supplier bargaining on the other hand is a weak force because of a large selection and ease of substitutability. (Maresova & Kuca, 2014)

There are numerous competing companies within the medical device industry. Competition in the medical device industry is strong due to low product differentiation, low switching costs for buyers, as well as changes connected with reimbursement and regulatory policies respectively. (Wipperfurth, et al., 2010)

A medical device is defined as an instrument, apparatus, appliance or diagnostic reagent used for:

i. The diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or
ii. Restoring, correcting or modifying any somatic or psychic or organic function; or
iii. The diagnosis or prevention of pregnancy.

The device should achieve its intended use through pharmacological, chemical, immunological or metabolic means in or on the human body. It may only be assisted in its function through these means. (South Africa, 1965)

The South African Health Product Regulatory Authority (SAHPRA) defines a manufacturer in South Africa as a natural or legal person responsible for the design, manufacture, packaging or labelling of a medical device before it is placed on the market in the manufacturer's name, regardless if the operations are conducted by the legal person or a third party. (SAHPRA, 2015)

South Africa's medical device industry was a previously unregulated industry, unlike most other medical device industries around the world. The Medicines and Related Substances Amendment Act 14 of 2015 brought significant changes to the then-existing regulatory atmosphere in South Africa. (Saidi & Douglas, 2018) The Amendment brought about a new regulatory authority by the government, SAHPRA. Previously, medical device regulations covered electronic products only. The medical device definition now broadly covers all device from consumables to (Magnetic Resonance Imaging) MRI scanners. (Saidi & Douglas, 2018)

The fundamental changes brought about by the amendment include the establishment of a regulatory authority, tier-based licensing and registration as well as sales and distribution regulations. (South Africa, 2016) SAHPRA is responsible for the regulatory oversight of medicines, medical devices, complementary medicines, foodstuffs, cosmetics and related substances. (SAHPRA, 2015) The Medicines Control Council (MCC) has been replaced by SAHPRA, which is an extension of the state outside public service, but is still subject to provisions of the Public Finance Management Act 1 of 1999. The authority is empowered to register medicines, medical devices, in-vitro diagnostic devices, complementary medicines and foodstuffs. SAHPRA is also assigned to periodically re-evaluate and re-assess products. (Saidi & Douglas, 2018)

The Amendment also includes a four-level risk classification system for obtaining medical device licenses to manufacture, import and distribute. The manufacture, importation,

exportation, distribution and wholesaling are all subject to regulations depending on their risk classification and intended use. (SAHPRA, 2015) Risk classification is broken down into Class A – low risk; Class B – low-moderate risk; Class C – moderate risk; and Class D – high risk.

The 2015 Act Amendment prohibits the importation of Class B, Class C and Class D medical devices and IVD devices for products that are not registered in South Africa. Under the new Act, only registered products may be sold in South Africa. Domestic manufacturers, wholesalers and distributors are required to apply for licenses, while foreign manufacturers do not. (Saidi & Douglas, 2018)

2.7 Previous Research Conducted

Deloitte and Touche (2014) conducted research in partnership with the Department of Trade and Industry to develop a strategic guide for the medical devices industry of South Africa. The aim of this study was to support the long term growth of the medical devices industry through strategy development and policy intervention.

Deloitte and Touche's (2014) strategy recommendations included:

1. To improve collaborative efforts between the state and businesses in an attempt to grow the industry. This can be achieved through a quarterly forum between key government representatives and private sector stakeholders as well as the appointment of an inter-ministerial champion to ensure that all stakeholders are kept account and judged on performance-based measurements.
2. To introduce an effective regulatory framework and mandatory quality standards for all medical devices to be enforced by government. These include the introduction of the international standard ISO13485 as a quality management standard for local manufacturers as well as regulatory body licenses.
3. To record all customs data to an 8-digit level. The availability of customs data is only available for a limited number of products. As a result, it is difficult to identify products that make up the biggest trade proportion as well as the import composition of medical devices.
4. To develop efficient incentives for local manufacturers to flourish and to attract manufacturing foreign direct investment. Existing incentives must be reconsidered and effective channels must be established to increase the awareness of the available incentives.

5. Human capital development in South Africa must be developed to develop the current manufacturing base with the view of further industrialisation to high technology manufacturing. Without skills development being addressed, other policies may not be as effective.
6. To rebalance South Africa's medical device trade, locally manufactured products must enter global supply chains and key growth markets. Government must consider financial assistance to cover the regular costs for market entry into these countries.

(Deloitte & Touche; Department of Trade & Industry, 2014)

To better understand South Africa's medical device industry, Deloitte and Touche (2014) recommend further research in the following areas:

1. A study into lab equipment used in medical diagnostics which were not included in the study.
2. A study into the global trends to see which markets are sectors are growing.
3. A study to clarify issues with re-exports.
4. A study into the state and potential future role of complimentary services.

(Deloitte & Touche; Department of Trade & Industry, 2014)

2.8 Summary of Literature

The literature reviewed has covered all aspects of competitive forces experienced in the medical device industry, strategic frameworks implemented in industry, the South African medical device marketplace and forces faced by start-ups and SME's in South Africa. This Chapter forms the basis of the comparative analysis, deductive content analysis as well as participant observer reflection in *Chapter 4*.

CHAPTER 3 RESEARCH METHOD

This Chapter presents the research methodology used in this exploratory, qualitative study. It contains a research design which describes the semi-structured interview process as well as procedures implemented for the analysis of the data. Data analysis procedures are presented in three steps:

1. How data is prepared for analysis.
2. How data is organized after preparation.
3. How data is then reported.

Participant observer protocols observed by the researcher are also presented in this Chapter. The Chapter concludes with techniques used to guarantee the reliability and validity of the study.

3.1 Research Design

This research required qualitative methods to achieve its objectives. Achieving research objectives set out in *Section 1.4* required gaining insight to the problem through noting trends in experiences of medical device manufacturers as well as noting opinions of key South African manufacturers. Qualitative research seeks to understand a phenomena in a context-specific settings where the researcher does not attempt to manipulate the phenomenon of interest. (Golafshani, 2003) Qualitative research in healthcare services allow people to speak in their own voice, rather than conforming to categories and terms imposed on them by others. It allows for further inquiries into developmental and historical processes within companies. (Sofaer, 1999)

Although the medical device industry is a global industry, many restricting factors were attributed specifically to South African regulations as well as the South African market environment. (South African Medical Technology Industry Association, 2014) To understand the competitive forces that medical device companies face in South Africa, semi-structured interviews were conducted with local manufacturing companies. Semi-structured interviews allow for a more in depth understanding of information obtained. (Creswell, 1997)

Panel discussions on the other hand, are appropriate for environments where participants exchange different views among experts. (Creswell, 1997) The nature of the interviews conducted did not allow for a panel discussion as sensitive strategic information could not be shared with direct competitors.

Other methods such as surveys, questionnaires or structured interviews do not allow for flexibility in questions and answers. Survey answers lack detail and ask closed questions which generate quantitative data. It does not allow the researcher to understand the thoughts, behaviours and/or emotions of the interviewee. (Creswell, 1997) However, semi-structured interviews allow the generation of qualitative data through open questions where interviewees can respond in-depth, using their choice of words. As a result, there is a higher data validity as the interviewer may probe for further understanding and clarification. (Creswell, 1997)

Semi-structured interviews were the most appropriate means of understanding problems and situations in each company given that all business models and/or revenue models are specific to a single enterprise or group of enterprises. Data was extracted from South African manufacturers to adapt theoretical frameworks to the South African medical device market environment.

The interviews were conducted using the following approach which are expanded upon in *Section 3.1.1* to *Section 3.1.5*:

1. Draft the interview
2. Pilot the questions
3. Select interviewees
4. Conduct interviews
5. Analyse interview data

(Wilkinson & Brimingham, 2003)

3.1.1 Drafting the Interview

Interview questions were drafted around key themes to ensure that no issues were overlooked and interviews followed a logical progression. (Wilkinson & Brimingham, 2003) Themes/Categories were identified that relate to the competitive market environment of medical device manufacturers in South Africa.

The interviews were drafted to address the following issues:

- The barriers to entry faced by companies upon start-up in the medical device manufacturing industry.
- The competitive forces faced by the firm in the South African market environment.

The factors that have ensured the firm's success within the medical device manufacturing industry.

The number of questions, the type of questions and sequence of questions were designed to obtain the necessary information with respect to the research field. Flick (2009) suggests that there is no recommended number, type or sequence of questions. The interviews included a comprehensive background of the company, a market background of the market they operate or compete in, obstacles to the firm's growth, as well as strategy development and strategy implementation. The interview structure and questions can be found in *Appendix A – Interview Questions*.

Audio recordings have been used extensively by researchers in the past. (Creswell, 1997) Hence, audio recordings of interviews were used for the one-on-one interviews conducted and recordings were subsequently transcribed to capture all necessary information.

3.1.2 Piloting the Questions

Piloting questions of an interview eliminates ambiguous questions and generates feedback regarding the flow of the interview. Interview questions should be easy to understand, and questions and procedures should be refined through pilot testing. (Wilkinson & Brimingham, 2003; Creswell, 1997)

Interview questions were piloted on one participant in the research. This participant is an experienced member of the medical device manufacturing industry in South Africa and served multiple roles in the industry including being a manufacturer. The responses were assessed in order to determine if sufficient information was obtained to understand the medical device industry the company operates in, the competitive environment the company operates in and elements of strategy incorporated into the company.

3.1.3 Selecting Interviewees

Two methodologies most commonly used for selecting sample groups includes purposeful sampling and random probability sampling. Random probability sampling allows generalization from the sample to the population it represents, and is more suited to quantitative studies. (Patton, 1990) Purposeful sampling can be described as selecting a sample based on the purpose or aim of the research. (Marshall, 1996)

Random sampling proved to be inappropriate because participants chosen would not provide an in-depth knowledge of the research topic that was required. Purposeful sampling was selected as the sampling method because of the in-depth information and thorough

understanding of the research topic it provides. As a result of selecting a purposeful sampling strategy, the following risk mitigation factors were outlined by Marshall (1996):

- Selecting a sample to suit researcher bias.
    - This was avoided by selecting participants from different medical device sectors, with different manufacturing operations.
- Selecting a sample that would not be large enough to represent the variation in the population.
    - This was avoided by selecting participants from various medical device sectors, with differing business models, in different locations and different company sizes.
- Selecting a sample that would not achieve the objectives of this research.

Numerous purposeful sampling methodologies were outlined and proposed by Patton (1990), Marshall (1996) and Miles and Huberman (1994). (See *Appendix B – Purposeful Sampling Strategies*)

For the purposes of this research, a combination of extreme or deviant case sampling, critical case sampling, criterion sampling, chain sampling and maximum variation sampling was used.

Criterion sampling was selected to determine the type of participants that could provide the necessary information to achieve the research objectives. A sample of six CEO's, founders, directors and/or senior management of a group consisting of South African medical device manufacturers were interviewed. The pre-determined criteria used to select participants are as follows:

1. The participant must have been involved through the company's initial growth stages.
2. The participant must have been involved in strategy development and/or strategy implementation within the company.
3. The participant must have served a senior management position at the firm.
4. The participant, including the company they represent must be a compliant member of the South African Health Products Regulatory Authority.

The criterion sampling method formed the basis of all other sampling techniques. All participants must have fulfilled the above criteria to qualify for participation in this research.

Extreme or deviant case sampling was chosen as participants were selected based on their success as a medical device manufacturer in South Africa. Participants that have both failed as a medical device manufacturer as well as participants that have had success in the industry

based on their number of customers, products manufactured and rapid, steady growth were selected. The selection of these participants enhanced the study through the identification of key factors that resulted in the firm's decline and the firm's success.

Critical case sampling was chosen as participants could provide key insights into a highly regulated industry with a strong competitive environment. Key participants were identified that could provide essential information and insight into the medical device manufacturing industry that standard size, smaller firms could not.

Chain sampling was selected as participants were identified using a key resource in the medical device manufacturing industry in South Africa. The resource first used served multiple roles in the industry and was able to identify key manufacturers across South Africa in different medical device sectors. The recommended participants were then interviewed where they were also used as resources to identify other key members of the industry to participate in this research.

Maximum variation sampling was selected to maximise the central themes that existed across different participants. The method aimed to maximise the diversity of participants through their geographic location, medical device sector, the manufacturing capacity and operations, and company size.

3.1.4 Conducting the Interviews

3.1.4.1 Interviews

Interviews were conducted using recommended protocol for semi-structured interviews. (Wilkinson & Brimingham, 2003)

1. The setting of the interview should not appear to be confrontational or intimidating.
2. The interview venue should be quiet, free from distraction and allow for the recording of the interview.
3. The researcher should obtain informed consent from the participant prior to the interview.
4. The interviewer should sit alongside the interviewee and recording device be placed in an area that will not distract the interviewee.
5. The interviewer should introduce themselves, the purpose of the study, the structure and format of the research, how data will be used and how anonymity is guaranteed.
6. Questions should be open ended in order for the interviewee to provide as much information as possible.

7. Interviewee responses should be repeated to clarify what has been said and to encourage further elaboration on what has been said.

Interviews for this research were conducted at the business premises of selected participants. The interview venues were located at the office blocks of each company. Where face to face interviews were not possible, interviews were conducted via teleconferences.

Prior to the interview being conducted, interviewees were informed of the research through a letter of participation. Written consent and verbal consent to conduct the interviews as well as record them were also obtained. (Ethics Clearance Number: **MIAEC 049/18**) A letter of participation and letter of consent can be found in *Appendix C – Ethics Documentation*. Informed consent was also requested during the interview to participate in the research as well as to record the interviews. Participant signed documents and researcher interview notes can be found in *Appendix E – Signed Documents and Researcher Notes*.

All interviews followed a standard structure of an introduction of the interviewer followed by an introduction by the interviewee. Interviewees were guaranteed complete anonymity by not divulging the company name, the company location, the medical devices manufactured by the company, or the interviewee name. Data presented in this research was censored to ensure complete anonymity of all participants.

All questions were open ended and allowed for interviewees to provide as much information as possible. Following the answers to open-ended questions, follow up questions were asked to further probe for more information.

