

# SME Internationalization: Investigating Antecedents and the Effect of Organizational Capabilities on Strategy in the German MedTech Industry

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**Abstract** This paper is focusing on SME internationalization and investigates the antecedents and the effects of organizational capabilities on strategy in the German MedTech industry. However, the impact of existing research in this field is relatively poor and is not yet applicable in other countries or industries. As a consequence, a systematic review of the literature has been conducted. The results have shown heterogeneous research results in the field of strategy and capabilities and the need for further research in this context. In a focus group discussion antecedents as well as the most important factors related to strategy were emphasized and further important aspects that focus on capabilities were revealed. Overall, the review indicates an initial conceptual model, in which significant findings could be identified. During the focus group discussion subject matter experts refined them in a country-, industry- or firm-specific way. The results will serve as a strategic input for SME's in the German MedTech industry.

**Keywords** Internationalization, SME's, MedTech, Antecedents, Organizational Capabilities

this industry face a fundamental challenge. High product development costs with respect to a distinctive innovation strategy force companies to increase turnover and recover investments via internationalization, while this is constrained by financial and managerial resource limitations or challenging environmental factors such as regulations. There is a strong motivation for such SMEs to find a way to successfully internationalize their business - otherwise they might disappear from the market sooner or later. This would have an economic impact both on the industrial development in Germany and on the healthcare system [66].

The aim of this research is to find out which specific factors influence the strategic approach and consequently the development of international ventures in German MedTech SMEs, how organizational capabilities are related to their strategic approach and what influence they have on strategy execution. Based on theoretical justification and on an empirical investigation, a conceptual model of international expansion in this industry leads to understand the behavior of such SMEs and evaluates important ingredients of success and identifies those that appear to be most prevalent.

## 1. Introduction

Germany is the third largest medical technology provider in the world. German small and medium sized enterprises (SMEs) enjoy universal recognition as manufacturers of medical technology (MedTech) products [41]. They play an important role in their domestic market as veritable niche leaders. They are strong in domestic and EU markets, but compared to other high-tech industries most of them are under-represented in the large overseas markets and in the growth markets. But today healthcare market growth rates in Germany and the EU are stagnating due to restrictions on taxation and social security contributions, whereas foreign markets develop dynamically [34]. Consequently SMEs in

### 1.1. Research Questions and Gaps in Knowledge

In strategy development firms have different strategic options and internationalization can be an important element to support a firm's overall strategy. In the context of strategy, the internationalization process is complex and determined by many different factors that encourage or discourage international involvement. There is some disagreement within the literature in terms of the relative significance of internal versus external contingency factors. According to Murray et al [43] researchers have conceptualized the environment as one of the key constructs of understanding organizational behavior and strategic approach depending on the competitive setting of the business. In contrast, Leonidou et al. [36] holds the view that internal organizational characteristics are more important, particularly in an

organizational and managerial context. Nevertheless, the findings suggest, that whilst there are some common processes and patterns among firms' internationalization, the variations can be explained through contingency theory. However, this neglects the specific industry context in which the firms operate as an important factor in their internationalization process.

According to Vignali [63] the necessity of the development of a strategy and the need of proper execution cannot be questioned. Consistency of the elements and activities that refer to the strategy is a prerequisite of a company achieving success on the market. Nevertheless strategy development, implementation and execution of German SMEs vary over time. Some decades ago with 11% only a minority of these SMEs agreed to have strategic planning. In the recent years, meanwhile 54% of these companies came to a formal and written strategy paper, which they use as a guideline for their daily business decisions [21]. But different research studies show heterogeneous results regarding content and depth of the incorporated strategy elements and are addressing the need of further research.

Organizational capabilities affect the development and execution of firm's internationalization strategy and therefore its performance [42]. Through the lens of the resource-based view capabilities, a firm's management skills or its organizational processes for instance, are valuable and rare [4]. Following knowledge based theory, a firm's capability to co-ordinate internal competencies enables the transformation of knowledge into value creating processes [15]. But there is a discourse on the impact of capabilities on strategy and firm's success. Atuahene-Gima [2] and Murray [43] highlight the influence of organizational capabilities in the context of the strategy development. In contrast Lages et al. [35] sees little empirical evidence of strategic impact of capabilities on strategy and performance in the context of internationalization. Hence Theodosiou and Katsikeas [60] consider firm's capabilities as a specific field of interest for future research.

According to the resource based view, firm size plays an important role with respect to SMEs internationalization process and Shaw and Darroch [53] observe a notable gap in the literature particularly concerning the role of organizational capabilities for SMEs.

Hence the research investigates which specific factors influence the strategic approach to international ventures of in the MedTech industry. Furthermore it intends to find out about the impact of strategy development on the internationalization of German MedTech SMEs and how do organizational capabilities affect the internationalization strategy execution of German SMEs in the MedTech industry.

## 1.2. Research Context and Relevance of the Research

This research context was chosen for several reasons.

