Growth MEDICS

Accelerating Global Growth
For Medical Device Companaies

E-Book:

"Guide to Success: An introduction and overview of the European Medical Device Market"

International Organization for Standardization
ISO
13485
Quality Management System

GrowthMedics is an ISO 13485 market development provider based in the Netherlands and the UAE with its mission to make worldwide medical device companies successful in European and Middle Eastern healthcare markets.

www.growthmedics.com

Introduction to the e-book

Having assisted numerous medical device and IVD manufacturers, CMOs, and medical software companies in expanding into the European and MENA markets, we have acquired profound insights and experience regarding their needs, challenges, and goals for achieving successful market share in international markets.

Navigating European healthcare markets can be a daunting task, with each market featuring its own unique cultural, economic, and market dynamics, especially for new market entrants.

Our aim is to provide you with introductory knowledge in specific categories, which will hopefully aid in making more informed decisions when planning your expansion into Europe.

Should any questions arise or if further information on specific themes is needed, please do not hesitate to contact us at **contact@growthmedics.com.**

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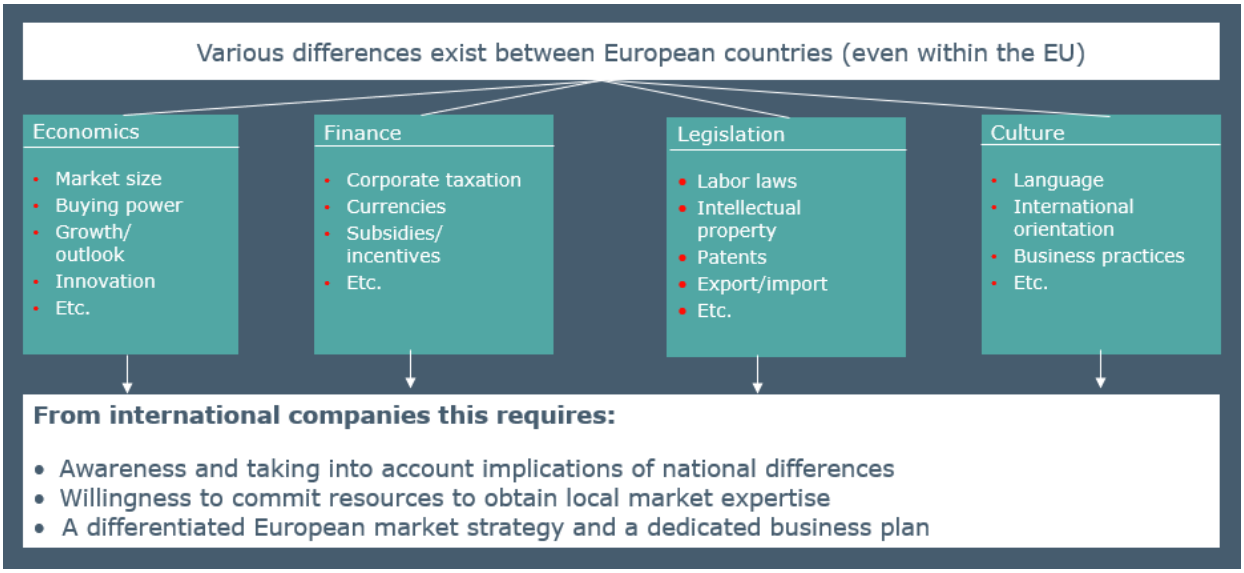
1. Navigating the complexities of the European market

Doing business in Europe can present significant growth opportunities for medical, IVD device manufacturers and software developers. Being the 2nd largest medical device market after the United States, representing 27.3% of the world market, the European market counts 600 million people, 34,000 medical technology companies and an average of 11% of GDP spending on healthcare.

Considering a fragmented market

The 26 EU member states and 17 non-EU member states present a unique set of complexities, differences, and dynamics due to the continent's diverse cultures, economies, and regulatory environments. Each with its own legal framework, business practices and cultural norms. Understanding the landscape and tailoring strategies to suit the specific business environment of each country are key to navigating the complexities of doing business in Europe.



DEntering a new market, especially one as diverse as the EU, can be intimidating. But an open mind and an eagerness to learn will help you succeed.

Key considerations before entering a new European market:

•Assessing your regulatory compliance (MDR / IVDR) and obtaining the CE mark.
•Mapping European wide and local market needs and addressable market sizes.
•Determining value proposition towards competitors.
•Identifying key reference areas (KOL's, influencers, university hospitals) and key partners.
•Gap analysis on local product requirements, documentations and cultural practices.

Assessing the European medical device size
The European medical device market is a dynamic and ever-evolving landscape. Its strengths lie in its ever-evolving technological landscape, strong regulatory framework, purchasing power and strategic position in the international market.
The market witnessed significant growth over the past years and is expected to continue to grow. Growth is mainly fueled by the aging population. Europe has one of the highest median ages globally, driving demand for medical devices related to age-associated health conditions. Innovations in medical technologies, such as wearables, telehealth, and robotic surgery, were propelling market growth. In addition, several European nations and the European commission have invested in healthcare infrastructure and R&D improvements.

Over 60 million surgical procedures are conducted annually, marking a 3% growth from the previous year, indicating the need for innovative medical technologies
Europe has seen a 5% increase in patient beds, now counting 5 beds per 1,000 individuals
An additional 250 hospitals were established in the past year
Total healthcare expenditure is about € 1.9 trillion, a growth of 4.5% YoY

The European market is estimated at ~€ 150 billion in 2021. largest medical device markets are Germany (25.8%), followed by France (14.3%), UK (10.4%) and Italy (9%). Same for the IVD, however Italy has a largest presence of IVD compared to the UK.

The largest export markets are the USA (40.3%), followed by China (125) and Japan (6%). The largest import markets are the USA (42.4%), followed by China (17.6%) and Mexico (7.9%). The largest importers of medical devices are Germany, closely followed by the Netherlands, with substantial differences followed by France, Belgium and UK. France, UK, Italy and Spain import more medical devices compared to their exporting.

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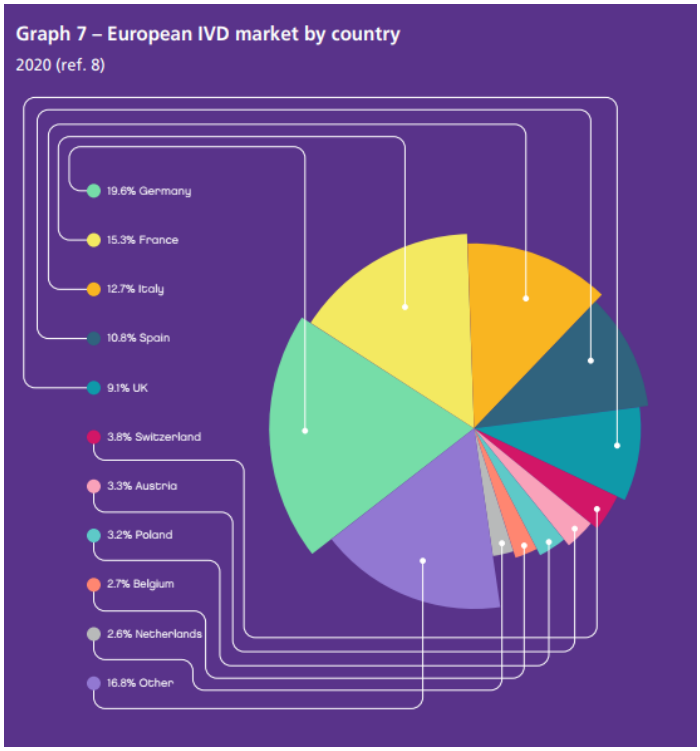