Once all interviews were transcribed, the transcriptions were forwarded to interviewees to confirm that information provided in the interviews accurately reflect the thoughts and opinions of the participant, and to provide the opportunity to add any further information to the transcript.

3.1.4.2 Participant Observations

In addition to the interview data analysed, an account of the medical device manufacturing industry was presented by the researcher as an active participant in the industry. The researcher, described as an active participant, has been affiliated to the industry and is fully understanding of all industry norms, customs and operations. (Spradley, 1980) Participant observation can be described as a data collection method that aims to learn about the activities of a group under study through observing and participating in activities. (Dewald & Dewald, 2002) This is, the

process of learning through exposure to or involvement in the day-to-day activities of the researched group. (Schensul, et al., 1999) It is dominant in social studies where the researcher seeks to become a member of a group, organization or event under study. (Vinten, 1994) By being immersed in the group of study, the researcher hopes to be in a position to obtain more information at a greater depth than would be possible from the outside looking in. (Vinten, 1994)

The researcher as an employee describes full immersion in the organization, where the intents and purpose of the researcher is one with the employees worked with in the organization. Vinten (1994) argued that experienced participant observers supplement the research method using other methods and approaches. This allows a more comprehensive understanding of the matter being studied as well as guaranteeing the rigour of the study. (Vinten, 1994)

Rankin and Bertrand (2005) described a method to prepare participant observer protocol. The protocols below should show clear information on the processes as well as demonstrate that the researcher has weighed potential harms against benefits of the research.

1. Methodology – The researcher should explain the setting of the Participant Observation, including what potential interactions are involved, how data will be gathered, and what issues will be discussed formally.
2. Participants – The researcher should describe who the people or group are, and reflect on potential ethical issues that may arise in the context of the research.
3. Potential harms – The researcher should expand on the extent and variety of potential harms to the researcher.
4. Privacy and confidentiality – The researcher should provide information about how data gathered will be safeguarded and how sensitive information will be censored.
5. Informed consent – It is necessary for the researcher to obtained verbal or written consent from the group being researched.

The limitations of active participation include the selective nature of recordable data, the bias in the analysis of collected data; the researcher's view will interpret how data is interpreted and analysed. (Schwartz & Schwartz, 1955)

3.2 Data Collection and Analysis Procedures

Data collected from interviews was subjected to a deductive content analysis. Data analysis was conducted during the interview and after the interview. Content analysis is a method which

may be used for both qualitative data, and quantitative data in an inductive or deductive way. Inductive content analysis can be described as a standard content analysis, while deductive content analysis can be described as a directed content analysis. When using content analysis, the aim is to build a model to describe the phenomenon in conceptual form. (Shrivastava, 2018)

Both inductive and deductive content analysis are conducted in three phases: Preparation, Organizing and Reporting. These are explained in more detail below.

3.2.1 Preparation

The preparation phase is similar for both inductive and deductive content analysis. Inductive content analysis is where data is 'coded' into explicit categories and described by identifying patterns and using statistics. (Hseif & Shannon, 2005) Concepts, categories or themes are derived from the data. Deductive content analysis can be described as an approach to validate or conceptually extend a theoretical framework or theory. (Hseif & Shannon, 2005) It can be used when the structure of analysis is based on previous knowledge. (Elo & Kyngas, 2007)

Inductive content analysis is used when there are no previous studies of a phenomenon or it is fragmented. A deductive approach is useful when testing previous theories in previous situations or to compare categories at different time periods. (Elo & Kyngas, 2007)

3.2.2 Organization

Key concepts and variables were identified from previous research in the South African medical device industry, the South African market environment, strategy literature and start-up companies. Data was then allocated to predetermined concepts and analysed for patterns and other similarities.

Interview recordings were transcribed and used to generate data consisting of the following themes:

1. The number of founding members and their background.
2. The company's core operations from inception to the date of interview.
3. The company's target market, export ratios and customer base.
4. The competitive environment at inception, and how the environment changed in current markets.
5. The market growth and company growth therein.
6. The obstacles to growth in the medical device manufacturing industry.
7. The regulatory problems faced by companies in the South African market.

8. A basic, generic strategy for the business.
9. Business survival and growth strategies.

3.2.3 Reporting

Interview results were reported in the following categories:

1. The business background: This included the number of years of operation, company size, company growth, and motives for manufacturing medical devices.
2. The market environment: This included the competitive environment the business operates in, what makes the market attractive, its limitations and issues therein that medical device manufacturers face.
3. Strategic objectives: This included formalized strategies implemented within companies, survival strategies, growth strategies and success factors which have ensured the businesses success.

Once the analysis of interview data was completed, an in-depth literature review was conducted on business strategy, the medical device industry in South Africa, and the South African market environment was conducted. A comparative analysis between the literature review and interview data was then conducted using the below procedure:

1. List all limitations of the industry, success factors of the industry, proposed strategies and recommendations for the industry as obtained in interviews.
2. List all limitations of the industry, success factors for business growth, theoretical strategies and recommendations from the industry as obtained in literature reviewed.
3. Compare all categories obtained in the research with academic or theoretical frameworks.
4. Indicate differences between information obtained from industry participants and theoretical frameworks and comment on the suitability of theoretical frameworks in the medical device industry.

A comparative analysis is used to compare or contrast two or more things that can have similarities yet have crucial differences. (Walk, 1998) The analysis is focussed on the explanation of differences and similarities between two or more groups.

3.3 Reliability and Validity

Reliability is a concept used for testing or evaluating quantitative research. (Golafshani, 2003) The concept of reliability in qualitative research is also referred to as ‘dependability,’ which

closely corresponds to reliability in quantitative research. (Lincoln & Guba, 1985) To reveal the congruence of reliability and validity in qualitative research, Lincoln and Guba (1985) stated that there is no validity without reliability.

Validity is a qualifying check or measure of research. Creswell and Miller (2000) suggested that validity is affected by the researcher's perception of validity in the study. Researchers have as a result, generated more appropriate terms for validity such as: quality, rigour and trustworthiness. (Golafshani, 2003) Sustaining the trustworthiness of a research report depends on establishing confidence in the research findings. (Golafshani, 2003) Rigor of a study is determined by exploring subjectivity, reflexivity and the social interaction of interviewing.

To ensure the credibility, validity, rigor and trustworthiness of the results of this research, the following strategies were used:

1. Triangulation – Information was cross-checked over multiple procedures or sources. This included data triangulation, where multiple sources of data used to help understand a phenomenon, and methods triangulation, where two research methods were used to help study a phenomena. (Burke Johnson, 1997)
2. Low Inference Descriptors – Descriptions phrased close to the participants' accounts, researcher's interview notes and verbatims were used when analysing data. (Burke Johnson, 1997; Morse, et al., 2002)
3. Reflexivity – A self-reflection on potential biases, predispositions and how it affected the research process and conclusion was done by the researcher. (Burke Johnson, 1997; Morse, et al., 2002)
4. Participant Feedback – Feedback and discussions of the researcher's interpretations and conclusions from interviews were collected from participants for further insight, verification and to assess whether concepts adequately reflect what is being investigated – also a measure of credibility (Long & Johnson, 2000; Burke Johnson, 1997)
5. Dependability – A study is deemed to be dependable if another researcher can follow a trail used by the researcher and arrive at the same or comparable conclusion. Dependability was ensured in this study through a detailed explanation of research methodology in light of existing dependable research, data analysis and results, allowing for this methodology to be replicated. (Coughlan, et al., 2007)
6. Transferability – A study is deemed transferable if findings can be applied outside the context of the study situation. The results, conclusions and recommendations of this study

can be transferred to similar highly regulated industries in South Africa such as food, microbiology and pharmaceuticals. (Coughlan, et al., 2007)

CHAPTER 4 DATA ANALYSIS AND RESULTS

This Chapter details the results of all interviews with South African medical device manufacturers conducted between 2018 and 2019. It contains a deductive content analysis of interview data, a comparative analysis of literature reviewed, and a participant observer reflection.

4.1 Participant Overview

Six semi-structured interviews were conducted with medical device manufacturers across South Africa. Research participants were selected using sampling techniques described in *Section 3.1.3*. Participants and their companies must have satisfied the criteria outlined in *Section 3.1.3* before being eligible to participate in the study. All six manufacturers that were identified participated in the study. The participants selected all had expert knowledge of business operations and the medical device manufacturing industry in South Africa in general.

Due to the sensitivity of the data collected, all manufacturers will be referred to as Company A, Company B, Company C, Company D, Company E and Company F. All specific product data, company locations and company names have been omitted to ensure complete anonymity of all participants. Participant information can be found in *Table 4.1* below:

Table 4.1: Participant Information

Company Name	**Medical Device Sector**	**Years of Operation**	**Interviewee Position**
Company A	Dental supplies	>30	Regulatory Affairs and Quality Manager
Company B	Consumables	2	Founder
Company C	Consumables	7	Founder, Managing Director
Company D	Consumables	>25	Co-founder, Managing Director
Company E	Hygiene	>20	Technical Director
Company F	Consumables, Capital Equipment	>50	Managing Director

Of six businesses that participated in this research, Company B only manufactured for two years before shutting down. Company C has manufactured consumables for 7 years, and in comparison to other participants can be considered a new manufacturer.

66.67% of participating companies all manufactured consumables. Medical device consumables can be defined as single-use or reusable equipment including syringes, needles, sutures, packaging, tubing, catheters, medical gloves, wound dressings and other devices and tools used in a hospital or surgical environment. (Instron , 2019) To ensure complete anonymity, specific products were omitted from the data analysis and results, and were referred to as 'consumables.' This was also as a result of the minimal number of medical device manufacturers in South Africa.

4.2 Deductive Content Analysis

The deductive content analysis laid out in *Section 3.2* was reported in three categories: The Business Environment, the Market Environment and Strategic Objectives. The complete content analysis can be found in *Appendix D – Interview Data*.

4.2.1 The Business Environment

4.2.1.1 Founding Member Background

Founding members of all companies have all had previous experience in an industry prior to establishing the current medical device companies. 66.67% (4/6) of participating company founders had experience in the medical device manufacturing industry prior to starting their companies. Founders have had experience in:

- Design of medical devices.
- Medical device industry involvement as a non-manufacturer or in another capacity.
- Experience at multinational medical device companies.

Four of six participants are founders of the medical device companies and were still managing directors of their respective companies at the date of interview. Participants that have had no previous experience in the medical device industry have had experience in a related industry, a business venture or the corporate environment.

4.2.1.2 Company Operations

83,33% (5/6) of participants have grown significantly from inception until present. Company B started business and manufactured for two years before shutting down. Reasons for shutting down included:

- All manufacturing operations were all outsourced with the exception of manual packaging operations.
- Manufacturing was not the sole focus of the founder/entrepreneur, but rather serving other roles in the industry.
- The company used a trademarked product and simply outsourced manufacturing in a very competitive retail environment.

Participant companies still in operation have all grown and have new customers and supply and manufacture additional products from inception until present. 66.67% (4/6) of companies began manufacturing from inception.

Companies that did not begin with manufacturing, began operating in the medical device industry as a distributor and consultant respectively. Companies that were founded pre-1990 now export and are the largest manufacturing participants in this study. All participants exhibit a pattern of steady growth over extended periods – the number of years of operation are a direct relation to the size of company and growth experienced. A list of companies in *Table 4.2* below,

sorted by year established, shows the size of companies and their operations through number of products manufactured and their target customers. Target customers are listed as priority customers first, per company. 66.67% (4/6) of companies supply public healthcare institutions and 75% of these, also supplied other customers.

Table 4.2: Company Sizes by Year Established

Company	**Year Established**	**Number of Products Manufactured**	**Target Customers**
Company F	1963	> 25	Export, South African private sector, South African public sector
Company A	1987	> 3000	Export, South African public sector
Company D	1993	13	South African public sector, Veterinary sector
Company E	1996	> 50	Export, South African public sector
Company B	2005-2007	1	Retail sector
Company C	2012	3-4	South African public sector (One province)

4.2.1.3 Raw Materials and Importation

50% of participants import all raw materials. Of the remaining 50%, Company A imports approximately 1% of raw materials, Company B outsourced all manufacturing operations locally, and Company D aims to procure only local goods. Reasons for companies not procuring raw materials locally include:

1. Raw material suppliers are not reliable. They are unable to meet lead times.
2. The quality of raw materials from local suppliers is inconsistent.
3. The lack of subcontractors, component manufacturers and raw material manufacturers in South Africa.
4. Raw material distributors have extremely high mark-ups on their products. The cost of importing these materials independently of these distributors is much less.

83.33% of suppliers all supply end users of the product, including wholesalers and distributors. Company C only supplies wholesalers and distributors of medical devices. In an attempt to increase sales, Company C now supplies end users.

4.2.2 The Market Environment

4.2.2.1 Competition

There was a trend of competition in the market where increases in the number of competitors were noted across all participating companies. All manufacturers experienced large numbers of competitors entering the medical device market in recent years.

66.67% of companies were founded before 2000. These manufacturers all share the following competition characteristics:

- At the time of inception, no other manufacturers existed in their medical device sub-sectors.
- Competition existed mainly from multinational companies that imported and distributed their products in South Africa.

Companies founded post-2000 have all dealt with other local manufacturers, importers and multinational companies. All participants have noted the increase in the number of importers and distributors in the medical device industry.

All companies now compete with:

1. Multinational companies
2. Middle Eastern and Far Eastern imports
3. South African importers and distributors
4. South African manufacturers

One participating company (Company F) is still the sole manufacturer of a specific product in South Africa. Reasons for this include:

- The company began manufacturing this product approximately 50 years ago.

- The product requires a large research and development component as it is part of the capital equipment sub-category.
- The capital costs of manufacturing this product is too much for SME's or start-up companies to invest.

Company E, that abides by regulations for medical devices as well as regulations regarding disinfectants and hygiene products, found that competition in this sub-sector has decreased and companies no longer supply the healthcare industry. This is due to the onerous costs of complying to two stringent sets of regulations.

50% of participants manufacture specialized medical devices that have a closer requirement for quality. As a result, these companies have minimal competition from other local manufacturers.