First, the MedTech industry is an important industry sector of the German national economy. Furthermore it is mainly based on SMEs, which drive innovation and competition. Firm size plays an important role particularly in the context of limited resources and knowledge. Organizational capabilities are crucial to develop singular managerial experience and skills of foreign markets and business practices into organizational knowledge. Shaw and Darroch [53] observe that particularly SMEs are severely affected by this fact in their internationalization process. Mathews [40] describes this lack of knowledge regarding SMEs as a barrier and further identifies relationship capabilities to play an important role for SMEs, since they drive the development of market relationship and consequently firm's collaboration network.

Second, although some internationalization theories are based on surveys in the healthcare sector, not all aspects of the current development are theoretically covered.

Recent research in the context of the MedTech industry emphasizes industry specific factors. According to Chatterji [12] economic success is e.g. more driven by regulatory knowledge than by technology or product-know how. Only a few MedTech SMEs have managed to internationalize their business against global NMEs and local competition in the overseas markets. Hence, there is a lack of specific predictions for the future development for this industry sector and related managerial implications. But it is important for the Healthcare-System that excellent healthcare services based on innovation and competition by SMEs can be provided also in the future.

## 2. Research Background

### 2.1. MedTech SME's in Germany

SMEs play an important role regarding the GNP or employment rate and are consequently called the backbone of German industry [27]. Today, Germany is one of the leading export nations along with the SMEs that are predominantly positioned and backing the current economic development [21]. Most German SMEs have international business and 69% of the companies have export business, but only 15% use representatives and less than 5% cooperate or have own subsidiaries in foreign countries [21]. For the future, it will become even more crucial for SMEs to intensify their international engagement [8].

The health care industry incorporates several sectors that are dedicated to providing health care services and products. According to industry and market classifications, health care includes many categories of medical equipment such as instruments and services as well as biotechnology, diagnostic laboratories and substances, and drug manufacturing and delivery. Medical equipment is used in nearly all medical applications and medical technology products can be found in all stages of human life to support

the health of human beings. Not at least with the help of highly innovative medical devices the possibilities in diagnosis, therapy and care have been developed significantly in the last decades, which consequently enable the a positive development of public health in many countries all over the world. Today's products available in this market include a wide range from high-end products, e.g. for diagnostics, therapy and monitoring, to commodities suitable to more general health care provision [41]. Medical devices that are designed and produced by German SMEs assist us during our whole life. Ultrasonic tests help in diagnoses during pregnancy, incubators support therapy in preterm birth, orthopaedic or ophthalmological devices correct deficiencies, devices for emergency care are crucial in case of accidents to save lives and implants such as pace makers or artificial hips when getting older.

As a result of significant demographic challenges and fast technological development, the world market for medical technologies currently totals in the region of more than EUR 200 billion per year - a figure that is increasing all the time [34]. As such, Germany is the third largest medical technology provider of products and medical services in the world [27]. In terms of new patent registrations, German manufacturers are positioned second after the USA, making Germany Europe's strongest region for innovation in this industry. The medical technology producers in Germany achieve approximately one third of their turnover with products that are less than three years old. More than two-third of the generated revenue in this industry belongs to SMEs [41].

Companies, technological products, markets and public authorities are some of the parameters that can be found in the described field of management research within German medical technology industry. It can be characterized as a high-tech sector with high levels of innovation and a strong export orientation. Around 15 per cent of all employees in this industry work in R&D, highlighting the significant importance Germany attaches to R&D and innovation in the medical industry [41].

The governmental German trade and invest agency highlights the medium-sized company oriented structure with niche products for specialist application as unique characteristic of German medical technology. Ninety-seven per cent of all medical technology firms in Germany employ less than 500 employees. These SMEs with less than 500 employees are accountable for roughly 40 % of the total turnover and more than 1,200 companies are active in this medical technology sector [34].

German companies servicing this market represent a turnover in total of 21,4 billion EUR in the year 2011. German medical technology export shares in target regions concentrate on the EU with 40% (increase versus previous year +6%), followed by North America with 20% (+13%), Asia with 17% (+26%) and remaining 33% belong to the rest of the world. The US is the largest national market followed by Japan and China, whereas German MedTech

SMEs often focus to the nearby EU countries [34]. Only few of them have managed to internationalize their business against global NMEs and local competition in the overseas markets.

## 2.2. Regulations in the Medical Device Industry

However, compared to other industries (e.g. the consumer industry), the MedTech industry is depending on enormous local regulations and authorities. The European medical device directive or the Food and Drug Administration (FDA) in the US are examples of strong regulatory foundations which have to be respected when operation in these healthcare-markets. These regulations differ significantly from country to country along with the lack of harmonization in legal provisions for international standards of regulations. Consequently, the investments for certifications - a prerequisite for entering the market - are significantly increasing [32]. The low level of worldwide harmonization of regulations in the medical business has an influence on many fields of activities across nearly all processes of a medical device manufacturer. This means that special requirements are needed compared to other industries e.g. in the product design phase in order to meet the product safety requirements. Different countries have different regulations according to the set-up the quality management system, the vigilance system, the classification of products with respect to applications or for the procedure of approval and certifications [7].