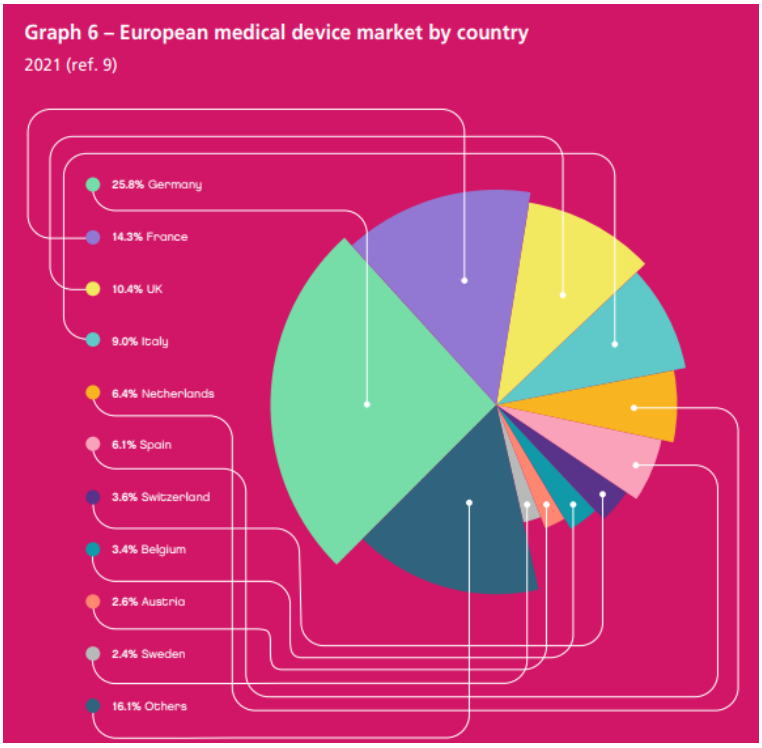

Source: *MedTech Europe*

2.1 Healthcare workforce in Europe

Europe boasts a robust healthcare workforce , comprising approximately 7.3 million healthcare professionals . This includes over 700,000 physicians , 2.4 million nurses, and a multitude of clinicians, technicians, and support staff. Such a substantial workforce emphasizes the demand for medical devices in the region.

EU HIRING AND WORKFORCE MAP

Map Conventions

- Social Security Taxes
- Unemployment
- Direct Employment In Medtech
- Hourly Labour Cost (In Euros)
- Working From Home
- Annual Working Hours

Netherlands

23,59%
3,60%
40,5
24,00%
1440

Sweden

31,42%
7,40%
27000
40,1
27,70%
1605

Germany

19,98%
3,40%
235000
39,5
17,30%
1386

United Kingdom

13,80%
4,80%
106500
41
17,40%
1668

Belgium

25,00%
5,80%
17800
43,5
26,40%
1586

Poland

22,14%
3,2%
12,5
6,90%
2023

Ireland

11,05%
4,80%
42000
37,9
33%
1772

Switzerland

6,4%
2%
63000
40,5
16,60%
1557

France

40,00%
7,60%
88000
40,8
17,30%
1505

Italy

30,00%
9,40%
118837
29,4
8,30%
1718

Greece

22,54%
12,20%
14,5
6,70%
2036

Spain

29,90%
12,30%
29000
23,5
9,60%
1686

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2.2 Market segmentation.

The European medical device market can be categorized into several key segments, each with its own growth dynamics:

1. Diagnostic Imaging: grow at a CAGR of 6% annually.
2. Surgical Instruments: the range of 3-4% annually.
3. Patient Aids:, this segment is growing at a rate of approximately 4-5% annually.
4. In-Vitro Diagnostics (IVD): IVD The European IVD market is expanding steadily, with an estimated growth rate of 5-6% annually.
5. Cardiovascular Devices: The growth rate for cardiovascular devices in Europe is around 4-5% annually.
6. Dental Equipment: moderate growth in Europe, with a growth rate of approximately 3-4% annually.

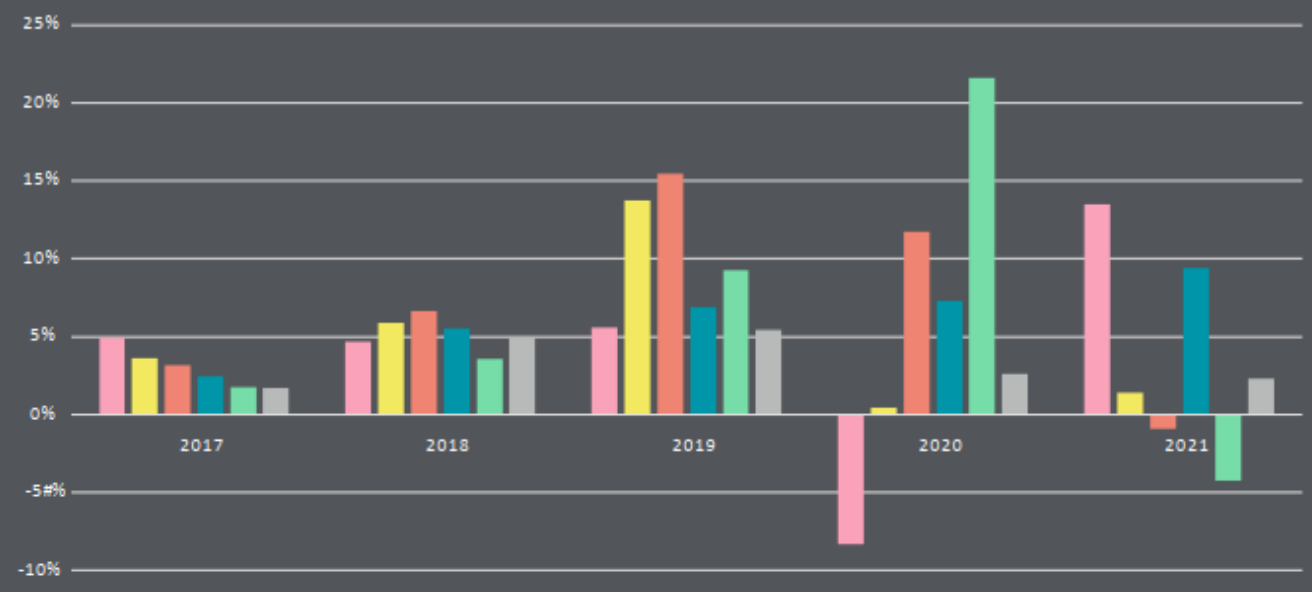
When comparing the European medical device market to the United States, some notable differences and similarities emerge:

- The European market is generally larger than the U.S. market, with a broader range of products and services.
- The growth rates in Europe, while steady, are often slightly lower than those in the United States due to varying factors such as healthcare spending, regulatory frameworks, and market dynamics.
- The United States has a higher healthcare expenditure per capita, leading to more significant purchasing power and faster adoption of advanced medical technologies.