All existing companies still experience significant growth and can be described as follows:

- Company A still experiences steady growth.
- 50% of companies experienced rapid initial growth which tapered off.
- The company growth of manufacturers that export, is reflected in the growth of volumes of exported products.

4.2.2.2 Obstacles to Growth

The obstacles to growth as experienced by all participating companies was summarized and ranked in *Table 4.3* according to the commonness of issues faced by participating companies. These obstacles included the regulatory atmosphere, raw material suppliers, imports and exports, cash flow, the private sector and funding and incentives.

Table 4.3: Obstacles to Growth

Obstacle to Growth	**Explanation**
The regulatory atmosphere	Regulatory compliance for manufacturers in South Africa is more costly than compliance for distributors in South Africa. Numerous licenses and certifications are required including a manufacturing license, a quality management system, product registration, product compliance and testing. South African regulations do not match international regulations. Application fees for a new manufacturing license in South Africa costs R23 980, while distribution licenses costs R14 300. (Republic of South Africa, 2019) Application fees for renewal of manufacturing licenses cost R20 900, while distribution renewal licenses cost R11 990. (Republic of South Africa, 2019)
Raw material suppliers	The availability of raw material manufacturers including components and machined parts were issues noted by multiple companies. The availability and reliability of skills to manufacture raw materials, testing and quality auditing were also problems noted.
Imports and Exports	The import duty structures on raw materials are often higher than import duties imposed on finished goods. Ports of entry and exit have regular unexpected delays, causing delays to imported goods and exported goods, affecting lead times. For example, polyethylene sheets required for hospital packs are charged an import tariff of 10% while the full hospital pack is imported freely. (Jacobsens, 2012)
Cash flow	Public sector payments are not received timeously. Raw materials and other goods must be paid for as cash on delivery, therefore, long payments affect cash flow.
Private sector	Local South African companies are unable to penetrate the private sector due to multinational company dominance.
Funding and incentives	There is a lack of funding incentives for medical device manufacturers in South Africa.

4.2.2.3 Regulatory Affairs

66,67% of companies all abided by all medical device regulations upon inception. Participating companies all noted several issues with the South African medical device regulatory environment which are described in no particular order in *Table 4.4*.

Table 4.4: Issues in the Regulatory Environment

1.	The regulations imposed by regulatory body SAHPRA in 2013 mirrors the pharmaceutical model. The nature of pharmaceutical products and medical device products are independent, and as a result, create compliance problems.
2.	There is conflict between South African regulations and international regulations. The South African regulatory body expects full compliance to local regulations. If companies export, they must incur costs of both South African regulation and international regulation.
3.	The costs of implementing a quality management system (ISO13485) within a medical device manufacturer is costly and can cost between R500 000 to R750 000, which may be unaffordable to start-up manufacturers. No auditors of this system are available in South Africa which further increases costs.
4.	Product certification costs are exorbitant, and there is no qualified local regulatory body available to conduct product testing.
5.	The cost of manufacturing medical devices is much higher than the costs to be a distributor.
6.	The incorrect classification of medical devices, medicines and borderline products creates more costs for companies to comply with. Complying to all regulations results in higher costs, and consequently, less sales.
7.	The import duty and tariff structure imposed by South African Customs is inappropriate and not suited to manufacturers. The import duty structure does not specify individual products or product families, but are grouped into large, unrelated products sharing similar raw materials. For example, tariff code 901939 is used to

	import all syringes, needles, catheters and other consumables. (Jacobsens, 2012) Product specific data is not available as a result.
8.	The definition of a medical device manufacturer in South Africa allows those companies not physically manufacturing a product to define themselves as manufacturers through simple packing, repackaging or labelling operations.

4.2.3 Strategic Objectives

All participating companies have had elements of strategy built into company culture and company operations. No participating companies noted any formalised survival strategies or growth strategies.

4.2.3.1 Value Proposition

The value that participants brought to the medical device industry to give them competitive advantage included:

1. Brand representation
2. Product quality
3. Reduced cost through import substitution
4. Product innovation
5. First to market
6. After sales technical support

4.2.3.2 Overall Business Strategies

All research participants have incorporated various elements of strategy into their business operations and culture. Overall business strategies may also include survival strategies defined by participating companies upon inception. Overall strategies, common to the survival strategies defined in *Table 4.6*, are strategies which have retained importance from business inception to present operations. These elements of strategy, ranked by most common strategic elements found in participating companies are noted are in *Table 4.5*.

Table 4.5: Elements of Strategy Incorporated into Companies

Element of Strategy	
1.	Ensuring full regulatory conformance at all times. As a result, ensuring products are export-ready.
2.	Maintaining a strong focus on product quality with respect to conformance and patient safety.
3.	Focusing on a niche within the medical device market.
4.	Conducting market research on import substitutions to reduce costs in South Africa.
5.	Always seeking new customers. Not being reliant solely on the public sector for business.

4.2.3.3 Survival Strategies

Similarly to the elements of strategy implemented in companies seen in Table 4.5, no formalized survival strategies were noted by research participants. Survival strategies are important strategies defined by participating companies at their inception. Upon inception, founders incorporated strategies from their previous experience in the medical device industry and other industries. Survival strategies, ranked according to the most common by participating companies, are described in *Table 4.6*.

Table 4.6: Company Survival Strategies

Survival Strategy	
1.	Brand awareness – To create an internationally renowned brand of products. Brand representation is the most important factor in the medical device industry.
2.	Products – To create high quality products and to ensure product compliance always. To conduct market research to choose which imports may be substituted and produced at cheaper prices.
3.	Cash Flow – To ensure that all capital equipment and other costs are paid for using cash, avoiding any company debt.
4.	Customer Relationships – To establish and maintain good customer relationships. To always find new customers and not be reliant on current customers.
5.	Collaborations – To participate in medical device collaboration opportunities such as Medical Device Manufacturers South Africa (MDMSA) and others.

4.2.3.4 Growth Strategies

Research participants have developed numerous growth strategies focussed on products, regulations, manufacturing and business operations. These strategies are described in *Table 4.7*.

Table 4.7: Company Growth Strategies

Business Area	**Growth Strategy**
Product	• To improve product quality and implement continuous improvement procedures. • To focus on product development and being first to market. • To steer away from commodity medical devices and focus on products with a greater requirement for quality.
Regulations	• To ensure all regulations are complied with at all times. • To ensure product certifications, product compliance and be export-ready.
Manufacturing	• To be responsible for all stages of the value chain, which include being responsible for all stages of manufacture.
Business Operations	• To use key opinion leaders in the market to drive product. • To market the business and products strategically under the 'locally manufactured' banner. • To increase the number of customers being serviced.

4.3 Comparative Analysis

A comparative analysis was conducted for all research participants on theoretical frameworks of strategy, competitive forces in the medical device industry, the South African market environment, and success factors of SME's in South Africa.

4.3.1 Success Factors of SME's in South Africa

The success factors of SME's in South Africa were further categorized into internal success factors and external success factors. Similarities and differences between the internal and external environment described in *Section 2.5* and what participants experienced is described in *Table 4.8*. This information was extracted from the interviews conducted.

Table 4.8: Comparative Analysis of SME Success Factors

Factors	Company A	Company B	Company C	Company D	Company E	Company F
Company Demographics	There is a strong focus on product differentiation through product development and being first to market. The survivability of the firm is not compromised due to being in operation for more than 30 years, as well as the availability of required resources.	The size and age of company affected the survivability of the firm as there were only 2 active members while the company operated. The product manufactured was not differentiated. The product was trade-marked, but the brand was not well renowned and multiple others manufactured the same product.	Although a small firm, the survivability of the firm was not compromised due to the sustainable competitive advantage created through import substitution products. The age of the firm was not a factor due to entrepreneurial experience in a related industry.	Sustainable competitive advantage was created through import substitutions at much cheaper prices. The firm's survivability was not compromised as the firm began as a trader and thereafter began manufacturing, the founder was experienced in the medical device industry and	Sustainable competitive advantage was created through a patented product purchased. The size of the firm and age of the firm did not compromise the survivability of the firm as the products manufactured were of the highest quality.	The age of the firm and size of the firm did not affect the survivability of the firm as a result of the number of years in operation. A sustainable competitive advantage was created through high quality products manufactured for more than 50 years.

				established a brand prior to manufacturing.		
Entrepreneur Demographics	• Entrepreneur demographics are an influential factor in SME performance and competitiveness. To protect the anonymity of firms, gender of entrepreneurs and founders were not discussed. South Africa has taken the initiative to support female entrepreneurs and to afford them the opportunity that they would once have not had. • All firms, including Company B which was shut down, were founded are run by competent entrepreneurs with the relevant experience, skills, problem-solving ability and education required to operate a business efficiently, specifically within the medical device industry.					
Previous Experience	Founders gained previous work experience, specifically in the medical device industry. Although there was no experience in starting a business venture, previous industry-	Previous work experience, business ownership experience and industry-specific experience were all factors that founder of Company B had experience in. The business still, however, failed.	Founder of Company C gained experienced in a related industry, but had no experience in the medical device industry or business venture experience.	Founder of Company D gained industry-specific experience in the medical device industry at a multinational. No business venture experience was gained prior to establishment.	Founders of Company E gained work experience in a corporate environment before establishment of their firm. No prior business venture or	Founder of Company F gained industry-specific experience with regards to design of medical devices. Current managing director had gained previous

	specific experience was sufficient.				industry-related experience was gained.	business venture experience prior to managing the firm.
Economic	• All participants experienced economic conditions faced in South Africa. Interest rates in South Africa are high which limits the amount of capital that can be raised . • Value Added Tax in South Africa was raised to 15%, corporate tax was also raised in South Africa further reducing the profit incentive. This serves as an obstacle to all new start-up businesses and manufacturers.					
Policy-Institutional	• The medical device industry in South Africa deters entrepreneurship due to the number of macro-economic policies, legislation, frameworks and laws which govern the industry. Companies must comply with all legislation and all regulatory frameworks to trade within this industry. • All participants have abided by all stipulated regulations. However, due to the costly nature of implementing new procedures and abiding by regulations, new businesses are deterred from the industry due to the large capital investment required for registration and trade. • Medical device regulations have been documented and implemented in South Africa. These regulations are not strictly enforced, and have resulted in many non-compliant firms still being allowed to trade. This is another hinderance to entrepreneurship in the medical device industry.					
Socio-Cultural	• Manufacturers require public infrastructure and servitudes to be installed for efficient business operation. This infrastructure is available in South Africa to service medical device manufacturers.					

	• Capital and funding schemes are available in South Africa for business development. These funding schemes are not well advertised, and as a result, participants and other medical device companies are unaware of governmental support or funding schemes available for further business development. • Access to technology is a large contributing factor in the medical device industry as a result of ongoing research and development in healthcare. Although new technologies are available, the capital requirement for local manufacturers is too large to sustain, which results in limited access to the technology required. • Access to skilled labour in South Africa is problematic. Appropriate skilled labour is not available for component manufacturing, raw materials manufacturing and other machining which may be required.
Market Opportunity	• The medical device industry is a growing industry growing at approximately 10% per annum which promotes entrepreneurship in South Africa. (South African Medical Technology Industry Association, 2014) • The steady demand for products in South Africa and across the medical device industry attracts entrepreneurship. • Access to the medical device industry and the barriers to entry are a deterrent for new SME's due to the presence of multinationals and other well-established brands, the regulatory environment and the capital investment required for medical device manufacture.

4.3.2 Obstacles to Growth in the South African Medical Device Industry

Obstacles to growth noted in participating companies were compared to obstacles to growth experienced by South African small to medium enterprises. Obstacles to growth faced by South African SME's from the literature included:

1. Lack of Access to Finance
2. Lack of Collateral
3. Crime
4. Lack of Owner's Equity Contribution
5. Bad Credit Record
6. Insufficient Government Support
7. High Production Costs
8. Inadequate Market Research
9. Lack of Information Technology
10. Corruption

South African medical device manufacturers (research respondents), however, experienced obstacles to growth which included:

1. The Regulatory Atmosphere
2. Raw Material Suppliers
3. Imports and Exports
4. Cash Flow
5. Private Sector
6. Funding and Incentives

Five of the top ten obstacles to growth faced by South African SME's were faced by the South African medical device manufacturers in this research.

Lack of access to finance, lack of collateral and insufficient government support are closely linked to funding and incentive problems faced by medical device manufacturers. Lack of access to finance includes the unavailability of government grant schemes, and preferential loan schemes for companies to implement in new business ventures or growth opportunities for existing companies. Lack of collateral refers to the unavailability of specific owned assets or other items used to secure repayment of loans from the lender. Insufficient government support refers to the lack of government departmental involvement in the industry to promote local SME's.

High production costs are linked to imports and exports as well as raw material suppliers. High production costs include high overhead costs as well as expensive labour costs in comparison to other bulk manufacturing countries such as China. Imports and exports refers to the large number of imported medical devices in South Africa that compete with locally manufactured products as well as the high quality medical devices exported from South Africa which could be used in health institutions locally. Raw material suppliers refers to the lack of reliable local raw material manufacturers and suppliers in South Africa.

Inadequate market research is linked to the regulatory atmosphere and the lack of knowledge regarding laws, regulations, licensing and other regulatory aspects. The lack of medical device regulations in South Africa allowed businesses to operate without any standards. The introduction of medical device regulations in South Africa in 2015 introduced exorbitant costs which current businesses were not previously aware of. (Company.D, 2018)

4.3.3 Strategic Frameworks

Overall business strategies, survival strategies and growth strategies were analysed in comparison with strategic frameworks: Porter's 5 forces, Microforces within Competitive Rivalry and Barriers to entry, The Delta Model and Blue Ocean Strategy.