Regulations, which force to reveal technical details in documents and tests, can create tensions with different impacts on SNEs and MNEs in the context of technical know-how and risk. Knowledge prevention and the related perceived risk can also play a role for innovation driven SMEs when considering internationalization strategy.

With respect to marketing strategies, this often means delays for meeting the time to market announcements followed by additional market entrance costs and permanent expenses to run the organization in compliance according to the different national standards [23].

Following the resource-based view, it is much more difficult for SMEs in the MedTech sector to expand and internationalize their business compared to NMEs or the global players in this market. To maintain the structures and to achieve necessary certificates and approvals required in order to serve a specific market worldwide could be a real challenge, assumed by a set of generics in small market or low volume medicines [18].

## 3. Literature Review

### 3.1. Literature Review Design

Conducting a literature review is a means of gaining insight into a particular field of study, including theories,

main contributors, key variables, methods and history [68].

The literature review also helps to distinguish what research topics already have been visited and what has been addressed for future research.

As suggested by Tranfield et al. [61] for management research prior to the beginning of a review a scoping study was conducted to assess the sizes of the literature on the field and to delimit the subject area by finding studies of different subject areas. This led to deeper information about the quantity of scholar articles regarding key terms in the title of this review and provided a better overview of frequently used sources. The scoping study was conducted in different stages based on an Internet search with specific combinations of search terms such as SMEs, Strategy, Healthcare, Medical Technology and Regulations. Due to the vast amount of empirical research in this field of research, some rather strict selection criteria had to be defined. Finally approximately 40 studies, articles and research papers passed the gate to the step synthesis. In the next step, a qualitative synthesis of the empirical articles that is meeting these criteria was developed by comparing and contrasting the results of the individual studies and by generating categories and core concepts. Consequently, the final result of this step is a table, containing the common synthesized concepts and results from all articles reviewed in the process of this literature review.

In a next step, sources and databases have been evaluated by a peer review. Additional journals have been selected as valuable sources. As a result a manual search of research articles in the last 10 years in the Journal of International Marketing and in the journal of Academy of Management Journal has been performed and the results were added. Based on the entire outcome, in form of identified constructs and synthesized concepts, a conceptual framework was developed in several steps in parallel with the literature review. Results of new research and literature-net based in-depth surveys helped finally to sharpen and refine the overall framework that is shown at the end of the chapter.

### 3.2. Basic Theories and Internationalization Strategies

Internationalization from the view of a company can be described as the process of becoming multinational. In the first phase of this process a company sells its products in the domestic market. In a second phase the company begins selling its products abroad. The next step in the internationalization process may be the establishment of an international sales network. Then the process of internationalization has advanced so far that the individual company has manufacturing, sales and R&D in a number of countries and it becomes multinational [38]. Many of the selected studies and articles refer to a functional model based on Porter's five forces model [48]. But also other established constructs such as Dunning's [17] OLI Model or Johansen and Vahlne's [28] Uppsala Stage Approach are often named

theories in the context of internationalization strategies. Based on the generic orientation of strategy [51], firms have different strategic options and internationalization can be an important element to support a firm's overall strategy.

Theoretical frameworks regarding internationalization often draw to one of the three main strands of the literature, namely the stage theory, contingency theory (ies) and the resource-based view. The different internationalization approaches recognize the multiple influences on the internationalization process and are linked to different fields of research such as export behavior, international marketing, marketing and resource-based literature etc.

Although export is only one characteristic of firm's internationalization it can be understood that various factors influence the strategic decision-making and execution. A review regarding research articles in the context of export business [36] shows the various facets of this subject matter. The issue of overall export strategy was most often examined in conjunction with antecedents (e.g., environmental, firm, or product) and/or outcomes (e.g., export performance) of marketing strategy standardization or adaptation. But also export products in the context of standardization versus adaptation was a dominant topic, followed by branding strategy and new product development. Export pricing/financing and export distribution/logistics have been traditionally an attractive subject for many export researchers.

## 4. Results

### 4.1. Critical Reflection on Internationalization Strategies

Internationalisation as strategy process within the international business research may be blurred by the multidisciplinary nature of the field. Stage models of Internationalization, SMEs' deficiencies related to strategy, structure and administrative processes - it can be questioned whether these patterns and models still fit in general.

Circumstances have changed and internationalization theories do not cover all aspects of the current development in the world [24]. Transportation has become cheap and information technology enables close cooperation all over the world. The availability of knowledge in the times of the internet and real time information at any place in the world are enablers for recent developments but also caused a change regarding established business paradigms. Therefore it is not surprising that the theoretical framework of internationalization theories is going to be enhanced. SME specific aspects are more integrated. One example is Mathew's [40] LLL model, which describes the lack of knowledge of SME's but also the possibility and consequently the importance on the development of leveraging their capabilities. Johansen and Vahlne's [29] liability of outsidership approach references to this collaboration aspects because networks and collaboration

drive relationships and hence facilitate business networks, which are elementary for business success. The established internationalization Uppsala Stage theory has been also revisited. Knowledge creation has been added to recognize the fact that new knowledge is developed in relationships. According to Dunning and Lundan [14] the OLI approach has been also extended with respect to strategic alliances. But this can not cover the whole range of phenomena regarding SMEs' internationalization. Other modern empirical findings demonstrate that SME internationalization modes are not path-dependent, emergent or incremental [52].