Future Market Segments: Emerging technologies like AI-driven devices, telehealth equipment, and wearable medical devices are future segments showing potential. Companies considering entry should focus on understanding regulatory requirements, embracing innovations, and building strong networks within European healthcare communities.telehealth equipment, and wearable medical devices are future segments showing potential. Companies considering entry should focus on understanding regulatory requirements, embracing innovations, and building strong networks within European healthcare communities.

Graph 11 - European medical technology growth rates by sectors

2017-2021 (ref. 9)



3. Selecting the most successful European export country

Most non-EU medical device manufacturers initially choose the United Kingdom or Germany as their first preferred target market due to lower language barriers and market size, therefore they are also one of the most competitive markets and may also not be a fit for your specific solutions. Another assumption often made is high priced premium devices have lower chances for success in Eastern European countries due to lower purchasing power.

Selecting the right market is crucial and hinges on myriad factors, including regulatory adherence, market demand, and logistical considerations. Market research reports are fine to understand market sizes, however each product is specific and would require a custom approach based upon the capabilities and solutions of the specific manufacturer.

It involves researching the potential size for the solutions offered, the market dynamics, local market feedback and pilot testing.

1. **Market performance**
   Research the growth of the market and for your specific product group. Understand the growth factors, consumption and current solutions and alternatives offered in the market. It could lead to choosing a future promising market, over a traditional market.

2. **Demand certainty**
   Importing figures will show whether local producers are not able to meet current market needs offering consistent opportunities for foreign manufacturers. Analyze customer needs and expectations, which features and benefits are currently being offered by competitors and what determines buying behavior.

3. **Market entry barriers**
   Even though the EU has overarching trade policies, there will be country specific market entry barriers. These barriers could be higher language barriers such as France compared to the Netherlands, specific local regulations, cultural barriers, tariffs, reimbursement structures and more.

4. **Profitability**
   The unit per price and volume will determine the profitability of a product. What are the prices consumers are willing to pay and how much are competitors and current alternatives costing, how much efforts are needed, what should be distributor margins and other factors such as logistics, import duties should be mapped.

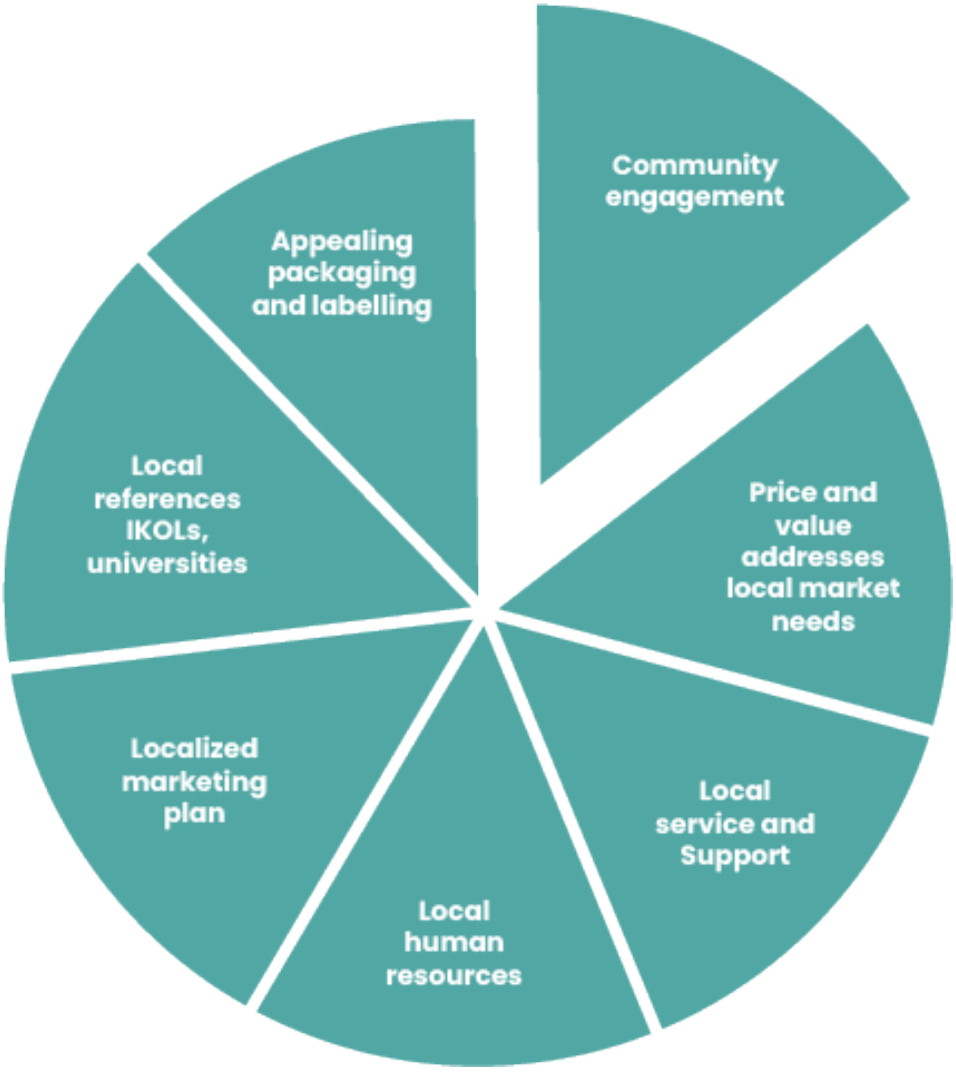
5. **Market viability assessment**
   Test the outcomes in a pilot. Select a shortlist of 2-3 most attractive countries and a shortlist of key stakeholders such as KOL's, top distributors, university hospitals and end-users such as patients or healthcare professionals to request feedback on your current offerings. Both outcomes will give you the input to craft your local market strategy and planning.

- Where can you go where your competition can't go or is not going?

- Are your current offerings matching customer and market needs and which adjustments are required? Adjustments can be in products, support, logistics, labelling?

- Some markets are easier to enter than others and require less resources. Germany and France are the largest markets, but sometimes smaller countries can be create a successful launchpad.

    - As an example a healthcare apparel premium goods supplier had their largest market share in European countries. Despite the fact nurses are making minimum wage (€500 - €1000,-) They were willing to pay € 100,- for a set of premium uniforms, while countries such as the Benelux and Germany buying more simple, functional uniforms set. Culturally wise, aesthetics and image plays a more important role in Eastern Europe compared to Western European markets.



Considerations when selecting and entering a new market after regulatory assessments

Emerging markets to consider

Emerging countries such as Poland, Hungary, and the Czech Republic, have been growing in both medical device manufacturing and purchasing power. Lower production costs and skilled labor have attracted manufacturers, while improved healthcare infrastructure has increased demand for medical equipment.

1. Central and Eastern Europe (CEE): Countries in this region, such as Poland, Hungary, and the Czech Republic, have been growing in both medical device manufacturing and purchasing power. Lower production costs and skilled labor have attracted manufacturers, while improved healthcare infrastructure has increased demand for medical equipment.

2. Nordic Countries: Denmark, Sweden, Norway, and Finland are not only known for their innovative healthcare systems but are also hubs for medical device manufacturing and innovation. These countries have high purchasing power and invest significantly in healthcare technology.

3. Germany: As one of Europe's largest economies, Germany has a robust medical device manufacturing sector. It's also a key market for purchasing medical equipment, driven by its large population and high healthcare standards.