4.3.3.1 Porter's 5 Forces

Table 4.9: Competitive Forces Experienced in the Medical Device Industry Compared to Theoretical Forces

Competitive Force	**South African Medical Device Industry (Research Respondents)**
The Threat of New Entrants	The threat of new entrants can be described as a high impact force on the medical device industry. Businesses and potential start-up manufacturers face: • Economies of scale – The inability to produce products on a scale large enough to compete with other local manufacturers or importers. • Product Differentiation – Creating brand awareness is an issue for South African manufacturers when competing with already established brands. • Capital requirements – The capital requirement to construct a medical device manufacturing facility is onerous, and unaffordable to start-up companies. • Government policy – Barriers to entry are created through manufacturing licenses required, quality system requirements, compliance costs and product certification costs.
The Bargaining Power of Suppliers	The bargaining power of suppliers can be regarded as a low impact force. There are multiple suppliers of all products available internationally. Medical devices are undifferentiated, therefore switching costs are minimal.
The Bargaining Power of Customers	The bargaining power of customers or buyers can be regarded as a medium impact force. Customers are able to switch to other suppliers with low switching costs. Buying power has become consolidated.

The Threat of Substitute Products or Services	The threat of substitutes is regarded as a medium impact force. There are multiple medical devices performing the same function, and further developments are made on medical devices, yet company growth is unaffected. This is as a result of steady increases in demand for current medical devices.
Competitive Rivalry	Competitive rivalry or jockeying for position in the market can be regarded as a high impact force. Multiple companies and manufacturers compete in the South African medical device industry. Competition in the industry is high due to low supplier switching costs. Products are perishable in the medical device industry and fixed costs are high. Rivals are diverse in origin and have different strategies.

Following Porter's 5 Forces, a comparison was done between what South African medical device manufacturers in this research experienced, and microforces within competitive rivalry and the barriers to entry in the industry. (*Table 4.10*, *Table 4.11*)

Table 4.10: Competitive Rivalry Microforces and South African Medical Device Manufacturers

Competitive Rivalry Microforce	**South African Medical Device Manufacturers (Research Respondents)**
Commitment	South African manufacturers are committed to the market and have made efforts to grow their companies in the industry. Companies are determined to supply their products as first choice over multinationals, importers and distributors.
Number	A large number of competitors exist within the South African market. This market continues to grow. Competition is composed of importers, distributors and other manufacturers. There is a rapid, steady rise in the number of importers in South Africa.
Similarity	Numerous sub-categories of medical devices exist within the market. Manufacturers are able to select from a large range of products. Various business models exist within the industry and businesses are able to tailor their business model to their product and other requirements.
Mindset	Multiple strategies are used in the medical device manufacturing industry. These strategies are depended on the market being supplied, and the product manufactured.

Table 4.11: Entry Barrier Microforces and South African Medical Device Manufacturers

Entry Barrier Microforce	**South African Medical Device Manufacturers (Research Respondents)**
Information	Gaining knowledge of competencies and key skills required for medical device manufacturing is difficult unless entrepreneurs have worked in the medical device industry, have a flair for design, or have related industry or business venture experience.
Economic	The economic factors to enter the medical device industry in South Africa are onerous. The compliance costs, construction costs of a manufacturing facility, marketing costs and capital equipment costs are unaffordable to start-up companies.
Physical	The South African public health sector's tendering system has allowed customers to gain access to more clientele. The availability of resources in the medical device industry in South Africa is minimal. Resources include skilled work, capital, and the relevant expertise.
Psychological	The medical device industry in South Africa is a steadily growing industry. All new regulatory compliance and transitions to new systems have made the industry uncomfortable for its participants.

All participating companies noted that there were no formalised business strategies, survival strategies or growth strategies. Elements of The Delta Model are discussed in *Table 4.12* below.

Table 4.12: The Delta Model and South African Medical Device Manufacturers

Delta Model Element	**South African Medical Device Manufacturers (Research Respondents)**
Mission of the business	All medical device manufacturers have clearly defined their business scope and core competencies. Core competencies required to manufacture were determined by founders, all of which, had experience in the medical device industry or a related industry.
Competitive Positioning and Industry Structure	Participant companies were established prior to new regulations being enforced in South Africa. All founders were familiar with industry threats and opportunities before determining a competitive position for their company. All companies presented a competitive position or value proposition which were built into the company's culture and operations.
Strategic Agenda	South African manufacturers did not set out action-driven tasks to achieve company objectives. Company objectives were not formalized and clearly communicated to all employment levels at their respective companies.

An element of Blue Ocean Strategy found in *Section 2.3, 'Reach Beyond Existing Demand'* was used by Company A. Blue Ocean Strategy was not otherwise implemented in other participating medical device manufacturers.

4.4 Participant Observer Reflection

Using the process outlined in *Section 3.1.4.2,* a protocol for conducting participant observation was developed as follows:

- The researcher was employed at a medical device manufacturing firm from 2017 in the capacity of a quality officer. Although the researcher was employed at a medical device manufacturing firm, the group investigated was the medical device manufacturing industry at large.

- The researcher was expected to perform duties as required at the company to ensure complete quality compliance to all newly implemented regulations.
- Data specific to competition amongst local manufacturers, the market environment as well as policy and regulations were collected in an electronic research journal.
- Only key aspects of the medical device manufacturing industry and the regulatory framework were recorded as a part of this study.
- No potential harm to the participant were noted in the study.
- Pseudonyms were used for any companies or organizations named in the research. All sensitive operational or strategic information was censored.
- Verbal informed consent was obtained from company directors to conduct participant observation while employed full-time.

Participant Observation allowed the researcher to gain sufficient knowledge of the medical device industry environment, the market environment, the competitive environment, manufacturing operations and newly imposed legislation.

The researcher focussed on issues that included competition within the medical device industry, the regulatory framework that governs the medical device industry and opportunities for company growth in the South African medical device industry. The results of the participant observation exercise brought to light multiple problems faced by medical device manufacturers and are presented in *Section 4.4.1* and *Section 4.4.2*.

4.4.1 The Market Environment

- Competition in the medical device industry has steadily increased.
    - Increases in competition were noted largely by importers, distributors and general traders. This was also confirmed by research participants that competition in the medical device industry has increased through a number of new importers, wholesalers and manufacturers.
    - The number of manufacturers in South Africa have increased. However, core manufacturing operations have not increased due to the definition of a medical device manufacturer in South Africa.
- Importers have proved to be the largest competition problem for local manufacturers in South Africa. Importers are able to supply products from the Far East and Middle East at a fraction of the price that manufacturers are able to supply locally.

- The South African public health sector provided the largest opportunities for business in South Africa. The public health sector remains extremely price sensitive. Public health institutions were willing to compromise quality of products for pricing.
- Health institutions continue to procure goods from companies that are unlicensed and/or incompliant manufacturers. This was confirmed by research participants as the implemented medical device regulations are not stringently enforced. As a result, health institutions continue to procure from incompliant companies.
- Public sector payments are not timeous and have a high impact on cash flow of small business. All products or raw materials procured, are purchased as cash on delivery, however, customer payments are not collected timeously. This is as a result of misappropriated funds, corruption and inappropriate disbursement systems.
- Private healthcare groups have not attempted to support local South African business. Applications and registrations to be suppliers were regularly ignored by private healthcare groups despite fulfilling all criteria.
- Brand awareness and representation are important factors in determining medical device sales. End users of devices are more comfortable using a trusted, known brand than other products serving the same intended purpose.

4.4.2 The Regulatory Atmosphere

- Regulations imposed in 2013 on the medical device industry are not aligned to international regulation imposed in other regions of the world.
    - A manufacturers license or distributors license must be issued to trade in the medical device industry.
    - ISO13485 is a requirement for medical device manufacturers and cost between R500 000 – R1 000 000 to implement in an existing company.
    - Product certifications are required such as South African Bureau of Standards (SABS) for manufactured products.
    - A sterile environment of the lowest acceptable quality capable of fitting one manufacturing line costs a minimum of R1 500 000.
    - South African medical device authorities require technical files for medical devices specific to South African regulation only.
    - To export, CE certification must be obtained for medical devices. CE certification per product can cost between R1 500 000 – R2 000 000.

- Public health institutions still accept products from medical device companies that have not obtained licenses 5 years after regulations were imposed.
- SAHPRA and The National Department of Health have had endless technical and administrative issues, and have been unable to issue new licenses timeously or deal with regulatory problems.
- The pharmaceutical regulatory model was mirrored for medical devices, and proved to be an inappropriate system governing medical devices.
- Funding and incentives are available to small local manufacturers, but are not communicated to all industry stakeholders.

CHAPTER 5 DISCUSSION

This Chapter discusses research findings in terms of the *Critical Research Question* and *Research Objectives* in conjunction with literature reviewed in *Chapter 2 Literature Review*. It aims to answer the research question through discussing:

- The framework used to analyse competitive forces experienced in the industry, discussing reasons that local companies are not starting up in the medical device manufacturing industry.
- The comparative analysis conducted in *Section 4.3*.
- Reliability and validity of the study.

As a result of the high barriers to entry in the South African medical device industry, namely the regulatory atmosphere, Porter's 5 Forces was used as the primary strategic framework to analyse the competitive forces faced by South African medical device manufacturers. This framework was used to identify individual competitive forces faced by manufacturers. An alternate framework, PESTEL, which defines the Political, Economic, Social, Technological, Environmental and Legal environment a business operates in, was not used to identify the competitive forces faced by local medical device manufacturers. (Yüksel, 2012) The South African medical device industry is dominated by a stringent regulatory framework. This dominates the macro-environment of the medical device manufacturing was therefore not the appropriate tool to identify individual challenges in the South African medical device manufacturing environment.

5.1 Competitive Forces

To understand the competitive forces experienced by local medical device manufacturers in South Africa, it was important to identify competitive forces faced by start-up companies and SME's in the South African marketplace. A deductive content analysis of data collected from interviews was conducted to understand the market environment South African medical device manufacturers operated in, the challenges faced in the market and counter-measures implemented to mitigate these challenges.

Four of six companies that were interviewed manufactured medical device consumables. (*Table 4.1)* The consumables medical device sub-sector is the most cost effective sector to manufacture medical devices in. (South African Medical Technology Industry Association,

2014) Although start-up capital remains high, the capital required is much less than supplying capital equipment, diagnostics, electronic medical devices and other sub-sectors.

5.1.1 Medical Device Manufacturer Founding Members

All founding members and managing directors of medical device manufacturing companies had prior experience in industry. According to Kunene's (2008) internal success factors of South African SME's, previous experience and industry-specific experience are important factors in influencing the entrepreneurial process. Being a highly regulated industry with multiple barriers to entry, it is imperative for founders of medical device manufacturing firms to have experience prior to starting manufacturing operations. (Cone & Walker, 2003) If experience in the medical device industry specifically is not gained, it is important for founders to gain experience in a related industry, in design and development of technical products or business venture experience. Prior to the establishment of Company E, founders gained experience in senior management positions at corporate firms being responsible for senior level decision making. Prior to the establishment of Company F, the founder gained experience in design and development of other products, while the current managing director also gained experience in a business venture prior to taking over the role. (*Table C.0.1*)

5.1.2 Company Growth

Manufacturers that have started-up in the medical device industry all show good growth following establishment. A pattern of steady growth over extended periods was revealed for existing companies. All existing participating companies experienced rapid growth upon inception which tapered off. However, growth remained steady for all existing companies. (*Table C.0.1*) In addition to this, the choice of products manufactured proved to be a determining factor in the success of the business. As competition with distributors and importers increase, it is vital for companies to select products with closer attention to quality. Due to stringent labour regulations, higher production costs and lesser capacity, South Africa is unable to compete with Middle Eastern and Far Eastern imports. Therefore, products that have a closer requirement for quality and those that are not suitable to simple mass production are better suited to South African manufacturing conditions. (Company.F, 2019)

Competition from importers and distributors are another high impact force in the medical device industry. Due to the price sensitivity of the industry, end users, predominantly in the public health sector, are willing to compromise quality for price. Company B, for example shut down following two years of operation, as a result of the product selected, among factor factors.

Although the product was trademarked, multiple importers, distributors and multinationals also sold this product to retailers and health institutions. However, Company B could not keep up with demands of retailers or prices retailers expected as a result of a multitude of other suppliers. According to Porter's 5 Forces model, this is an example of a high threat of substitute product. (Porter, 1979) It is significant to note that a trademark is specific to a product brand and does not prevent sale of the same product under a different brand name. (Companies and Intellectual Property Commission, 2019)

5.1.3 Market Conditions

Company A, Company D, Company E, and Company F were all founded before 2000 where market conditions in the medical device industry were different to market conditions that were faced from 2010-2018. (*Table 4.2*) The data shows that although the survival strategies of these companies were not relevant to current market conditions, the strategies implemented by these companies to mitigate newly imposed medical device regulations in South Africa were relevant to all start-up medical device manufacturers.

Start-up problems faced by Company C were most relevant to market conditions faced in 2018 as a result of the date of establishment, six years prior. Company C immediately faced competition from multiple importers, distributors and other manufacturers in South Africa. The products manufactured by Company C did not require a sterile environment, thus venture capital was minimal. The data shows that capital costs in the medical device industry were a large deterrent to companies as a result of capital equipment and compliance costs. (*Table 4.3*) The costs of creating a sterile environment to manufacture medical devices are the largest proportion of capital equipment costs as noted by the researcher in *Section 4.4.2*.

5.1.4 Raw Materials

Raw materials and the importation of raw materials proved to be a problem for local medical device manufacturers. (*Table 4.3*) Sourcing raw materials and components were problematic for manufacturers in South Africa that felt that the quality of product and the availability of the product were inconsistent. Furthermore, local suppliers of raw materials that imported their products, marked-up these products unreasonably as opposed to the cost of manufacturers independently purchasing the products overseas. (Company.F, 2019) Companies in South Africa are encouraged to manufacture locally, but are not further encouraged to procure raw materials locally. The Department of Health and The Department of Trade and Industry frameworks do not extend further than encouraging basic manufacturing of medical devices as

noted in the Black Industrialist Scheme funding incentive application form. (The Department of Trade and Industry, 2019) The problems faced to procure raw materials locally further escalates production costs through additional shipment costs, delays in the arrival of goods, customs checks and delays, import duties and South Africa's volatile exchange rate. (*Table 4.3*; Kunene, 2008)

5.1.5 Competition

A trend of increased competition was found across all companies, except company E. Companies faced increasing competition from importers, distributors and multinationals as well as other local manufacturers as seen in *Section 4.2.2.1.* Although the number of local manufacturers increased, the number of importers and distributors further increased. Despite incentives to manufacture, the number of importers and distributors continued to increase as a faster rate than the number of manufacturers. The number of distributors and importers have increased due to the ease of registration to be a distributor; the lack of responsibility for products as they are not manufactured by the distributor; the minimal costs of registration for importation; and distribution as noted in Section *4.2.2.3*.