## 4.2. Influencing Factors

It is obvious that the process of strategic decision making and strategy execution is determined by many different factors. Strategic decisions are therefore depending on different antecedents which are related to various factors. Some scholars group them into classes such as external environment, internal environment and product-market structure. The contingency theory recognizes the importance of external environmental factors of firm's strategy that affect organizational actions. Leonidou [37] focuses on environmental and internal factors, particularly in an organizational and managerial context. This means that internal factors such as capabilities also affect a firm's internationalization strategy [42]. Following the knowledge based theory, a firm's capability to manage internal competencies enables the transformation of knowledge into value creating processes [15] and particularly organizational capabilities influence strategy development [2].

According to Theodosiou et Katsikea [60] the strategic fit of marketing strategy and its influence on performance outcome is influenced by three macro-environmental factors (regulatory environment, technological intensity and velocity, customs and traditions) and three micro-environmental forces (customer characteristics, product life cycle stage, competitive intensity).

Some scholars distinguish between endogenous or exogenous factors, others recognize them as positive triggers that encourage international involvement, or negative barriers that discourage it. Psychological distance is often named as barrier. The perception of barriers differs between NMEs and SMEs. Scholars agree that foreign country related topics like risk and hazards have more influence on SMEs' decisions. Particularly to safeguard know how characterizes a main difference whereas criteria like transaction cost seem to work on both SME and MNE.

There is some disagreement within the literature in terms of the relative significance of internal versus external contingency factors. The extant literature emphasizes the significance of external triggers, such as the market structure. According to Murray [43] researchers have conceptualized environment as one of the key constructs of understanding organizational behaviour and strategic approach depending

on the competitive setting of the business. In contrast, Leonidou [37] holds the view that internal organizational characteristics are more important, particularly in an organizational and managerial context.

As a result of a qualitative synthesis based on the findings from the reviewed articles, three different categories of influencing factors can be distinguished. Although the definition which specific variables represent the different categories in this framework will be described later, it can be recognized that a perspective respecting product, firm and environment related factors could group most of the factors extracted from the literature review.

## 4.3. Strategy Approach

Literature about strategy covers a broad field of subject matters. In management research, strategy related to economics was developed at Harvard Business School in the 1950s. According to the comprehensive approach which is chosen in the context of this review, strategy can be understood as a seamless merger of all activities of a company [51].

According to Whittington [67] different perspectives of strategy can be found in research with a different focus over the last decades. Chandler's "Structure follows Strategy" approach [11] illustrates an functional perspective, which shows that there is a relationship between organization, structure and strategy. According to Murray [43] to develop a level of strategy fit that is consistent with organizational resources determines firm's success.

The necessity of the development of a strategy and the tactics appropriate for the achievement of that strategy is widely agreed. How to bridge strategy and tactics, needs to be thought out during the process of strategic planning. According to Vignali [63] this process is wise to view as somewhat separate and related to the strategic level of management. Looking through the lens of the resource based view this construct of strategy development and strategy execution is from special interest for SMEs and also in the context of this research.

A subset of strategy is strategic planning. Strategic planning is influenced within a company by a range of factors, e.g. its culture, leadership, size, ownership, perceived market share and industrial sector [19]. According to the literature there seem to be significant differences in the development of a strategy and decision making processes between global players and SMEs. Based on the experience of the authors, this is also true within the segment of healthcare and different MedTech companies according to the development of their business strategies. The strategic decision management in SMEs follows different stages [64]. Based on a product an environmental scan regards risk and opportunities is followed by an organizational analysis regards strength and weakness of internal factors. Based on this result, a firm specific strategy can be formulated. Consequently the construct of formal strategy development

and execution, which is influenced by various factors as described before, has its firm specific characteristic regards meaning, strategic elements or tactical implementation. Consequently the strategic approach seems to be moderated by other variables, summarized under organizational capabilities and described in the chapter below.

#### 4.4. Capabilities

Through the lens of the resource-based view, capabilities are valuable and rare. They can be viewed as bundles of tangible and intangible assets, including a firm's management skills, its organizational processes and routines, and the information and knowledge it controls [4]. Following the knowledge based theory, intangible assets such as knowledge and firm's capability to manage internal competencies enables the transformation of knowledge into value creating processes [15]. There is a discourse on the impact of capabilities on strategy and firm's success.