4. Middle East: Countries like Saudi Arabia and the United Arab Emirates have experienced rapid economic growth, resulting in increased purchasing power for advanced medical devices and technologies. They are emerging as important markets for medical equipment.

In conclusion, the European medical device market is diverse, with varying growth rates across segments. While Europe lags slightly behind the United States in terms of growth, it remains a key player in the global medical device industry. Emerging regions and countries in Europe and the Middle East offer significant opportunities for manufacturers, driven by both expanding manufacturing capabilities and increasing purchasing power in healthcare.

4. Cultural selling differences In europe.

Cultural selling differences can vary significantly across different European regions due to the continent's diversity in languages, historical backgrounds, economic development, and social norms. Here's an overview of some cultural selling differences by European region:

- Western Europe (e.g., Germany, France, the United Kingdom):
  - These countries tend to have a more formal and structured approach to business interactions.
  - Decision-making can be hierarchical, with a clear chain of command.
  - Punctuality is highly valued, so arriving on time for meetings is essential.
  - Business relationships often take time to build, and trust is crucial.
  - In France, building rapport and establishing a personal connection is particularly important.
- Southern Europe (e.g., Italy, Spain, Greece):
  - Relationships are highly valued, and business often revolves around personal connections.
  - Meetings may be more relaxed, with discussions about personal life common.
    Negotiations may take longer as building trust is a priority.
  - Punctuality is less strict than in Western Europe, and schedules can be flexible.
    Northern Europe (e.g., Sweden, Norway, Denmark, Finland):
  - Business culture in Northern Europe is characterized by efficiency and professionalism.
  - Decisions are typically consensus-driven and made collectively.

- Punctuality and timeliness are highly regarded.
- Personal space is respected, and communication tends to be direct and to the point.

- Eastern Europe (e.g., Poland, Hungary, Czech Republic):
  - Relationship-building is important, but business relationships may be more formal.
  - Decision-making can be influenced by factors like personal connections and trust.
  - Personal interactions outside of business settings may help build trust.
  - Punctuality is appreciated, but flexibility may be more acceptable.
  - Nordic Countries (e.g., Iceland, Norway, Sweden, Finland, Denmark):
  - Nordic business culture values egalitarianism and transparency.
  - Decision-making is often consensus-based, with an emphasis on collaboration.
  - Punctuality is crucial, and meetings tend to be efficient and focused.
  - Informal dress codes and a relaxed atmosphere in meetings are common.

- Central Europe (e.g., Austria, Switzerland):
  - Business culture can be a mix of Western and Eastern European influences.
  - There's an emphasis on professionalism and punctuality.
  - Decision-making processes may be more hierarchical in some cases.
  - Building trust through personal connections can be important.

- Balkans (e.g., Serbia, Croatia, Bosnia and Herzegovina):
  - Relationships and personal connections are highly valued.

- Decision-making may involve multiple levels of approval and consensus.
- Meetings can be informal, with discussions extending to personal topics.
- Flexibility and adaptability are key to navigating business interactions.

- Benelux (e.g., Belgium, the Netherlands, Luxembourg):
  - Business culture is characterized by pragmatism and direct communication.
  - Decision-making is often based on consensus, but efficiency is highly valued.
  - Punctuality is important, and meetings are typically well-organized.
  - Networking and personal connections can play a role in business success.

It's crucial for businesses looking to operate in European markets to adapt their selling and marketing strategies to the specific cultural norms and preferences of each region. Building relationships, understanding decision-making processes, and respecting local etiquette are key to successful selling across Europe. Additionally, seeking local expertise or partners can be invaluable in navigating cultural nuances and achieving business success in these diverse markets.

5. Pitfalls and challenges when selling into the European market.

In previous sections we explained the differences among European markets and the importance of assessing the market prior to rolling out your expansion plan. We've learned it is not always about the biggest market or the market with the highest purchasing power. At GrowthMedics we've been in some cases more successful for high priced medical goods in Eastern Europe compared to Western Europe.

The growth potential in European markets are significant but not an easy task. Especially for medical companies with little presence in international markets. More competition, pressure on hospital budgets, regulatory requirements, increasing labor costs while navigating complex fragmented markets and patient expectations – the numbers don't lie, 70% of companies fail internationally.

We've seen cases where medical companies rushed into Europe without really understanding how things work on the ground. Sometimes, language barriers made it tough to connect with potential customers or not have adequate local sales representation. Or missing the mark by not aligning prices or services with what the market expects.
The most common European expansion pitfalls we have experienced among medical companies:

1. Inadequate Market Research: A major reason why medical companies stumble abroad is insufficient market research. Failing to understand the unique needs, regulations, and competitive landscape in EU and MENA markets can lead to a wastage of time and resources. Consulting with experts, conducting not only desk- but also field research and pilot testing will ultimately save time, money and increase ROI.

2. Lack of supporting sales structure: Managing sales from oversees will maintain operational complexities such as time zone, language barriers, cultural misalignment and inefficiencies of travelling resulting into ineffective representation, lower sales success, and less effective engagement with local customers. Having local sales representation is a must for international long-term sales success.

3: Overlooking Regulatory Hurdles: Navigating the labyrinth of regulations in different countries can be overwhelming. Companies often overlook the importance of complying with local laws and standards, leading to costly

delays or product recalls. It will require budgeting, planning and making adjustments to your processes such as labelling, shipping and implementing requirements such as having an Authorized Representative.

4 Product / Service Adaptation: Often companies do not realize the unique needs of local markets and the need for adaption that will require resources, flexibility and management commitment to make changes in the short term to gain long-term sales success. These could be having local customer service support, warranty changes, language adaptation, or launching a product with less or different features to be able to compete and attract new customer growth.

5 Resource allocation: Companies that are successful in international markets have a long-term plan and are investing in supporting resources such as marketing materials and tools facilitating distributors, educational platforms and building referral resources. Building a brand and becoming a trusted player in EU and MENA markets will require full long-term commitment.

Ask for our E-Book on: Successfully establishing distributors in Europe for medical device and IVD companies

6.Engaging successful distribution partnerships in Europe

The most successful manufacturers in international markets working through channel partners are the ones that are the most committed and engaged with their distributors. They have incorporated an infrastructure that is aimed to integrate and serve distributors to local market needs. They are willing to make changes and be flexible to secure a successful position in those markets.
From our experience we often see a new market being entered by passively or pro-actively looking for a distributor selling into that market without having a relative understanding of local market needs. Or manufacturers committing to distributors without a proper due diligence on their capabilities or expecting the distributor to act and ask questions for support.

The right partner can make or break the success in that territory.

A good product or service will not always sell well if you don't have the right channel partner. A distribution strategy starts from:

- How and where do customers purchase the products?
- How does the chain of command look like, who are the key influencers?
- What are the service expectations of the customers?
- Where are key customers located ?
- How does the infrastructure of competitors look like?
- What are the internal corporate strengths and weaknesses?
- What are attractive pricing models for distributors and end-users?

Considerations when selecting your distributor

- Conduct market research: Before choosing a distributor, conduct market research to identify the potential demand for your products in the target market. This research can help you understand the competitive landscape

and identify any potential barriers to entry.