Company A, and Company F were both founded pre-1990, and had no competition from local manufacturers at their times of inception respectively. The number of manufacturers of medical device products in South Africa has grown as a result of South Africa's strategic objectives and focus industries. (The Department of Trade & Industry, 2018) The presence of multinational companies is predominant in private sector health institutions. With South Africa's strategic objective of local procurement in the healthcare industry, more local companies – manufacturers and distributors – are supplying public healthcare. (Western Cape Government - Health, 2019)

Company E, found that the competition in the hygiene healthcare sector decreased over time. This was due to additional regulations specific to hygiene products being enforced in South Africa. The additional regulations imposed large cost implications for all those in the healthcare industry. Furthermore, hygiene products were classified by the regulatory authority as a medicine, and not a medical device when regulations were implemented in South Africa. (Medicines Control Council, 2015) This implicated further increases in costs which hygiene manufacturers were not willing to accept. Competition in the hygiene industry did increase, but competition within the healthcare sector decreased. Classification of medical devices, medicines and borderline products are a significant factor in determining the number of

competitors in the industry. Regulations imposed on hygiene manufacturers required additional microbiological testing, which was not available in South Africa and had large cost implications to undergo testing in another country as experienced by Company E.

5.1.6 The Regulatory Environment

The largest problem faced by participants was the inappropriate regulatory atmosphere which their businesses operate in. Costs of regulatory compliance in the medical device industry are exorbitant as explained by interviewees (*Table 4.4*) and participant observer experience in *Section 4.4.2*. As a result, medical device customers and end users still procured goods from unlicensed companies and incompliant manufacturers. It is evident that the lack of knowledge of all aspects of regulatory compliance in the industry has negatively affected businesses.

Prior to 2013, the medical device industry was an unregulated industry in South Africa. Regulations exist in other parts of the world and these are enforced for companies that already trade in the industry. South African companies have already begun exporting medical devices and are compliant to stringent regulatory systems such as Conformité Européenne (CE) across the European Union and Food and Drug Administration (FDA) in the United States. (European Union, 1993; U.S Food and Drug Administration, 2019) However, imposing new legislation in South Africa has resulted in additional regulatory costs for already compliant manufacturers who now face South African regulatory costs and foreign regulatory costs. It is important for regulations in South Africa to align with regulations that have been implemented in other successful healthcare industries around the world such as Europe and the United States of America.

It is critical that the South African regulatory system accommodates specific consideration for the medical device industry. A preliminary study of key participants in the industry reveal that a mirror of the pharmaceutical model is not appropriate as the intended use of the two groups are different. (Global Medical Technology Alliance, 2012) The manufacturing processes are very different, and medical devices do not require the extent of regulation that pharmaceuticals do.

Import duty structures on raw materials have also negatively affected medical device manufacturers. Because of the unreliability and inconsistency of local raw material suppliers, manufacturers were forced to purchase raw materials from other countries. (*Table 4.3*) The import duty tariff structure in South Africa is an inappropriate system as it does not allow for sufficient data to be extracted. Products imported and exported are not closely monitored due

to grouped tariff headings, and products moving in and out of the country cannot be identified as noted by the researcher when attempting to obtain importation data from the South African Customs and The Department of Trade and Industry. (Deloitte & Touche; Department of Trade & Industry, 2014)

Certain finished products in South Africa do not have import duties imposed on them, but raw materials required to manufacture these goods, have import duties imposed on them. Further knowledge of import duties and importation of goods is clearly required manufacturers across all industries. To avoid paying import duties in South Africa on raw materials and components, these components should be placed into a 'rebate store' area where officials can inspect and thereafter rebate the import duties paid on those goods; provided that there is sufficient proof that the products imported are used in a manufacturing process and are being exported. (South African Revenue Services, 2019)

5.1.7 Cash Flow

Cash flow problems were created only by public health sector institutions in South Africa. In other words, public health institutions do not guarantee timeous payments and are also not subject to interest on overdue payments as stipulated by The National Credit Act (No.34 of 2005). (South Africa, 2005) Public health institutions have stringent payment policies and often do not stick to timeous payments. This causes major cash flow problems for companies as goods purchased overseas have strict payment policies where products must be fully paid up on delivery. The delay of money coming in to the company as compared to the speed at which money leaves companies causes cash flow restrictions. (*Table 4.3*)

5.1.8 The Private Sector

The private sector was a large problem for local medical device manufacturers and other local companies. The presence of multinational products and brands in private sector hospitals are high. (Deloitte & Touche; Department of Trade & Industry, 2014) Multinationals are tied down to long-term contracts with large discount schemes, thus creating difficulty for penetration of the market for smaller, local companies. Private healthcare groups have not committed themselves, like public healthcare, to strategic procurement of locally manufactured products. This was highlighted by the lack of documentation available from private sector healthcare for tender bidding as well as the lack of documentation explaining private healthcare preferential procurement.

5.1.9 Funding and Incentives

Although companies felt that funding and incentives to manufacture were lacking, South Africa has implemented schemes and grant incentives for companies to manufacture and to pursue short-to-medium term manufacturing projects. The funding is, however, focussed on microenterprises, and companies that are BB-BEE compliant. (The Department of Trade and Industry, 2019) There has been no direct link from relevant governmental departments to all medical device manufacturers and companies to inform those of incentives to manufacture and to localize operations. In addition to this, membership at medical device collaborations such as Medical Device Manufacturers of South Africa (MDMSA) and South African Medical Technology Industry Association (SAMED) are voluntary.

5.2 Internal and External Success Factors of South African SME's

Internal and external success factors for South African SME's defined by Kunene (2008) all had an impact on medical device manufacturers in South Africa. Company demographic factors, entrepreneur demographics and previous experience were important internal factors affecting manufacturers. (*Table 4.8*)

5.2.1 Company Demographics

The size and the age of the firm were important factors to consider as brand representation in the industry is important as seen in strategies implemented by participant companies. Brand representation is built with the age, size, product and competitiveness of the company. Previous experience is a factor that affects the success of the firm, specifically due to the highly regulated nature of the medical device industry.

5.2.2 Economic Factors

Economic factors have a high impact on all industries in South Africa. The enterprise density of 2%, and medical device company growth proved that there is still space for new company growth in the South African medical device manufacturing industry. (Kunene, 2008) Although existing companies, including those in this study, have significantly grown, high interest rates and taxes have plagued the entrepreneurial process in the South African medical device industry.

5.2.3 Policy-Institutional Factors

Policy institutional factors had a high impact on the medical device industry in South Africa. A prohibitive regulatory framework governing medical devices has deterred new business and new manufacturers. Regulatory compliance costs have proved to be too expensive for any start-up manufacturer to cope with. (Company.D, 2018) All research participant companies were founded prior to regulations in South Africa being developed in 2013 and enforced in 2016. (*Table 4.2*) Company D, stated that if it knew the cost of compliance before establishing the company, the founders would have reconsidered venturing in the medical device industry. Company A, Company E and Company F abided by international regulations for export purposes. *(Table C.0.1)* The cost of compliance to South African regulation was minimal as a result of international certifications already attained.

5.2.4 Socio-Cultural Factors

Socio-cultural factors proved to have a medium impact on medical device manufacturers. South Africa's strategic objectives have created rapid industrial development around the country, enhancing the accessibility to public services. (Mashaba, 2016) Several funding schemes are available to enhance access to capital funding for manufacturing projects such as The Department of Small Business Development Funding and the Department of Trade and Industry funding opportunities. (The Department Of Small Business Development, 2019; The Department of Trade and Industry, 2019) The issue faced by South African manufacturers include stringent labour regulations which hinder competition, compared to that of Middle Eastern and Far Eastern mass manufacturing countries. (Company.F, 2019)

5.2.5 Market Opportunity Factors

Market opportunity factors had a high impact on medical device manufacturers in South Africa. The medical device industry continues to grow globally and within South Africa as described in *Section 1.1*. Demand for products also continually increases despite further developments and new products being released to the industry. Problems faced by start-up companies included the prohibitive regulation in South Africa as well as the increasing amount of competition in the market.

5.2.6 Obstacles to Growth

Obstacles to growth of medical device manufacturers were closely linked to the obstacles to growth faced by South African SME's. ***(Error! Reference source not found.)*** Local medical

device manufacturers noted the lack of funding and incentives to manufacture which equates to:

- The lack of access to finance through banks, investment portfolios, private funders and government initiative.
- The lack of collateral through assets of capital equipment required to provide as security to finance.
- Insufficient government support through lack of import duties, lack of government grants and funding incentives for manufacture, and lack of support to ensure regulatory compliance.

High production costs were linked to imports and exports as well as raw material suppliers. Raw material suppliers in South Africa do not guarantee quality and availability, and are also grossly marked up. Competing with importers and the price of imported goods proved to be difficult for local manufacturers as a result of much cheaper production costs elsewhere.

Inadequate market research was linked to the regulatory atmosphere and the lack of knowledge regarding laws, regulations, licensing and other regulatory aspects. Regulations may be product specific and lack of market research could result in unforeseen manufacturing and other cost implications.

Obstacles to growth faced by research participants in South Africa's private sector as well as in cash flow, are specific to the medical device industry. Although these are problems also faced by other industries, they are not problems that are faced immediately as compared to the top ten obstacles to growth faced by South African SME's outlined in *Section 2.5.3*. Medical device manufacturers were also subject to crime, corruption, lack of information technology, bad credit records and lack of owner's equity contribution, but these were not immediate threats to manufacturers as compared to the number of barriers to entry and the competitive rivalry within the industry.

5.3 Strategy and Company Strategic Objectives

Strategy in medical device companies was built into company culture and business operations. Companies used elements of strategy found in theoretical frameworks such as Porter's 5 Forces, microforces within Porter's 5 Forces (*Section 2.1*), The Delta Model (*Section 2.2*) and Blue Ocean Strategy. (*Section 2.3*)

The most important aspect of strategy implemented within medical device manufacturers was brand representation as noted in participant interviews. Brand representation is built with the quality of product, size and age of the firm, the reach of customers, key opinion leaders in the market and marketing strategy of the firm. To achieve good brand representation, firms must consider a number of factors, including what will give the company a competitive advantage over firms already established with high quality products and good brand representation.

As a result of the price sensitivity of the South African medical device industry, and based on interview data, this study identifies that the key focus areas for medical device manufacturers should be:

1. Regulatory Compliance
2. Price Reduction through Import Substitution
3. Product Quality
4. A Marketing Strategy
5. After Sales Service and Building Customer Relationships

Potential start-up companies focussed on innovation and being first to market will be faced with exorbitant capital costs and research and development costs. Research and development skills required for the development of new, innovative medical devices are not available in South Africa, and would require being outsourced to other countries which is time consuming and costly. (Company.E, 2018) Therefore, product innovation, product development and being first to market are not appropriate strategies for start-up medical device companies to implement in the South African industry.

Cash flow and liquidity are important aspects of start-up companies and are related to obstacles to growth faced by South African SME's: lack of access to finance and collateral as well as insufficient government support. The medical device sector most easily penetrable, is the public health sector as a result of all research participants supplying public health institutions among other customers. (*Table 4.2*) Problems experienced by companies in the public health sector include the delays in payment and extended payment periods as stipulated by government. Ensuring good debtors collection practice, avoiding company debt, and paying cash for any capital equipment, inventory or other related expenses.

Company growth strategies included strategies focussed on continually improving product quality and ensuring that regulations are always complied with. *(Table 4.7)* Established medical device companies were focussed on reflecting their company growth through exportation. Due

to the prohibitive nature of regulations in South Africa and the problems of penetrating the private sector in addition to South Africa's volatile economic status and exchange rate, the results show that companies are focussed on being export-ready and complying with international regulations.

Porter's 5 Forces framework allows companies to understand the true nature of the industry before establishing where to position themselves within the industry. (Porter, 1979) The highest impact forces on the medical device industry were the entry barriers and competitive rivalry or jockeying for position in the market. (*Table 4.9*) These forces and the microforces within these competitive forces define the medical device industry in South Africa and allow start-up firms to develop and implement appropriate survival strategies.

The Delta Model provides a comprehensive strategic framework defining the business scope and core competencies of the business, and allows core competencies to support the development of the strategic positioning of the business and identify resources and skills for implementation. (Hax & Wilde, 2003) Although elements of The Delta Model were appropriate to implement within medical device firms, the model as a whole is not suitable due to its comprehensive planning and analyses of industry structure, industry attractiveness, core competencies and resources and skills required to implement the strategy. (*Table 4.12*)

Blue Ocean Strategy requires firms to find new, untapped market space. In the medical device industry, research and development costs are exorbitant, and finding new products, or developing products further may be too costly for start-up manufacturers. The element of Blue Ocean Strategy followed by companies focussed on innovation and product development is: 'Reach beyond Existing Demand.' (Kim & Mauborgne, 2005) Manufacturers focussed on product development and innovation aimed to be first to market and to continuously develop current products further, thus creating additional demand.

Medical device companies have been founded using the entrepreneurial process more than formally planning strategies. The formalized planning of strategies was non-existent in all participating companies. Previous experience factors, characteristics of the entrepreneur, understanding the medical device industry's competitive environment and regulatory atmosphere are more important than formally planning strategies.

5.4 Participant Observations

The participant observation protocol observed by the researcher included many similarities to the data extracted from research participants, and the literature in *Section 2*:

1. Research respondents also confirmed the increase in competition in the South African medical device industry through importers, distributors and other manufacturers. The researcher noted that importers were the biggest competition which was also confirmed by research respondents. This was further confirmed by obstacles to growth of imports and exports found in *Section 2.5.3*.
2. The researcher noted that public sector health institutions provided the greatest opportunities for business. An obstacle to growth experienced by local medical device manufacturers included private sector penetration. Four of five active research respondents relied on public sector institutions as their primary income.
3. Although public sector health institutions provided the biggest opportunity for new business, the researcher noted cash flow problems as a result of delayed government reimbursements which was also confirmed by research respondents.
4. A significant finding by the researcher included funding incentives that were available to smaller local manufacturers. This, however differed from the findings from research respondents who felt that no funding and incentives were available to grow manufacturing operations. Obstacles to growth found in *Section 2.5.3* also confirmed that South African SME's felt they receive insufficient government support and lack of access to finance. This implies that funding and incentive schemes are not being effectively communicated to South African medical device manufacturers.