Strategy capabilities, meaning the strategic fit of a firm's strategy according to resources both in development and execution is seen as an antecedent for competitive advantage and economic success. Organizational capabilities may have an influence on the relationships of this construct and therefore internal organizational capabilities such as organizational learning, coordination mechanism and relationship capabilities are of particular interest. Also firm size plays an important role particularly in the context of limited resources and knowledge. Organizational learning capabilities are crucial to develop singular managerial experience and skills of foreign markets and business practices into organizational knowledge. Following the resource-based view, Shaw and Darroch [53] see particularly SMEs severely affected in their internationalization process by the lack of capabilities. Once the requested information is available and knowledge is captured, further organizational capabilities are needed to span people together in order to enable distinctive activities which contribute to firm's success by deploying organizational routines and processes. Therefore coordination mechanisms are seen as a valuable capability. Relationship capabilities are also important because recent literature highlights networks and collaboration as important factors for SMEs, since they drive the development of market relationship and consequently firm's business network.

Finally, these different capabilities can be combined in a second order construct named organizational capabilities, which is supposed to have a moderating effect on both, the strategic and the tactical level of firm's internationalization and thus on its international ventures.

#### 4.5. Competitive Advantage and Economic Success

Studies referring to firm's international performance and economic success employed a wide variety of export performance measures, ranging from economic (e.g., export

sales ratio, export profitability, export market share) to non-economic indicators (e.g. new products exported, export market penetration, and number of export ventures). According to Cavusgil, Tamer and Zou [11] the economic success of export ventures, which are defined as a single product or product line exported to a single export market, can be measured more precisely than periodically added margins related to a product-portfolio. According to Leonidou and Katsikeas [36], who examined research articles over the past decades, export performance was the one of the most researched topics. This is attributable to the fact that export performance is the end result of the firm's marketing efforts and other business activities in foreign markets, providing an indication of its overall success or failure and determining further continuation of or withdrawal from exporting. Since export performance is influenced by various factors, a number of different relationships have been investigated such as export performance related to marketing strategy or to other background variables such as firm size, quality, or relationships with foreign customers.

Some scholars emphasize special key factors in the context of economical success and foreign business. Lages et al. [35] focuses in his research on quality and innovation as determinants of performance in international ventures. Leonidou [36] sees the relationship of export performance and product quality as important but widely researched whereas the relationship of export performance and product innovation is seen as rarely investigated. However, technical innovation is also identified as a strategic key factor [56]. This is relevant in this research context since MedTech companies in Germany achieve approximately one third of their turnover with products that are less than three years old [66]. Leonidou and Theodosiou [60] highlight that the adoption of specific national export-promotion programs positively strengthens the firm's export-related resources and capabilities, which are instrumental in developing a sound export marketing strategy, and achieving competitive advantage, which in turn helps to achieve superior export performance. National export-promotion programs can be seen as drivers of organizational resources and capabilities with effects on strategy, competitive advantage, and performance. Narooz and Child [46] stated substantial differences around the institutional support for SMEs and in their cultural norms towards network relationships by questioning twenty SMEs from developing as well as from developed economies. The survey demonstrates a lack at some SME decision makers' networking behavior in response to specific institutional conditions. Although national export-promotion programs can provide such information and education, this leads to a further aspect highlighted below.

Today many companies are involved in international ventures. However, according to Felicio, Meidutė and Kynik [19] a cultural context influence on internalization can still be recognized. Based on a sample of 526 SMEs, the importance of the relationship between individual global

mindset and corporate global mindset and the influence on the SMEs' internationalization factors could be indicated. Culture is a complex construct and can be defined as the impact of language, education and socialization processes on the mindset of the respondents. The country and cultural influence on the behavior of employees and managers and their management knowledge and thinking is a topic of research in the field of international and cross-cultural management. Calof and Beamish [9] identified that decision makers perceived benefits, cost and risks of internationalization culture have an influence on firm's internationalization. They draw upon the so called opportunity-based view, which supports the idea that entrepreneurs can model the organizational behavior and characteristics of their firms to pursue opportunities abroad. Dimitratos, Johnson, Plakoyiannaki and Young [13], who performed a case study on high-performing internationalized SMEs in knowledge intensive sectors, indicate that namely risk attitude, market orientation and networking propensity matter for firms regarding the exploitation of opportunities in the context of international ventures.

Theodosiou and Katsikeas [60] have a focus on previous research in terms of other key variables like environmental, organizational, and managerial factors as well as export marketing strategy, export marketing capabilities, and export competitive advantage, which have a significant impact on export performance (e.g., [20], [36], [42], [43]). Barney [70] highlights firm resources leading to sustainable competitive advantage by focusing on internal resources like physical capital, human capital, and organizational capital. Katsikeas [69] sees superior export performance linked to competitive advantages in specific competences and capabilities. These capabilities comprise: organizational learning, relationship capabilities and quality capabilities.

This means that specific organizational capabilities are related to the execution of a certain strategy in order to do successful international business. However, a chain of effects is related to international ventures with the aim to achieve competitive advantage, leading to economical success. Summarized, some factors have direct or indirect influence on the economical success of international ventures. Some of these factors are important in a general context, while other factors have a specific weight in the context of SMEs or the MedTech sector. Hence this will be respected in the next section when investigating the specific variables representing the constructs in the selected research context.