- Evaluate the distributor's expertise: Evaluate the distributor's expertise in the medical device industry and their knowledge of the local market. A distributor with experience in your product category can provide valuable insights into the market landscape, regulatory requirements, and customer preferences.

- Evaluate the distributor's network: Evaluate the distributor's network and distribution channels. A distributor with an extensive network of contacts can help you expand your reach quickly and effectively.

  Negotiate terms and conditions: Negotiate terms and conditions that are favorable to both parties. This can include commission rates, marketing support, and exclusivity agreements. It's essential to have a clear understanding of the terms and conditions before signing any agreements.

- Most distributors want to have exclusivity to their market. The goal is to create a win-win for both parties. As a manufacturer you want to lock out underperformance and secure continuous growth. When providing an exclusive agreement consider the following:

  - How large is the market and does the distributor have the personnel and resources to serve the entire market?
    In which regions is the distributor active, how does their regional revenue flow look like?

  - To what extent is the distributor willing to invest? Exhibiting at tradeshows, setting up webinars, translating documentation, investing in online marketing and stock, investing in dedicated sales managers and so on.

  - Is the distributor willing to commit to activities. We usually put activities first as sales are an outcome of activities. Targets are good but if the distributor does all the activities and invests in a market and sales targets aren't achieved, there could be underlying issues such as product/market fit, or the financial structure setup may not be feasible. Is the distributor carrying competitors? Are they willing to give insights in their sales funnel, sales meetings on site, how open and willing to become a partner are they?

- Provide ongoing support: Provide ongoing support to the distributor, including training, product information, and marketing materials. This can help ensure that the distributor is well-equipped to promote and sell your

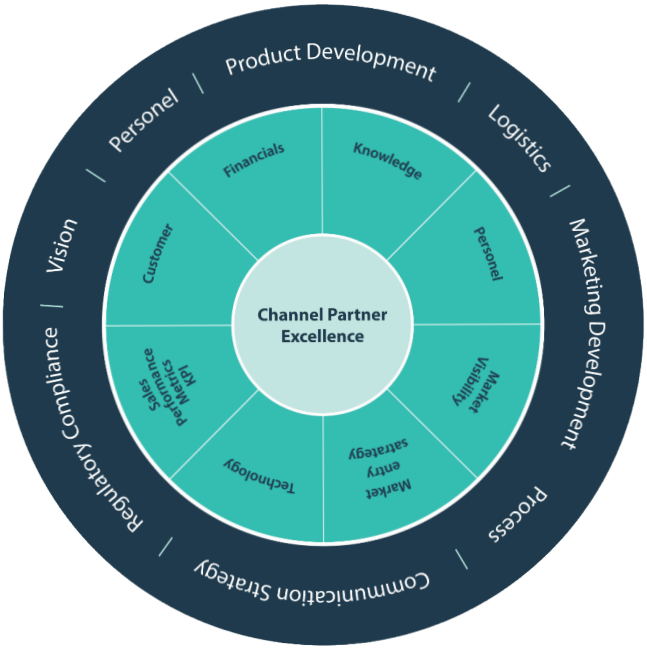
products effectively.

Distributor Optimization framework to achieve channel partner excellence

Distributors are a key part of your organization as they represent your brand and you as a manufacturer rely heavy on the sales success they will achieve. Often the role of a distributor is underestimated, and we experience distributors are underserved.

Manufacturers providing the right support and attention to distributors and having their internal organization's infrastructure setup that way, achieve excellent channel partner performance.

In our other blogs you can read about distributor strategies and types of distributors. This model will apply to any distribution model and presents a framework for the manufacturer and distributor. By working on this framework as a checklist and implementing the needs associated to support growth in local markets, a stronger partnership and aligned expectations will occur.



Manufacturer
Processes the manufacturer should design and structure to support distributors

Distributor
Processes the manufacturer should design and structure to support distributors

Channel partner excellence
The goal is to achieve a mutual successful relationship and success in local markets

Manufacturer		Distributor	
Product Development	Having the ability and a process to continuously develop new improved products and the adaptability to implement local feature requests	How well equipped is the distributor with latest technologies in sales, marketing, CRM, communications. What is needed to become more effective in the sales process.	Technology
Logistics	An efficient structure to supply channel partners and end-users whether through a warehouse, master dealer incl. pre-selected freight forwarders and a process or a b2b ordering platform.	Which pricing models are used in the market and are they up to date and competitive in the market. The inflation in the supply chain has impacted price increases but will the current pricing, discount and margin structure take the business in 2023 to the next level?	Financials
Marketing Development	A global and local marketing strategy to act on local market needs, challenges, and opportunities. A continuous development of new translated materials and activities to support distributors with a direct marketing presence.	What activities will help create brand awareness among customers and influencers. What education information or product knowledge will be delivered to whom and how?	Market visibility
Process	An international process from shipping, to invoicing, ordering, onboarding new distributors, support plans.	How will progress be recorded, measured and optimized? How will success be determined? Activities create the numbers.	Sales performance metrics
Communication strategy	Corporate communication on who, what elements and when are being communicated. Distributors are a key sales part of the organization and need to be aware of corporate goals and developments.	How well are your distributors trained? What is their onboarding process for your products? Will there be coaching, training and roleplay? How well can demonstrations be provided.	Knowledge
Regulatory compliance	Complying and maintaining international market requirements.	What is the process for introducing new features and products? Relationships with KOLs and key reference partners are crucial for product launches and testimonials.	Market entry strategy
Vision	Formulating an international growth vision and keeping your channel partners close and involved. They can play a key part in future growth plans.	What is the customer strategy? How will satisfaction and upsell be implemented. How are re-orders planned and what will be improved to increase satisfaction and growth on existing customers.	Customer
Personel	Managing your partners oversees, locally, customer service, account management who will lead the efforts efficiently and effectively and how will support, trainings be provided.	Who is in charge of what, how well are sales processes implemented. How capable is the staff to talk with clinicians, how do call scripts look like.	Personel

Distributor onboarding processes

The framework show having processes and communication is key to achieve the desired success. This framework mainly focuses on managing the infrastructure for existing distributors but as existing distributors the onboarding of new distributors is very important. The better distributors are engaged and started from the beginning, the more efficiently and successfully they will represent you in their territories.

An example of sequences and simultaneous steps for onboarding distributors is listed below:

- Outbound lead calling and appointment setting scripts and trainings
- Have a shared Onedrive / dropbox folder continuously updated with all relevant documents
- Have a sales and marketing plan with milestones in place from the start
- Have a format to share other distributor successes with new distributors
- Structure for Phone/video calls with distributor sales and marketing key contacts
- Schedule and attend onsite training and marketing meetings with distributor teams
- Plan for congresses and on-site support needed
- Use email for all key contractual documents as attachments
- Attend initial demos in the field with distributor KOL's
- Teach how to counter competition and pricing conditions
- Negotiation of contract and initial order including demo and repair support units
- Support distributors and end-users with whatsapp group support channels
  Monitor and support with rapid response for all protocol and marketing questions

- Plan reorder cycles with distributor price and bonus negotiations
- Arrange credit terms or with a letter of credit, initially CIA (Cash in Advance) is recommended
- Use an MDR contract or request documentation to make sure the distributor is aware and is compliant with the MDR regulations

GrowthMedics has established hundreds of distribution partnerships and has access to 5000+ medical device and IVD distributors in the European market.

Reach out to us to learn more about our track record in establishing distribution channel networks and our channel management services.