5.5 Reliability and Validity

To determine the reliability and validity of this study, six techniques described in *Section 3.3* were used.

5.5.1 Triangulation

The results of this research were gathered from three sources:

1. Literature reviewed
2. Semi-structured Interview Data
3. Participant observer protocol

Data obtained from interviews were cross-checked by externally transcribing verbatim interviews. Transcripts were cross-checked by the researcher against recorded interviews.

Two research methods were used to conduct this study: semi-structured interview process as well as participant observer protocol.

5.5.2 Low Inference Descriptors

The analysis of data was done using interview transcripts, in conjunction with researcher interview notes (*Appendix E – Signed Documents and Researcher Notes*) and descriptions close to participants' accounts. Interview data found in *Appendix D – Interview Data* was derived from word for word descriptions as given by participants. (*Censored verbatim transcriptions are available on request*)

5.5.3 Reflexivity

The researcher, an active participant in the industry, conducted a self-reflection on problems faced by medical device manufacturers in the industry as well as regulatory problems faced by industry. To avoid researcher bias, participants were requested to review results which 50% of participants responded to. (*Appendix F – Participant Feedback*)

Data obtained from interviews was verified with literature pertaining to the South African market environment and the South African medical device industry.

5.5.4 Participant Feedback

Following participant interviews, interviewees were supplied with their respective transcripts to comment on:

- Whether the interview answers still reflected their views accurately.
- Whether the participant felt that the interview and questions asked were sufficient to achieve the objectives of this research.

Feedback from participants is found in *Appendix F – Participant Feedback*.

5.5.5 Dependability

The dependability of this research was guaranteed through detailed explanations of the complete research methodology, data analysis and results as seen in *Chapter 3 Research Method* and *Chapter 4 Data Analysis and Results* .

5.5.6 Transferability

The transferability of this study was guaranteed as the results and conclusions of the study can be applied to other related industries such as food, microbiology and pharmaceuticals. All industries are highly regulated industries in South Africa with several barriers to entry.

CHAPTER 6 CONCLUSIONS AND RECOMMENDATIONS

The aim of this research was to establish reasons for the lack of local manufacturers starting up in the South African medical device industry. The research was conducted through semi-structured interviews to understand the issues faced by current local manufacturers in the medical device industry. It is however, important to note that further research may be required as a result of the exploratory nature of the research topic. There was limited data available due to the limited number of compliant medical device manufacturers in South Africa available to participate in the research as well as the limited data available of imported medical devices and exported medical devices.

Conclusions of this research included the various reasons that medical device manufacturers have not started up in the industry, and recommendations for potential start-ups to mitigate immediate problems faced in the industry. Recommendations also included changes in policy and future policy development as well as ways to attract new businesses to the industry.

6.1 Conclusions

The medical device manufacturing industry lacks companies starting up because:

1. The capital investment required to manufacture medical devices in the largest barrier to entry faced by potential start-up companies. Construction of a sterile environment to manufacture and regulatory compliance costs are the highest contributors to capital investment required. Furthermore, external factors such as the lack of funding and incentive schemes and the lack of communication of funding and incentives to medical device manufacturers, high interest rates and high tax rates in South Africa have all deterred potential medical device manufacturers from the industry.
2. The inconsistency of South African medical device regulations and the extended implementation has deterred potential start-up manufacturers from the industry. Implementation of a quality system, obtaining licenses, product certification and other ongoing implementation costs are unsustainable to start-up companies. South African regulations are inconsistent with international regulations, and the cost of compliance is doubled as a result of the additional exporting compliance required. Regulations are not strictly followed and incompliant companies still operate within the medical device industry. Namely, distributors and manufacturers that employ third party operations.

3. Brand representation and the unwillingness of end users and clients to switch to smaller, local brands deters potential start-ups from the medical device industry. Brand representation is the most import element of strategy in the medical device industry. Supply of medical devices is difficult for start-up companies with no product guarantees or track record of the performance of their product.
4. Cash flow problems deterred medical device manufacturers in South Africa. The public health sector provided the most opportunity to locally manufactured medical devices. However, payment terms of public health institutions and erratic payments affect the liquidity of start-up medical device manufacturers.
5. Complying to South African regulations does not translate to compliance elsewhere in the world and does not allow trade elsewhere in the world. Being a compliant local manufacturer allows for preferential procurement in the public healthcare sector, but does not guarantee penetration into the private sector. Private sector penetration is difficult for local manufacturers as a result of long-term contracts with multinationals and private healthcare groups' unwillingness to engage in partnerships and contracts with local manufacturers.

6.2 Recommendations

Recommendations for start-up companies to mitigate any immediate issues faced include:

1. To begin manufacturing operations with only packaging and labelling operations. This entails purchasing bulk medical devices from third party manufacturers, packaging and outsourcing sterilization processes if required. Packaging and labelling operations attempt to build the company's liquidity and capital to invest in equipment by avoiding large initial capital outlays. Once liquidity is confirmed, further investments into other stages of the manufacturing process can be done. Packaging and labelling constitutes being a manufacturer of medical devices in South Africa. (Medicines Control Council, 2015)
2. All regulations and quality standards must be met from inception. Costs of implementation of systems in companies at inception are lesser than costs of implementation of new systems and procedures in already existing, incompliant companies.
3. To create one brand as a company and build the brand around price competitiveness and product quality. To build brand awareness from inception, companies should engage in health promotion and also develop a comprehensive marketing strategy to promote the brand to the general public and potential customers.

Recommendations for changes in medical device regulations and future policy development include:

1. To develop a medical device regulatory structure specific to medical devices away from the pharmaceutical industry. This model should mirror Europe's CE conformity assessment model, or the United States FDA model. These working models have been in operation in their respective areas and exporting companies around the world conform to these regulations. The cost of compliance is reduced if systems, procedures and assessment costs are reduced.
2. To encourage all medical device manufacturers to be members of medical device company collaborations such as MDMSA or SAMED. This will allow companies to identify new opportunities in the industry, procure locally and consider possible joint ventures.
3. To identify and appoint a designated government representative in charge of the medical device industry. This appointment must be responsible for monthly/quarterly meetings of the medical device industry, industry breakfasts and networking meetings for companies, as well as quarterly funding opportunities meetings.
4. The appointed government representative should maintain close relationships with large importers and distributors, including multinationals. Services such as feasibility studies to localise operations, cost benefit analyses and finance and funding opportunities should be made available to these companies to begin manufacturing in South Africa.
5. SAHPRA, with the Department of Health should appoint quality management representatives available to implement quality systems, to externally audit quality systems and to certify quality systems. Training for medical device quality systems and product compliance is minimal in South Africa, and quality representatives should aim to alleviate misinformation.
6. Medical device procurement procedures should be adjusted to preferentially select those manufacturing in South Africa first. Those with the highest percentage of raw material procured locally and the highest percentage of manufacturing operations should be selected to supply as first option. Price flexibility should be 15-20% higher than imported goods, as imported finished goods may be subject to import duties of up to 20%. Other protection such as import duties and taxes should be added onto imported products if locally manufactured content is able to supply a minimum of 40% of national demand.
7. The import duty structure should be changed to an 8-digit descriptor. This would allow access to data of imports and exports of medical devices and for regulatory authorities to

understand the ratios of imported products to locally manufactured products. (Deloitte & Touche; Department of Trade & Industry, 2014)

8. To create a centralised payment system for public healthcare institutions to reimburse suppliers timeously. Software to upload invoices and proof of deliveries can be developed to ensure automated and timeous payments to suppliers.
9. Funding opportunities targeted at medical device regulatory compliance should be allocated. The costs of compliance are onerous and unaffordable for new companies. The availability of compliance funding will ensure that all manufacturers remain compliant at all times.
10. Monthly training for company authorized representatives should be hosted nationwide. This would allow companies to understand new enforced regulations and the requirements for companies to remain compliant at all times.
11. Financial assistance should be given to companies that are preparing to export. Compliance costs internationally are also strenuous on new manufacturers and affect the liquidity of the company as they are capital investment costs.

6.3 Scope for Future Research

After understanding the reasons that medical device manufacturers are not starting up in the industry, developing a comprehensive strategic framework for medical device manufacturers and enhancing access to the industry requires further research in the following areas:

1. Marketing strategies suited to the medical device industry, including alternative methods to build brand representation in the industry.
2. To investigate the relationship between the private healthcare sector with regulatory authorities and local manufacturing companies. To design an inclusive procurement system for both private healthcare and private healthcare incorporating local manufacturers and high quality products.
3. Understanding the medical device regulatory framework, problems with the framework and why the framework is unsuitable to medical device manufacturers. To thereafter design and implement a regulatory framework suited to the industry that minimizes compliance costs for companies and that companies are content with.
4. The design and control of a new importation and exportation tariff heading system for accurate importation and exportation data, and as a result more stringent import and/or excise duties on products.

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APPENDICES

Appendix A – Interview Questions

Interviewee Name: _____

Organization: _____

Informed Consent (Y/N): Interview ☐ Recording ☐

1. Introduction

When was the company established?

Who were the founding members (how many)?

Core operations of the business (from inception till now):

Was manufacturing always a vision for senior management of your firm (with reasons):

2. The Competitive Environment

What is the competition in the medical device manufacturing industry like (including the number of competitors, the growth experienced in the industry, reasons for growth rates, competition from non-manufacturers such as importers, wholesalers and distributers)?

What has been the biggest obstacles to growth in the manufacturing sector:

Economies of scale:

Competitive Rivalry:

Supply Chain Factors:

The Regulatory Environment:

Other(s):

3. Strategy

Of the previous obstacles to growth, what counter-measures were implemented to overcome these obstacles (attempt to list individually):

How important has developing and implementing strategies been in growing within the industry?

What strategies have been implemented within the company (Survival and Growth)?

Appendix B – Purposeful Sampling Strategies

1. Purposeful random sampling: Participants are randomly selected according to the credibility of information they provide. This method does not allow generalizations to be made to a population and avoids questions as to why certain participants were not selected.
2. Extreme or deviant case sampling: Participants are selected based on cases that can be described as unusual. The lessons from these cases are used to improve the typical cases.
3. Intensity sampling: Participants are selected that experience the phenomenon intensely, but not extremely.
4. Homogenous sampling: Participants are selected from one particular sub-group to obtain an in-depth understanding of the topic.
5. Typical case sampling: Participants are identified and selected according to their knowledge and experience that have provided typical cases of a phenomenon. This method, does not provide a generalization of the population, but only that of the selected participants.
6. Stratified purposeful sampling: Participants are selected similarly to typical case sampling but includes participants that can provide information on below average and above average cases.
7. Critical case sampling: Participants are selected when critical or essential information could be provided.
8. Chain sampling: Participants are selected using information-rich informants who ask resources associated with a phenomenon who the best resource is to speak to. As resources are asked, key names will be repeatedly mentioned.
9. Opportunistic sampling: Participants are selected as new data is collected, and is predominantly used in field research.
10. Criterion sampling: Participants are selected using predetermined criteria deemed as important or the most productive sample to achieve the research objectives.
11. Maximum variation sampling: Participants are selected to maximise capturing the central themes that emerge across participant variation. Participants with unique experiences are selected; variances in their experiences as well as common themes are analysed.
12. Convenience sampling: Participants are selected based on their level of simplicity. Factors such as ease of access and minimizing costs determine the sample group.

Appendix C – Ethics Documentation

16/07/2018

Dear Sir/Madam,

Re: Participation in Research on *Medical Device Manufacturing in South Africa*

Thank you for offering, via your response to the recent phone call, requesting your participation in a follow-up interview.

I, Ishan Maharaj, am a part-time MSc student in the school of Mechanical, Industrial and Aeronautical Engineering at the University of the Witwatersrand, under the supervision of Ms B. Sunjka. My MSc title is: *A Strategic Framework for Start-Up Medical Device Manufacturing Companies in South Africa.*

The medical device manufacturing industry is a growing industry within South Africa. However, there are very few new companies starting up within the sector. My belief is that the reasons for this can be attributed to the competitive forces experienced by companies in the industry. I would specifically like to understand the challenges experienced by existing firms in the industry, as well as the measures taken to survive and grow within the industry. Your knowledge and experience would contribute significantly.

The study will be conducted between July 2018 and October 2018. Involvement in the study will entail one (1) face-to-face interview with you, as a senior manager, at your convenience. To ensure confidentiality of the interview, I will be the only person in the interview. During this interview, I would like to understand how your company was formed, what the basic operations of the company were then, how the company has grown until now, the challenges faced for the company to grow, how these challenges have been managed and the survival and growth strategies implemented by the company. A short walk through the manufacturing facility would be interesting, if you have time and be willing to do so.

Participation in the study is voluntary, and you may withdraw at any time. Anonymity (regarding company name and any owner/manager/employee names) and confidentiality of information provided will be assured and respected. I would like to record the interviews, so I can later transcribe them. Your consent at the time of the interview will be requested. If you do not wish the interviews to be recorded this will be respected.

The results of the study will form part of my MSc research report, and may also be reported in academic papers and at conferences. A summary of the results of the research will be made available to you on request.

Please contact me if you have any questions regarding the research and participation in the study.

I look forward to hearing from you.

Yours faithfully,
Ishan Maharaj

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Supervisor: Tel: 082 570 6436 Email: Bernadette.Sunjka@wits.ac.za

Letter of Consent

I, _____, agree to participate in the MSc research entitled *A Strategic Framework for Start-Up Medical Device Manufacturing Companies in South Africa*, to be undertaken by Ishan Maharaj (Student Number: 597618) under the supervision of Ms B. Sunjka, and certify that I have received a copy of this letter of consent.