#### 4.6. Research Context Specific Factors

According to Hawawini [22] only for a few dominant value creators (leaders) and destroyers (losers) do firm-specific assets seem to matter significantly more than industry factors. For most other firms, i.e., for those that are not notable leaders or losers in their industry, however, the industry effect turns out to be more important for

performance than firm-specific factors. Hoskinson [25] highlights that theoretical and empirical findings obtained in a particular institutional context are not equally applicable in other countries. This means that the existing research constructs regarding SMEs' internationalization have to be considered also regards its country specific context.

This research is concentrating on SMEs in the MedTech industry in Germany. Hence the word specific here is related towards the firm size, the industry sector and firms' country of origin. The following section has the objective to confirm – as far as this was not done in the previous sections- that the more general findings or concepts from the literature are also applicable in this specific context. There is also the intention to make further contributions on a more detailed level in order to select distinguished factors and variables, which represent the constructs in the specific research context best. The following findings will start with general SME related findings, then add the focus on SMEs in the MedTech industry and finally reflect country specific factors of such companies. Furthermore, the section should be a rationale and a starting point for assembling an initial framework based on the introduced constructs and relationships drawn from the literature.

Through the lens of the resource-based view, the firm size plays an important role. This is supported by various research articles, which refer to the statement “An SME is not just a small big firm” while addressing that SMEs have specific characteristics.

Although firms' internationalization is based on established theories, specific internal and external factors play an important role for SMEs in this context. According to the knowledge based theory, internal factors such as organizational capabilities enable firm's internationalization strategy by enabling the transformation of knowledge into value creating processes. Recent research describes e.g. the lack of knowledge of SME's and the importance of leveraging their capabilities, on relationships and business networks. Most SMEs have international business. 69% of the companies have export business but only 15% use representatives and less than 5% cooperate or have own subsidiaries in foreign countries [21].

This might be associated with the results of study conducted by the German Chamber of Commerce. Based on several hundreds of answer in this survey management resources, lack of experience and financial resources were identified as barriers. More than two-third of the generated revenue in Germany's MedTech industry belongs to small and medium sized enterprises [34] and as outlined by recent research networks and collaboration are a way to compensate lack of knowledge and capabilities which often characterize the situation in SMEs' business. As a result, the second order construct of organizational capabilities, which has been shaped and detailed by introducing three specific organizational capabilities related to learning, relationship and coordination mechanism as representatives can be confirmed in the specific research context.

From another perspective, Julien [31] identified in a literature review sixteen competitive factors that small firms use. The majority of them refer to product strategy (such as scope, differentiation, technology etc.). Namiki [45] empirically show that SMEs use 4 types of competitive strategy. An approach reflecting an innovation position and niche operation has a positive effect on firm's internationalization and profitability [49]. SMEs' performance is likely to improve as they increase the degree of formal planning routines adopted from MNEs with respect to strategy and innovation [59]. Product development leading to innovation supports also the successful internationalization approach of MedTech SMEs [26]. More evidence of country specific behaviors of Japanese, British, US and German MedTech SMEs can be found in a study which compares different export strategies [65]. British companies were dominated by UK supply and demand considerations, Japanese companies invested heavily in distribution and support channels, whereas German companies have built their shares on technological advantage and direct sales. Although the study is some years old, German MedTech enterprises still have a strong approach towards technological leadership. In terms of new patent registrations, German manufacturers are positioned second after the USA, making Germany Europe's strongest region for innovation in this industry [41]. The results revealed the heterogeneity of MedTech companies and the distinctive features of the German MedTech SMEs regarding innovation process.

Therefore the second order construct, named market specific product potential, represents product related factors such as product competitiveness, product innovation and product quality. Products are the base for international ventures and their characteristics have high impact on firm's strategy in this research context.

Although competitive products and services are the base for international ventures they have always to be considered in the context of the specific situation regarding market and competition [60]. But also external industry specific factors have a strong impact. The importance of regulations in Healthcare has already been mentioned. Chatterji [12] highlights that specific environmental factors such as regulations and approvals in the medical markets and the related know-how have a huge impact on the economic success of foreign ventures of SMEs in this industry.

Hence specific environmental factors such as competition by MNEs or upcoming domestic firms in a foreign market, as well as market potential and medical regulations have a major impact on firm's strategy.

A survey in the MedTech industry that is focusing on SMEs in the UK gathered interesting results regards motivation, barriers and success factors in the context of internationalization [3]. Higher market size, guard own resources by entering more markets and greater profit were named as motivation, whereas finding the right partner, local competition and limited financial and management resources

were named as barriers. Product quality and competitiveness as well as an experienced management have been identified as success factors.

These findings support the already mentioned factors that are focusing on internal resources like physical capital, human capital, and organizational capital, and highlight some additional internal factors which have influence on the strategy on the internationalization of Medtech SMEs. Often, they have fewer skills and resources [37], which are obstacles in the internationalization process since experience and management skills are seen as important resources. This is in alignment with Theodosiou and Katsikeas [60] and Piakowski [48], who see managerial factors as crucial in this context. According to the resource-based view, human capital has an essential impact on the internationalization of SMEs, but it is also agreed that financial and human resources are limited in such firms. Onkelinx, Manolova and Edelman [47] identified that the role of firm-level human capital is of considerable importance for firms that follow a strategy of accelerated internationalization. But also information can be seen as critical resource [57], [60]. The role of information acquisition, dissemination and utilization is also confirmed by Theodosiou and Katsikeas [60], which see information as an antecedent to support the full range of of strategic and tactical decisions needed to enter and penetrate a foreign market.