7. Selling into European hospitals – what you need to know

On average healthcare represents 10% of GDP in European countries and about a third of their expenditure. There is a light trend towards centralizing hospitals and increasing beds over building new hospitals. The number of European hospital beds will continue to grow over the next years. The EU is ageing, offering long-term opportunities for medical device companies and healthcare providers. Figures currently show an average of 20% is 65+ years of age which will increase to 31.3% of the EU population in the next 30-50 years.

- There are currently 24,200 hospitals in Europe
- Hospital bed count forecast in Europe shows substantial growth from 2.4 million hospitals in 2018 to a forecasted 4.596 mln beds by 2025
- European hospital bed density in Europe is average 5.49 beds per 1,000 people
- Germany has the most private owned hospital beds and Hungary the most public hospital beds
- Germany, Austria, Hungary, Czech Republic and Poland have the most hospital beds per person while Italy, Spain, Ireland and the UK the least
- The biggest hospital revenues come from Germany hospital groups: Fresenius Helios, Rhoen-Klinken, Asklepios, Sana Kliniken, Capio (Nordics) and Gruppo San Donato (Italy).

Working directly with hospitals as a foreign medical device manufacturer, requires having an infrastructure that can provide local support. This could be through distributors, service partners or having your own sales representative. Without having boots on the ground, this will be an impossible mission.

Working with distributors can give you faster access to decision makers in hospitals due to existing contacts, but in cases where you do not have a distributor yet and you are looking to create references in the hospital, targeting hospitals can be very effective.

New innovative medical technologies focused to help hospitals reduce costs, reduce time and get better and faster treatment outcomes succeed well when selling directly to hospitals.

Example case:

An ultrasound manufacturer with new features will compete against existing ultrasound devices in hospitals. Hospitals will not likely make time and work with a new supplier unless it has a significant technological, cost saving or time savings impact.

An AI based developer of needle guidance software through ultrasound for specific anesthesia procedures, is being introduced new in the market and the hospital hasn't been aware of these types of solutions. The solution will help conduct procedures faster with better outcomes. In our direct approach to hospitals, we've been successful in engaging top doctors interested, resulting in demonstration and direct purchases with GrowthMedics' local sales representative in Europe.

- Serve hospitals direct only when you are able to provide local support whether through a distributor or own sales representative;
- Your chances of success will be higher if there is a significant clinical or time / cost savings value in current used products;
- It can be a labor-intensive process and identifying, speaking and demonstrating your solutions directly with surgeons and healthcare professionals;
- Setting up meetings and introduction at local congresses can be a productive way of getting direct feedback and building trust and becoming part of the network;
- CE requirements are mandatory, in most cases even in clinical evaluation trials.

Check out more case studies here

www.growthmedics.com/case-studies

8.Healthcare Financing and Hospital Demography

On average 80% of hospitals in Europe are public and financed through the government, executed by insurance companies or trust funds such as in the United Kingdom. There is a trend of growing private hospitals especially in Eastern and Southern European countries. Due to lack of staff and budget cuts, there are longer queues and there is a big service gap especially in those regions between public and private hospitals. We also see more and more international clinics and hospitals buying or establishing a presence across European countries.

Western Europe

- United Kingdom
  - Financing: Primarily through National Health Service (NHS) funded by general taxation and National Insurance.
  - Public/Private Split: 80% public, 20% private.
- Germany
  - Financing: Statutory Health Insurance (SHI) system, where employers and employees equally share the health insurance burden.
  - Public/Private Split: Roughly 50% public, 50% private.
- France
  - Financing: Predominantly through statutory health insurance, coupled with out-of-pocket payments and voluntary health insurance.
  - Public/Private Split: Approximately 65% public, 35% private.
    Southern Europe
- Spain
  - Financing: Public healthcare is funded through taxes, with an option for private healthcare financed through voluntary private health insurance.
  - Public/Private Split: 80% public, 20% private.
- Italy
  - Financing: Primarily through the National Health Service financed by regional taxes and national income taxes.
  - Public/Private Split: 70% public, 30% private

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Requirements for Selling

Medical companies aiming to sell into European hospitals must adhere to stringent requirements which might include:

- Certifications: Obtaining necessary certifications such as CE marking which demonstrates conformity with European standards.
- Local VAT Registration: Ensuring a local VAT registration to facilitate smoother transactions.
- Collaborating with Distributors: Working with established local distributors can aid in navigating the regional landscapes more effectively and providing local service. Many hospital require a service level agreement.

Check out our case study how we developed growth across University hospitals in Europe through our 3 months introduction program

www.growthmedics.com/3-months-pilot-program

9. Reimbursement in Europe

Medical device reimbursement in the European Union (EU) is a complex and multifaceted process that varies from one member state to another. Reimbursement pathways are complex and time consuming and the complexity varies per EU country.

Countries like Germany, France, and Italy often have complex and time-consuming processes, requiring extensive data and evaluation. Conversely, countries like the Netherlands and Sweden have more streamlined systems. It's essential for medical device manufacturers to carefully research and adapt their strategies to meet the specific requirements and complexities of each EU country they intend to enter. Local expertise and partnerships can also be invaluable in navigating these intricate reimbursement landscapes effectively.

Steps to Develop a Reimbursement Strategy

- To successfully navigate the European medical device reimbursement landscape, we suggest following these steps:

- Market Research: Identify the target countries and their reimbursement systems. Understand the specific requirements and evaluation criteria in each market.

- Clinical Evidence: Generate robust clinical data to demonstrate the safety and efficacy of your medical device. Adapt your study design to meet local requirements if necessary.

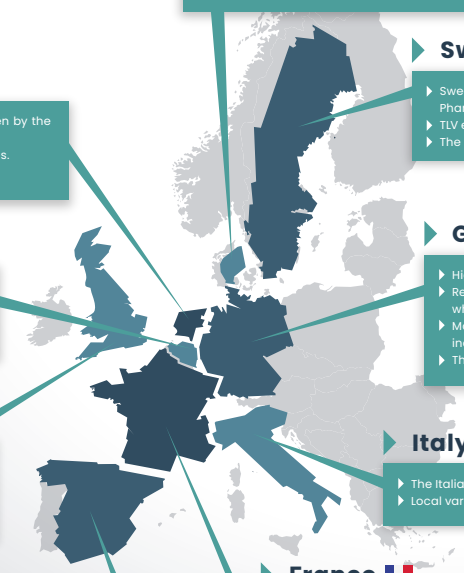
- Health Economics Data: Develop health economic models to showcase the cost-effectiveness of your device compared to existing alternatives.

- Engage with Authorities: Establish communication with relevant authorities and committees in your target markets. Seek their guidance and build relationships.
  Pricing Strategy: Determine a competitive pricing strategy that aligns with the reimbursement potential in each country.

- Local Partnerships: Collaborate with local distributors, healthcare providers, and patient advocacy groups to gain insights and support for your device.

- Regulatory Compliance: Ensure your device complies with EU medical device regulations (MDR) and local regulations.

EU REIMBURSEMENT LANDSCAPE



Denmark

- Sweden has a centralized reimbursement system managed by the Dental and Pharmaceutical Benefits Agency (TLV).
- TLV evaluates clinical effectiveness and cost-effectiveness.
- The process is relatively streamlined compared to some other EU countries.