I acknowledge that the research has been explained to me and I understand what it entails, as follows:
I agree to allow access to my company and manufacturing facilities for the purpose of this research.
There will be one interview, which is estimated to take approximately 30 – 45 minutes.
The interviews will be audio taped, and transcribed for analysis by the researcher – only if agreed upon.
The core manufacturing operations as well as products produced will be identified.
I will provide a brief tour of my manufacturing facilities at my discretion, and that the researcher will record her own observations.
The survival and growth strategies of the company will be identified.
The competitive environment around the firm will be mapped.
I have the right to withdraw my assistance from this project at any time without penalty, even after signing the letter of consent.
I have the right to refuse to answer one or more of the questions without penalty and may continue to be a part of the study.
I may request a report summary, which will come as a result of this study.
I am entirely free to discuss issues and will not be in any way coerced into providing information that is confidential or of a sensitive nature.
Pseudonyms will be used to conceal my identity, and that of my company, my employees, my suppliers and my customers. The information disclosed in the interviews will be confidential.
Audio-tapes and transcripts will be kept securely stored during the research and after the research has been completed.
This project was approved by the Faculty of Engineering and the Built Environment of the University of the Witwatersrand and the School of Mechanical, Industrial and Aeronautical Research Ethics Committee (non-medical) of the University.
If I have any questions or concerns about my rights or treatment as a participant, I may contact the Chair of the School of Mechanical, Industrial and Aeronautical Research Ethics Committee (non-medical) at (tel: 0117177343) or by (Bruno.Emwanu@wits.ac.za).

Signed: _____

Date: _____

Questions concerning the study can be directed to:

Ishan Maharaj

Tel: 0736861483 and Email: 597618@students.wits.ac.za

Supervisor: Ms B. Sunjka Tel: 082 570 6436 Email: Bernadette.Sunjka@wits.ac.za

Appendix D – Interview Data

Table C.0.1: Raw Interview Data

	Company A	Company B	Company C	Company D	Company E	Company F
Company Background						
Year Established	1987	2005/2006	2012	1993	1996	1963
Number of Founding Members	1	1	1	2	2	1
Founding Member Background	Had experience in design and manufacture of titanium products and heart valves before starting the company	Regulatory pharmacist - With experience in the medical device industry as a regulatory and quality consultant	Gained experience in family elastics manufacturing business, so used expertise in a related industry new venture	Family business. 1st partner - clinical input in terms of design and development. 2nd partner - experience in multinational medical device company	Both partners had corporate experience, but wanted to set up a smaller company able to adapt to dynamic markets	Founder experienced in design and development. Current CEO had experience in a business venture before taking over
Core Operation at Inception	Manufacturing Dental Products	Opened as a consultancy - began manufacturing shortly afterwards	Manufacturing Wound Care Products	Trading and importing medical devices	Purchased the rights of an active ingredient formulation, and developed a range of products not focussed in healthcare.	Manufacture low technology consumables, as well as capital equipment which is still the South African standard.
Core Operations Now	Manufacturing a larger range of dental products	Company does not exist anymore - sub-contracted all manufacturing except packaging which was done manually for retail.	Manufacturing wound care products - But a bigger range.	Manufacturing consumables from import substitution. Offer cleanroom services and contract packaging.	Moved into dental industry and that became the conduit into medical device industry. Manufacturing full product range for medical devices.	Importing and distributing consumables for multinationals, manufacturing consumables and capital equipment.

Manufacturing Capacity	Large capacity. Able to supply locally and export to Europe	Small capacity. Only manufactured for 4 years and was not able to fully supply local retailers	Only supplying goods in their province of operation, but have capacity to supply other provinces.	Supplying goods through public sector in South Africa and exporting goods into Africa.	Manufacturing is outsourced, but capacity cannot increase due to premises.	Exporting throughout the world as well as supplying throughout South Africa.
Importing or Only manufacturing	Less than 1%. Imported goods are insignificant	Only manufacturing in South Africa with all operations outsourced except packaging	Only manufacturing their own products. Raw materials are imported	Only supplying their manufactured lines	Only supply their manufactured lines.	Importing as well as supplying their manufactured products.
Target Customers	Top end users - cosmetic products.	Retailers such as Pick n Pay & Spar	Public sector healthcare institutions	Public sector healthcare institutions	Goods are only sold to wholesalers and distributors, not end users.	Public sector, private sector and international customers
	Supply within South Africa but most products are exported because they are cosmetic devices	Toy shops, retailers	Only supplying the province the company is based in	Healthcare institutions around South Africa. Also supplying veterinary industry	Public sector predominant but business model doesn't allow company to have access to customer database	
Value Proposition	Create innovative products, always further develop current products and be first to market.	Trade-marked product.	Good quality guaranteed at low prices	Direct import substitutions at a fraction of the price to multinationals	Focussed on product quality, product development and after sales or technical support	Good brand representation in South Africa, and products have become the standard in the country. So quality guarantee
Competitive and Market Environment						
Competition at inception	Only 3 or 4 manufacturers in the world.	Large competition from all over the world creating disposable products.	Importers and distributors	Only competing with multinationals as nobody in South Africa is making the product.	Different competitors for different products in their range	No South African competition from manufacturers for capital goods.

			Other local manufacturers	Importers and distributors of the product	Multinationals for major medical device products Lots of small local competitors for less complex, simpler products	Competing with multinationals who had a huge price tag compared to local
Competition now	Thousands of manufacturers from Brazil, Korea, Israel and other countries	Competition has grown to be even more than at inception	Increase in the number of importers	Compete with 4-5 local manufacturers of their products	Additional regulations have reduced competitors in the industry.	Competition has increased significantly (World recession has caused this)
	South Africa has 18 suppliers of these products	Increase in the number of importers and distributors	Increase in the number of local suppliers	Only compete with multinationals for specialized, technical products produced in South Africa	Competition has lessened because of compliance to healthcare AND disinfectant regulation	Large increase in the number of importers and distributors
	All South African suppliers are importers and distributors					Tendency to choose cheaper Eastern products
Market/Company Growth	Market growing slowly and steadily in South Africa.	Not enough information available. Company does not exist anymore	Rapid growth experienced upon establishment	Rapid growth initially which tapered off	Good market growth in public sector	Rapid growth when new products were added to the range. Expansion was rapid when business grew and products were diversified
	The company has exceeded South African market growth due to export capacity		Growth has tapered off, but still growing steadily	Looking for additional growth through other import substitutions	Company growth is best reflected in export growth	Growth has tapered off as incentives for manufacture now only focusses on microenterprises, and not bigger local firms

Obstacles to Growth	South Africa's volatile economy status	Finance - the access to finance for capital equipment	The lack of funding incentives and availability for small business	The power of multinationals using scare tactics to attempt to cut local suppliers from the market	There is limited antimicrobial testing available in South Africa	The regulatory compliance costs are too costly for small to medium enterprises
	Shipping status of raw materials as well as customs hold ups for exports			The exorbitant costs of complying with regulations.		The requirements are more onerous for a manufacturer than a distributor
			Local suppliers of raw materials are not reliable - with deadlines and quality	Complying with regulations is onerous	Forced to only supply to distributors and end users because of BEE regulations	There is a lack of sub-contractors who are able to perform machining and make components
	Debtors do not pay timeously including public sector hospitals and dental schools	The access to finance to comply with all regulations		The inability of local companies to penetrate the private sector despite being fully compliant		The training system is not creating enough skilled workers - labour regulations make it hard to compete internationally
			Import duties on raw materials and not on finished goods	Paying up front for specialist items from other countries - the exchange rate and cash flow implications	Increasing capacity (Due to inadequate facility)	There is limited availability of raw materials locally, and distributors impose ridiculous mark-ups. There is an inconsistency of supplies locally

Regulatory Affairs	Abided by international regulations from inception	There is conflict between South African regulation and international regulation.	Import duties are placed on raw materials and not on finished goods	To comply with regulations become extremely costly. Just to be ISO13485 compliant could cost half a million	To abide by disinfectant and healthcare regulations are extremely costly. Complying means loss of business because of increased costs.	Regulations have become too costly and stringent and deter innovation. There is more compliance to be a manufacturer than distributor.
					The declaration of products by SAHPRA has been to include them as medicines, not medical devices, which further increases costs	Companies have to double regulatory costs because RSA wants separate regulations away from international regulations.
	The pharmaceutical model has been 'copy pasted' to medical devices which is creating difficulty	Companies need to be ready for South African regulations AND international regulations.	In most cases there is a higher duty structure on raw materials than finished goods	Product certification is also costly, almost impossible for start-ups	Prohibitive regulations are causing manufacturers to leave healthcare and focus on other sectors	The definition of a manufacturer allows you to just label your goods and be called a manufacturer
						The duty structures and tariff structures are inappropriate
Strategy						
Basic strategy	Do not solely rely on government tenders and the public sector to grow the company	Look for customer specific requirements and develop a niche.	Price penetration, keeping the price as low as possible without compromising quality	To manufacture direct import substitutions.	To create a 'lean' model.	Not to push the Made in RSA banner. To sell products overseas as to convince people that if your product is good enough for Europe, it is good enough for Africa

	Be export ready as soon as possible	To look at alternate marketing away from healthcare such as exhibitions and social media	To maintain good customer relationships.	To focus within a specific niche	Ensure compliance always, and create the highest quality product such that it is the industry standard	To always ensure 100% regulatory compliance.
		To use key people in the industry to attempt penetrating the market		Always maintain high quality products		
Growth Strategy/Strategies	To create the best quality product that is compliant with EU regulations so it can be sold anywhere	To make use of the available government funding initiatives to maximise growth	To improve the aesthetic appearance of products to match multinationals	To become responsible for all stages of manufacture, effectively being responsible for the whole value chain	Strategy is not formalised, but rather built into culture	Look to move away from commodity products and cheaper consumables to avoid competing with labour
	Focussed on research and development and thereafter being first to market with products		To get products compliant and certified to the relevant standards	Improving current operations while still focussing on current product range	Focussed on customer service and compliance.	To focus on expanding product range to technical products with high demands for quality
	To rely on key opinion leaders in the industry to market products	To segment target markets and focus on specific areas	To begin selling directly to end users and not to distributors	To focus on innovative product development in partnership with research entities	To further develop products and expand product range, but with no interest to grow into a large, corporate company	Do not innovate as R&D costs are exorbitant. Follow new innovations, and maintain the best quality
			To increase capacity to match demand, and therefore achieve economies of scale	To ensure product quality matches EU quality to begin exporting		To market products strategically locally, and internationally. (Made in South Africa)

Survival Strategy	To find a clearly defined market for their product	To establish a good customer base with intents to purchase before starting up	To begin to build good face to face relationships with customers from start-up	To be a part of the manufacturing collaboration of MDMSA, use their benefits and source products locally	Focussed on high product quality, and compliance at all costs	Creating and building an internationally renowned brand more than strategic planning.
	To partner with research entities to develop products		Creating brand awareness from the beginning	Use the key contacts made in industry to establish a brand and promote locally manufactured products	Used knowledge of business to create a minimalistic business model	Create high quality products with the expert design team
	Ensure that everything was paid for with cash and the company was not debt ridden		Only make products to order and not to stock	Ensure that all products are primarily focussed on patient safety	Established strong relationships with distributors/customers	Keep increasing brand awareness and maintain quality to sell products at premium price
	Used technical knowledge to get business running as sanctions did not allow import into South Africa		To pursue finding new customers and not rely on the same ones	Conducted market research into products that could be manufactured much cheaper to save customers resources		

Appendix E – Signed Documents and Researcher Notes

Company A

Interviewee Name: [redacted]

Organization: [redacted]

Informed Consent (Y/N): Interview [Y] Recording [✓]

1. Introduction

When was the company established: [redacted] 1987

Who were the founding members (how many): 1 - ~~Founder~~ Managing Director.

Core operations of the business (from inception till now):

[redacted] 85 employees

4 sub-contractors

Do with them, 350 people.

Was manufacturing always a vision for senior management of your firm (with reasons):

2. The Competitive Environment

What is the competition in the medical device manufacturing industry like (including the number of competitors, the growth experienced in the industry, reasons for growth rates, competition from non-manufacturers such as importers, wholesalers and distributers):

3/4 manu in world. Now more than 1000.

3% p.a growth. – 3 p.a. Innovation!! Clear for niche markets.

Illegal marketing practice. eg kickbacks, selling products cheaper but no quality system.

What has been the biggest obstacles to growth in the manufacturing sector:
Volatile currency. Majority exported - Europe, Australia, US, Canada
Market entry. ~~Sout~~

Economies of scale: Not relevant.

Competitive Rivalry: Focussed on top end user. Innovation!

Supply Chain Factors: Customs - export - Italy, US. Subsidiaries in UK, US, Austr.

The Regulatory Environment: Expertise, lack of, will affect them.

Other(s):
Collection of money from debtors - SA public enterprises.

3. Strategy

Of the previous obstacles to growth, what counter-measures were implemented to overcome these obstacles (attempt to list indidivually):
- clear focus on specialist
- differentiation via Research
- get NB people to spk about product.
- people D&D. - research oderseas.
[redacted] FDA database.

How important has developing and implementing strategies been in growing within the industry:
choose your path & stick to that.

What strategies have been implemented within the company:

Survival: late 1980's, sanctions. Not easy to import. Make it locally. More helping business. [redacted]

Growth: Not focussing on govt tenders.
Focus on 1st world, then Africa.
28 countries in Europe - once you pass reg.
Lots of risk mitigation factors!!!
NHI - tenders more important.
Have to export.

Letter of Consent

I, [redacted], agree to participate in the MSc research entitled *A Strategic Framework for Start-Up Medical Device Manufacturing Companies in South Africa*, to be undertaken by Ishan Maharaj (Student Number: 597618) under the supervision of Ms B. Sunjka, and certify that I have received a copy of this letter of consent.