Hence the decision on grouping the factors in product, external and internal related categories reflected by second-line constructs can be confirmed. As outlined before, a product's competitiveness, innovation and quality is the base of international ventures and define firm's strategy, but also the market potential and the competition influence a firm's strategy as external factors in general. Regulations are an other important extral factor in the MedTech business. Information and knowledge, firm's resources regarding human and financial capital have been identified as internal factors as well as management skills and experience, which are recognized in the SME context as important representatives of the second-line constructs influencing a firm's strategy approach.

## 5. Results from the Focus Group Discussion

A focus group is a controlled group interview of a target audience demographic, often led by a facilitator. A set series of questions or topics are covered and the results can provide a dimension that is simply unavailable with the traditional survey approach [58]. Although focus groups can be a powerful tool in system development, the purpose is to obtain information of a qualitative nature from a predetermined and limited number of people [33]. Lindlof and Taylor [39] imply that group discussion produces data and insights that would be less accessible without interaction found in a group setting - listening to others' verbalized

experiences stimulates memories, ideas, and experiences in participants.

During a focus group discussion 10 subject-matter experts discussed antecedents, influencing factors and important ingredients for successful international ventures of German MedTech SMEs. Each of the participants has a profound business experience of more than 15 years, whereof at least 5 years in the MedTech industry. Most of them hold or held a management position such as founder, CEO or manager in SMEs with international business activities, in addition many of them have also experience in the management of MNEs or as consultants and therefore all of them could make significant contributions by their own experience. Due to the selection of the participants most aspects along the value chain could be considered as well as their specific impact compared with other industries or MNEs.

The subject-matter was introduced by a key note speech and the meaning of antecedents and influencing factors was illustrated by a case study of a German Medtech SME, which successfully managed its internationalization process. The following moderated discussion, which lasted 2 ½ hours, was recorded and transcribed. Finally the result was analysed and the results evaluated. The figure below shows the nominations of the most frequently mentioned influencing factors.

Summarized, the impact of specific internal organizational capabilities could be confirmed. The factor “cultural understanding” had high nominations and therefore has been adapted as moderating variable to the construct. The factor “operational excellence” was named also as an important factor and has been adapted to the construct “specific internal capabilities”.