Sweden

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Netherlands

- The Netherlands has a well-structured reimbursement system overseen by the National Health Care Institute (ZIN).
- ZIN assesses the added value and cost-effectiveness of medical devices.
- The Dutch system is known for its transparency and efficiency.

Germany

- Highly complex and stringent reimbursement system.
- Reimbursement decisions are made by the Federal Joint Committee (G-BA), which evaluates both clinical and economic aspects.
- Manufacturers often need to provide extensive clinical and economic data, including health economic studies.
- The process can be lengthy and resource-intensive

Belgium

- Sweden has a centralized reimbursement system managed by the Dental and Pharmaceutical Benefits Agency (TLV).
- TLV evaluates clinical effectiveness and cost-effectiveness.
- The process is relatively streamlined compared to some other EU countries.

United Kingdom

- Devices can be categorized into three groups: those recommended, those not recommended, and those with insufficient evidence.
- The reimbursement process can be transparent, but acceptance can be challenging.

Italy

- The Italian Medicines Agency (AIFA) manages reimbursement decisions.
- Local variations can make market access challenging.

France

- France employs a centralized reimbursement system managed by the French National Authority for Health (HAS).
- HAS assesses the clinical benefit and cost-effectiveness of medical devices.
- Reimbursement is categorized into several levels, with the highest level offering full coverage.
- The process involves expert committees and can be time-consuming.

Spain

- AEMPS evaluates clinical safety, efficacy, and cost-effectiveness.
- Devices can be reimbursed at the regional level, leading to regional variations.

Growth MEDICS
www.growthmedics.com

GrowthMedics has pan-European experts on board that can support with reimbursement analysis and strategies, get in touch with us for more information

Thorough research, strong clinical evidence, effective engagement with authorities, and strategic partnerships are essential components of a successful reimbursement strategy. By understanding the nuances of each EU member state and addressing potential pitfalls, medical device manufacturers can effectively bring their products to market and improve healthcare outcomes across Europe.

10. Hiring and payrolling in Europe

When establishing a presence in Europe and demand for your products are growing, the next step could be to hire someone on the ground. This E-Book has covered many topics which showed the EU market has differences by country, this also includes differences in labor-law, cultural norms, taxes, salaries and perception of work.

Hiring someone in Europe can be not only a complex process but what makes it more challenging is to have a successful hire. PwC published a study that showed a failure rate between 30% and 50% for oversees hiring. Therefore considering the costs and risks it is important to research the markets where you want to hire and have a strategic hiring plan in place.
In Germany, terminating the agreement can be a quicker procedure compared to the Netherlands; however, it's important to note that competition clauses hold greater significance in the Netherlands compared to Germany.

Hiring in Europe can be a costly investment especially if you have little to no presence and you want to minimize your risk, cost and remain flexible. Labor laws are strict and social taxes differ by country and are relatively high.

What happens if you have limited employees, and they decide to leave. You will lose valuable market data and insights in international markets and it will be difficult to recapture that.

Read our whitepaper about SDaaS solutions, which provides an alternative to hiring – **more cost-effective, lower risk and faster speed to**

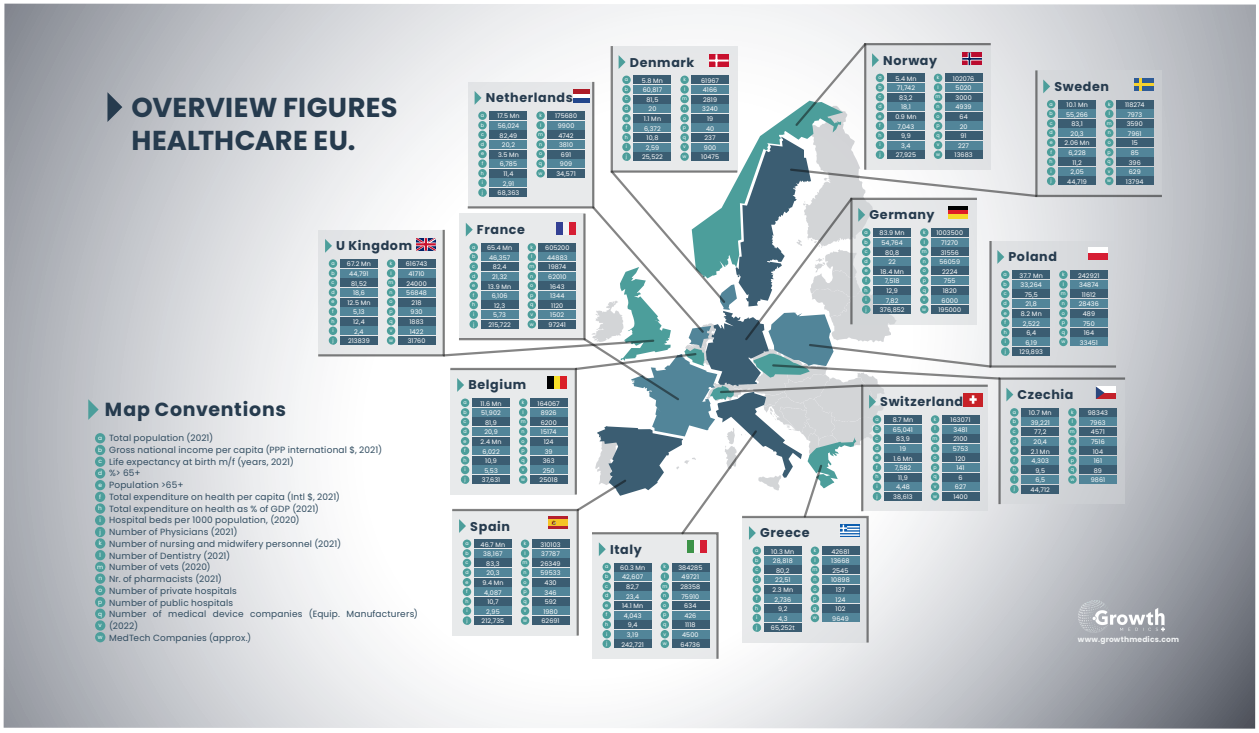
Western / Southern European countries	~Annual gross salary for international sales manager * Excl. Bonus	~ Employer costs (social benefits)	~ Total employment costs per year	~Incl. administration costs ** (5%)	Management time 20% (over employer cost)
Spain	€ 60K	30%	€ 89,700.00	€ 94,185.00	€ 107,640.00
Germany	€ 100K	20%	€ 138,000.00	€ 144,900.00	€ 165,600.00
Netherlands	€ 82K	24%	€ 116,560.00	€ 122,388.00	€ 139,872.00
France	€ 80K	45%	€ 133,400.00	€ 140,070.00	€ 160,080.00
Italy	€ 67K	30%	€ 100,100.00	€ 105,105.00	€ 120,120.00
Sweden	€ 83K	20%	€ 114,000.00	€ 119,700.00	€ 136,800.00
Average cost				€ 121,058.00	€ 138,352.00

PEO vs HRO services

You do not per se need an entity to hire someone in international. There are organizations such as GrowthMedics providing a full service from hiring, contracting and payrolling.

Professional Employer Organizations (PEO) acts as a co-employer. You technically hire your own staff and you are the employer of record. The PEO is responsible for providing payroll services compliant with local employment taxes.