I acknowledge that the research has been explained to me and I understand what it entails, as follows:
I agree to allow access to my company and manufacturing facilities for the purpose of this research.
There will be one interview, which is estimated to take approximately 30 – 45 minutes.
The interviews will be audio taped, and transcribed for analysis by the researcher – only if agreed upon.
The core manufacturing operations as well as products produced will be identified.
I will provide a brief tour of my manufacturing facilities at my discretion, and that the researcher will record her own observations.
The survival and growth strategies of the company will be identified.
The competitive environment around the firm will be mapped.
I have the right to withdraw my assistance from this project at any time without penalty, even after signing the letter of consent.
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I may request a report summary, which will come as a result of this study.
I am entirely free to discuss issues and will not be in any way coerced into providing information that is confidential or of a sensitive nature.
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Audio-tapes and transcripts will be kept securely stored during the research and after the research has been completed.
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If I have any questions or concerns about my rights or treatment as a participant, I may contact the Chair of the School of Mechanical, Industrial and Aeronautical Research Ethics Committee (non-medical) at (tel: 0117177343) or by (Bruno.Emwanu@wits.ac.za).

Signed: [redacted]

Date: 10 Dec 2016

Questions concerning the study can be directed to:

Ishan Maharaj

Tel: 0736861483 and Email: 597618@students.wits.ac.za

Supervisor: Ms B. Sunjka Tel: 082 570 6436 Email: Bernadette.Sunjka@wits.ac.za

Company B

Interviewee Name: [redacted]

Organization: [redacted]

Informed Consent (Y/N): Interview ☑ Recording ☑

1. Introduction

When was the company established: [redacted] - 2005 Separate bank 2006.

Who were the founding members (how many): 1 [redacted].

Core operations of the business (from inception till now): Starts fo-o

Manufacturing - [redacted]

Network - Pick n Pay & Spar. Entrepreneur

Sub-contracter ①, ②, ③, ④. Closed 2006 - not sales.

Was manufacturing always a vision for senior management of your firm (with reasons):

Yes. Before, [redacted] Big market. & some opportunities.

Longevity + build a brand. Not product route.

2. The Competitive Environment

What is the competition in the medical device manufacturing industry like (including the number of competitors, the growth experienced in the industry, reasons for growth rates, competition from non-manufacturers such as importers, wholesalers and distributers):

lots of competitors - Niche & competitiveness. Market entry.

Regulatory, Sales.

Growth slow - strengths for localization. BEE, tender adjudication, regulatory from govt, huge opportunities, incentives.

Imports killing manufacture. Price of imports.

Innovation at university etc.

What has been the biggest obstacles to growth in the manufacturing sector: Finance, equipment, overseas, import costs., capital costs accreditation.

Economies of scale: No. Finding niche..

Competitive Rivalry: Communication.

Supply Chain Factors:

The Regulatory Environment: SA is challenged. Conflict between our regulatory & international reg. CE mark.

Other(s):

3. Strategy

Of the previous obstacles to growth, what counter-measures were implemented to overcome these obstacles (attempt to list indidivually): Unique position. SEDA → marketing funding, funding. Local manufacturers. need to. Survival → opportunities. Working capital. → on your own. Some mentor /. partner / financial support.

How important has developing and implementing strategies been in growing within the industry: Soci Yes. very important.

What strategies have been implemented within the company:

Survival: Start in a certain sector & then retail sector.

Growth:

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Signed: [redacted]

Date: 14th August 2018

Questions concerning the study can be directed to:

Ishan Maharaj

Tel: 0736861483 and Email: 597618@students.wits.ac.za

Supervisor: Ms B. Sunjka Tel: 082 570 6436 Email: Bernadette.Sunjka@wits.ac.za

Company C

Interviewee Name: _____

Organization: _____

Informed Consent (Y/N): Interview ☑ Recording ☐

1. Introduction

When was the company established: 2012 Reg 2013

Who were the founding members (how many): 1

Core operations of the business (from inception till now): [redacted]

Was manufacturing always a vision for senior management of your firm (with reasons):

2. The Competitive Environment

What is the competition in the medical device manufacturing industry like (including the number of competitors, the growth experienced in the industry, reasons for growth rates, competition from non-manufacturers such as importers, wholesalers and distributers):

Min competition. Newcomer so prices

Rapidly grown. - competitive · quality & prices.

Currently, biggest problem importers.

5 years on your own

What has been the biggest obstacles to growth in the manufacturing sector: _____

Buying raw materials locally, weren't able to supply on time R exchange. (Now?).

Economies of scale: _____

Competitive Rivalry: _____

Supply Chain Factors: _____

The Regulatory Environment: _____

Other(s): _____

3. Strategy

Of the previous obstacles to growth, what counter-measures were implemented to overcome these obstacles (attempt to list indidivually): _____

How important has developing and implementing strategies been in growing within the industry: ____

What strategies have been implemented within the company:

Survival: _____

Growth: _____

Letter of Consent

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Signed: [redacted]

Date: 20/8/18

Questions concerning the study can be directed to:

Ishan Maharaj

Tel: 0736861483 and Email: 597618@students.wits.ac.za

Supervisor: Ms B. Sunjka Tel: 082 570 6436 Email: Bernadette.Sunjka@wits.ac.za

Company D

Interviewee Name: [redacted]

Organization: [redacted]

Informed Consent (Y/N): Interview ☑ Recording ☑

1. Introduction

When was the company established: 1993, manufact 2015

Who were the founding members (how many): 2

Core operations of the business (from inception till now):

Trading house. [redacted] SA & Into Africa.

[redacted] Contract manufacture, cleanroom contract.

Was manufacturing always a vision for senior management of your firm (with reasons):

as 1. ~~ret~~

2. The Competitive Environment

What is the competition in the medical device manufacturing industry like (including the number of competitors, the growth experienced in the industry, reasons for growth rates, competition from non-manufacturers such as importers, wholesalers and distributers):

Targeting 1 product being imported.

Did research

[redacted] ½.

Substantial in 1st year → tapered off → import substitute.

1 is specialised [redacted] 4 – 5 local manufacturing

niche.

brand awareness

90% public – 10% pvt.
Vet.

What has been the biggest obstacles to growth in the manufacturing sector: _____

Economies of scale: 60% capacity – 1 shift.

Competitive Rivalry: _____

Supply Chain Factors: Local suppliers reliable - consumables. Import specialised components.

The Regulatory Environment: (1) awareness – cost - SABS test R15 000. ISO reg. licensing.

2015?

Other(s): _____

3. Strategy

Of the previous obstacles to growth, what counter-measures were implemented to overcome these obstacles (attempt to list indidivually): Produce locally, own [redacted]
When not viable, collaborating with other locals.

How important has developing and implementing strategies been in growing within the industry: ____

What strategies have been implemented within the company:

Survival: Research – biobased + polymer science.
import substitutions.
Patient - focus: safety!!! NB. Quality over price.

Growth: [redacted]
Exporting - favourable to export. CE mark into Africa & Europe.

Survival, didn't have issues, why?

Letter of Consent

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Signed: [redacted]

Date: [redacted] 19/10/2018

Questions concerning the study can be directed to:

Ishan Maharaj

Tel: 0736861483 and Email: 597618@students.wits.ac.za

Supervisor: Ms B. Sunjka Tel: 082 570 6436 Email: Bernadette.Sunjka@wits.ac.za

Company E

Interviewee Name: _____

Organization: [redacted]

Informed Consent (Y/N): Interview ☐ Recording ☐

1. Introduction

When was the company established: 1996

Who were the founding members (how many): [redacted]. 13th year

Core operations of the business (from inception till now): [redacted] 28 products.

Licence for [redacted] Sub-Saharan Africa.

Was manufacturing always a vision for senior management of your firm (with reasons): Quantity Surveyor. Advised on product

2. The Competitive Environment

What is the competition in the medical device manufacturing industry like (including the number of competitors, the growth experienced in the industry, reasons for growth rates, competition from non-manufacturers such as importers, wholesalers and distributers):

Competition changed - not focussed on healthcare.
Vet + Agriculture. Dental Industry.
No company in SA - full range.
Specific competitors for certain products.
Multinational.
SAFmed.
↑ no. of competitors.
VC8054 → cost & development.
Dental distributors → ↑ good. Access to people who knew market.
Starting to see importers.

R&D?

What has been the biggest obstacles to growth in the manufacturing sector:
Price in local more stable
R&D → very limited antimicrobial testing. Access to knowledge in R&D.
Economies of scale:
Competitive Rivalry: Very high quality.
Supply Chain Factors:
The Regulatory Environment:
Other(s):
Distance to Factory.

3. Strategy

Of the previous obstacles to growth, what counter-measures were implemented to overcome these obstacles (attempt to list indidivually):
R&D - industry experts - not successful

Economies of Scale - 5S plan

How important has developing and implementing strategies been in growing within the industry:
No set strategy. Symptom of com
Company Culture. Bi Annual Quality Reviews.

What strategies have been implemented within the company:
Survival: Quality.
Growth:

Niche produ

Letter of Consent

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Signed: [redacted]

Date: 06/09/2018

Questions concerning the study can be directed to:

Ishan Maharaj

Tel: 0736861483 and Email: 597618@students.wits.ac.za

Supervisor: Ms B. Sunjka Tel: 082 570 6436 Email: Bernadette.Sunjka@wits.ac.za

Company F

Interviewee Name: [redacted]

Organization: [redacted]

Informed Consent (Y/N): Interview ☑ Recording ☑

1. Introduction

Core staff: 80-90.
Casual: 120-130.

When was the company established: 1963

Who were the founding members (how many): [redacted]

Core operations of the business (from inception till now):

Manufacture [redacted]

Equip [redacted]

Expanded → [redacted] Moved to [redacted]

Was manufacturing always a vision for senior management of your firm (with reasons): [redacted]

1963. - technical background with design flare.

2. The Competitive Environment

What is the competition in the medical device manufacturing industry like (including the number of competitors, the growth experienced in the industry, reasons for growth rates, competition from non-manufacturers such as importers, wholesalers and distributers):

① a lot easier - no cheap imports. Dominated market + export. International competition

② ~~Ride~~ Compliance Frenzy !!! Hard for SME's. Change so fast.

③ Import tough because of no. of competitors.

More growth in 90's. [redacted] in 2000 - new division [redacted]

Got CE mark in 1990's. International quality from then.

What has been the biggest obstacles to growth in the manufacturing sector:
Availability of sub-contractors. Skills base reducing.

Economies of scale: Duty on components !!!

Competitive Rivalry:

Supply Chain Factors: Local suppliers terrible!!!

The Regulatory Environment:

Other(s):

Marketing more than manufacture.

Trade off between labour & automation. Capital?

3. Strategy

Of the previous obstacles to growth, what counter-measures were implemented to overcome these obstacles (attempt to list indidivually):

Strategy or brand built ??

No duties - SO easy.

Business evolved with no strategy. Building the brand is invaluable.
Stay away from commodities with manufacture.

How important has developing and implementing strategies been in growing within the industry:

focus technical products - more quality.

What strategies have been implemented within the company:

Survival:

Less overheads, less R&D,
not innovators, high product.
More money on cosmetic improvements.

Growth:

True innovation - very rare.

Pushed European state, not African.

Quality - at the top.
Price - in the middle.

Someone once said if good for Europe,

Letter of Consent

I, [redacted] agree to participate in the MSc research entitled *A Strategic Framework for Start-Up Medical Device Manufacturing Companies in South Africa*, to be undertaken by Ishan Maharaj (Student Number: 597618) under the supervision of Ms B. Sunjka, and certify that I have received a copy of this letter of consent.

I acknowledge that the research has been explained to me and I understand what it entails, as follows:
I agree to allow access to my company and manufacturing facilities for the purpose of this research.
There will be one interview, which is estimated to take approximately 30 – 45 minutes.
The interviews will be audio taped, and transcribed for analysis by the researcher – only if agreed upon.
The core manufacturing operations as well as products produced will be identified.
I will provide a brief tour of my manufacturing facilities at my discretion, and that the researcher will record her own observations.
The survival and growth strategies of the company will be identified.
The competitive environment around the firm will be mapped.
I have the right to withdraw my assistance from this project at any time without penalty, even after signing the letter of consent.
I have the right to refuse to answer one or more of the questions without penalty and may continue to be a part of the study.
I may request a report summary, which will come as a result of this study.
I am entirely free to discuss issues and will not be in any way coerced into providing information that is confidential or of a sensitive nature.
Pseudonyms will be used to conceal my identity, and that of my company, my employees, my suppliers and my customers. The information disclosed in the interviews will be confidential.
Audio-tapes and transcripts will be kept securely stored during the research and after the research has been completed.
This project was approved by the Faculty of Engineering and the Built Environment of the University of the Witwatersrand and the School of Mechanical, Industrial and Aeronautical Research Ethics Committee (non-medical) of the University.
If I have any questions or concerns about my rights or treatment as a participant, I may contact the Chair of the School of Mechanical, Industrial and Aeronautical Research Ethics Committee (non-medical) at (tel: 0117177343) or by (Bruno.Emwanu@wits.ac.za).

Signed: [redacted]

Date: 4/1/19

Questions concerning the study can be directed to:

Ishan Maharaj

Tel: 0736861483 and Email: 597618@students.wits.ac.za

Supervisor: Ms B. Sunjka Tel: 082 570 6436 Email: Bernadette.Sunjka@wits.ac.za

Appendix F – Participant Feedback

Company D

Hi Ishan,

Everything looks good, just a couple of corrections;

- The SABS testing costs R15,000 per product to test and not R15,00
- Grammatical error “challenging lee times” should read lead times.

Some good news since our meeting. A local multinational has approached us with the intention of manufacturing some of their imported [redacted] We have signed a 10 year co operation/NDA with them which is potential a game changer in our business.
There is a trend in the local market which is as a result of The Dti placing more emphasis on procuring locally and substituting imports. The foreign owned multinational are changing their strategy to link up with local manufacturers to produce locally and replace costly imports but also to show government that they are committed to the local economy. Also good for offsets etc when calculating empowerment and B-BBEE points.

Regards

Company E

[redacted] Fri, Feb 22, 10:21 AM (12 days ago)

Hi Ishan

There are some minor errors in the transcription, but nothing of material difference. Would you like me to correct them ona Track Changes basis? They will not make much difference to the overall picture though?

Kind Regards!

[redacted]

Company F

[redacted] Mon, Feb 11, 6:12 PM

Hi Ishan

I'm a bit busy, so I've only skim read your attachment – looks good to me.

Regards