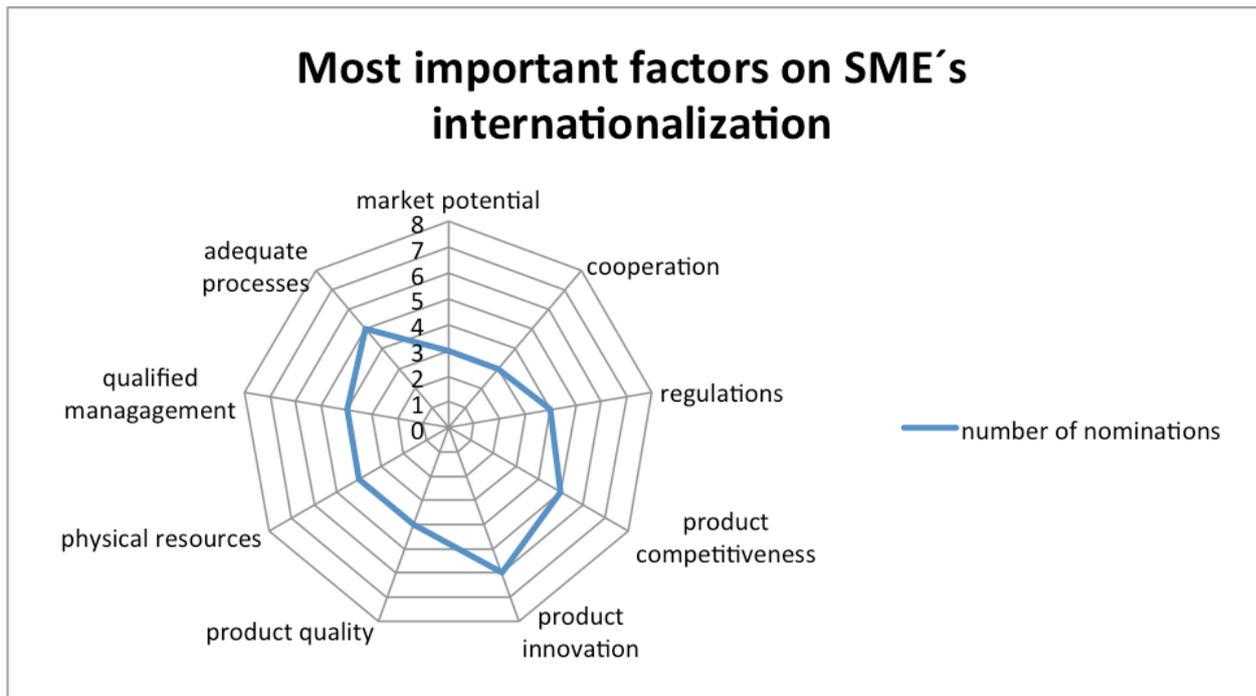


Figure 1. Most important factors as result of the focus group discussion

### Specific internal capabilities

**Organizational learning capabilities:**

- commitment to learning
- shared vision
- operational excellence

**Relationship capabilities:**

- long term relationship
- cultural competence
- partner involvement

**Coordination mechanism:**

- cooperation
- common work orientated goal
- communication

Figure 2. Factors representing the construct “specific internal capabilities”

Many of the identified factors from the literature review could be confirmed as being significant. Some factors which have been considered as less important had to be replaced by new factors. These new factors have been integrated and the initial frame work was adapted. The factor “processes” was adopted as a firm specific resource factor, whereas the factor “cooperation” was adopted as a external industry specific factor



Figure 3. Influencing Factors grouped by second order constructs

## 6. Discussion

It has been elaborated that SMEs in the medical device industry have to manage several specific challenges in adopting the right strategy for the future when willing to defend their position or to survive on the long range. While they have to foster continuous innovation and speed, they have to follow cost and time consuming regulation and approval procedures. The lack of know-how and resources can be limited by certain approaches, but not eliminated. Often they face the problem of finding the right partner to sell and service their products on the one hand, but having to prevent their know-how on the other hand, which both influences the internationalization strategy. Consequently, it became obvious that some theories, constructs and factors might be more applicable than others in the specific context of German MedTech SMEs. Thus the findings from the literature review related to internationalization theories have been synthesized with the results, which have been elaborated in the specific context of German SMEs in the Medtech industry during a focus group discussion. As a result, a conceptual framework is derived from the literature review. The components of the theoretical framework drawing on the contingency literature and the resource-based view are intended to describe the mechanism of constructs identified and influencing factors on strategy development as well as the execution of SME’s internationalization. According to the findings, the role of capabilities on international ventures is considered, too.

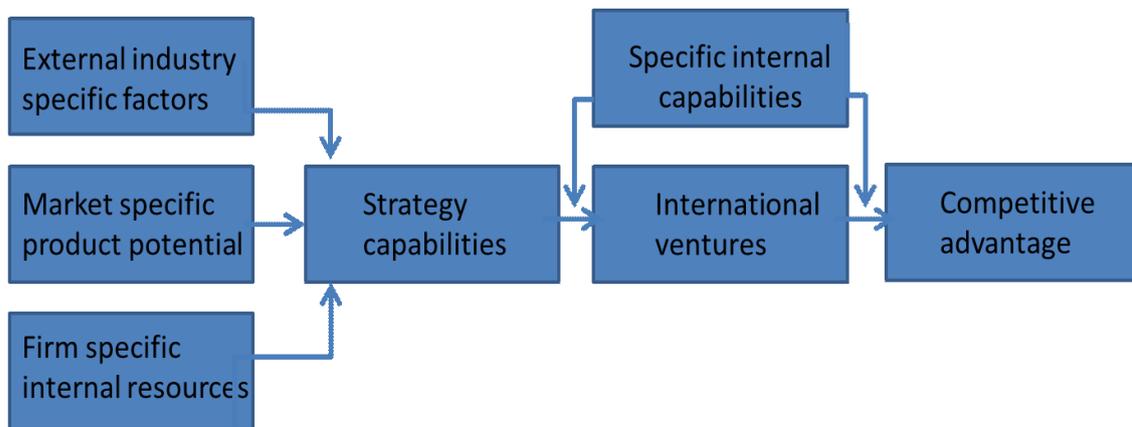


Figure 4. Conceptual Framework

## 7. Conclusions

The results are interesting for different groups such as the academic community, the industry and the governmental institutions with respect to export or to foreign direct invest organizations with respect to national export promotion programs designed for industry specific topics such as e.g. medical device regulations.

From a theoretical point of view, this piece of research is aimed to gather a deeper understanding related to the behaviour of SMEs in international ventures in a specific industry sector. The findings will help and contribute to evaluate the impact of organizational capabilities. From the perspective of the industry, this research will provide a scientific approach to the practical question of why some firms are more successful than others. This research will provide new insights with respect to the factors practitioners must consider when they intend to internationalize their business within this industry.

Second, the knowledge of which factors have the strongest influence on strategy decisions, will help the industry to derive managerial implications from the study. Business support providers might use these outcomes to meet international customer needs and assist firms operating within this sector.

It is obvious that a profound understanding of the constructs and relations which have an impact on the internationalization of MedTech SMEs in Germany can be used by business support providers and governmental sources to support and assist firms operating within this sector e.g. by national programs or individual consult.

Nevertheless, there is still the need for further investigation regarding context specific influencing factors on strategy development, which should be considered in an empirical research design.

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