A PEO may also provide unemployment insurance, handle claims against employees and manages the legal and financial aspects.
An Human Resources Outsourcing (HRO) organization doesn't become the co-employer and can fulfil specific tasks such as payrolling, benefits management, administrative tasks, recruitment and other services such as coaching, training and onboarding.



In the next 6 months the goals is to close 3-5 distributor contracts, 2 OEM agreements and 3 university hospital trials. There will be field trip with the CEO visiting and executing real time clinical demonstrations across several European markets with hospitals and distributors. Organizing a webinar for the market and visiting and exhibiting at upcoming tradeshows .

We can help recruit and payroll your employees across European and MENA markets

11. VAT and import duties in Europe

Regulatory importing

When importing your medical or IVD devices into the European Union as a non-EU manufacturer, you will need to meet the requirements of fiscal importing and regulatory (MDR/IVDR) importing guidelines. These are two separate legal silos.

The fiscal importer is the entity that takes direct possession of your products and either resells or uses your products. It can be a distributor, reseller, a patient, or healthcare professional.
When the consignee receives the goods, there will be responsibilities towards customs, which will be the paying for import duties and VAT if applicable, further explained in the section below.

The MDR/IVDR (2017/745) regulations stipulates non-EU manufacturers placing CE marked products in the European Union, will need to designate an importer. The regulatory importer will be jointly liable for products placed on the market and requires to comply with the obligations listed in Article 13 MDR/IVDR.

The importer is a separate economic operator as the distributor. They will have different liabilities and responsibilities. When you do not designate a regulatory importer, your distributor will automatically become your regulatory importer and put the distributor in place to meet these responsibilities and become liable. If the distributor is incompliant by not following the importer requirements, the manufacturer will in the end be held responsible too or will experience the consequences.

The regulatory importer does not physically need to receive your goods and can fulfill this role while not disturbing the supply chain of direct shipments to your customers.

It is therefore highly recommended to separate the regulatory importer from your distributor. As a manufacturer designating one single independent regulatory importer for all EU markets will:

- Avoid channel conflicts; by not having multiple distributors as your importer and customers of your distributors will not receive goods with labels of their competitor.

- Avoid market complications; your dependency on distributors will increase
- Minimize administrative burden and time; when having multiple distributors as your importer, each needs to have their own labels with each shipment and each importer will have their own process of verifying, tracking and post market surveillance, requiring manufacturers to deal with enquires and process among different importers
- Keep your distributors focused on sales and marketing of your devices rather than burdening them with administrative tasks. Most of the time distributors are also not specialized in regulatory requirements. To avoid incompliance risks, it is suggested to work with an expert regulatory import partner;

Read this whitepaper on complications of designating your (multiple) distributors as your regulatory importer

www.growthimports.eu/mdr-ivdr-importer-scan

GrowthImports is a regulatory importer compliant with the MDR/IVDR and can act as the single independent regulatory importer across all EU markets for non-EU manufacturers

Vat and fiscal importing

While all VAT guidelines are set at the European Union level, member countries are allowed to implement them as they see fit for their particular regions.

The good news is, in certain situations, businesses that are not based in the EU but have incurred VAT in connection to business activities in the region, are entitled to a refund on the VAT paid.

The VAT rates in the EU range from 17% to 27%, with Luxembourg having the lowest rate and Hungary with the highest. EU regulation requires VAT to be 'at least 15%', and the average among the 27 countries is 21%.

Aside from VAT, imported medical devices are charged with EU customs and import duties.

Import duties medical devices

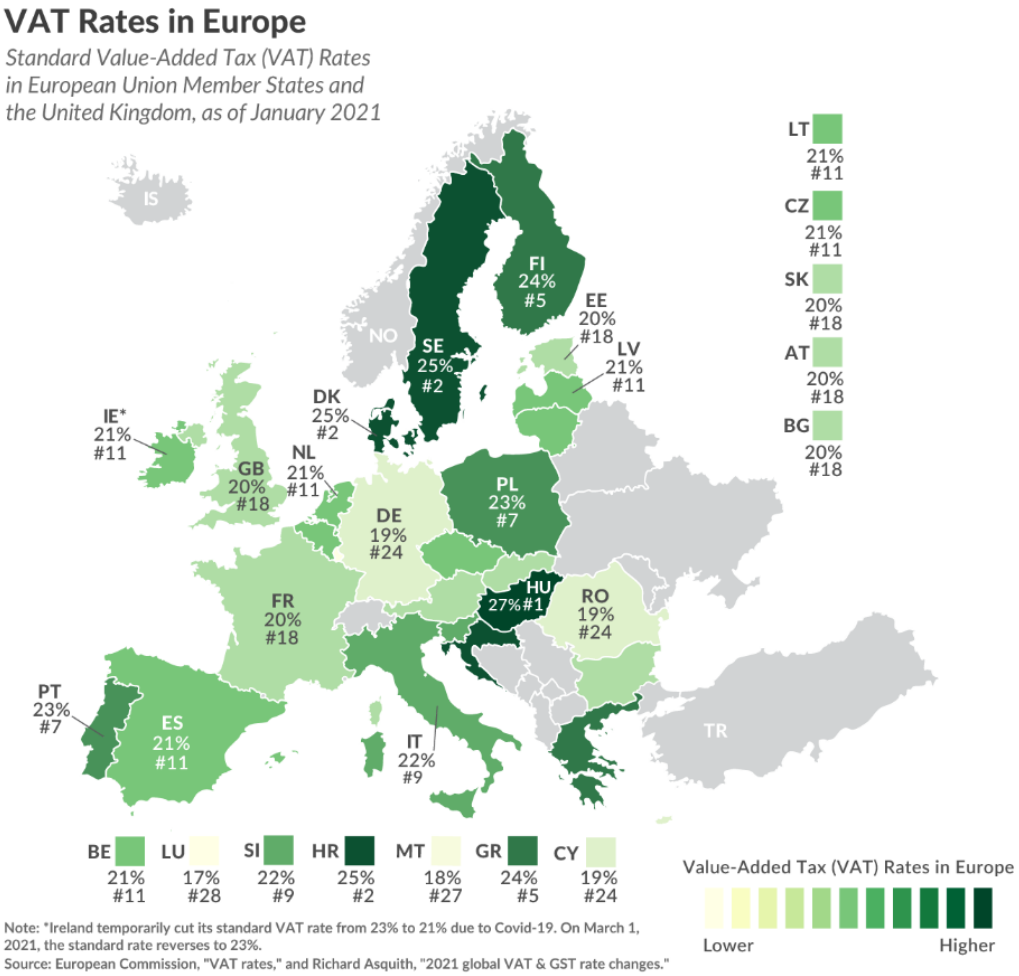
Import duties for medical devices can differ from 5% to 12% depending on country of origin, and type of device, outlined in the HS codes that typically start with 90, for example:

9021 - for orthopedic appliances, artificial body parts, and other appliances worn, carried, or implanted in the body to compensate for a defect or disability.

When you sell direct to end-users such as healthcare professionals or patients into the European market, the end-user will be the fiscal and regulatory importer and will be responsible for the VAT and import duties.

In some countries such as the Netherlands, If the end user purchases below €150,-, the import duties are not applicable but only the VAT.

If you are selling to other businesses to EU from a non-EU country, VAT is not applicable, however the import duties are.



Reverse-charge mechanism on import: Article 23

The reverse-charge mechanism on import means that you are not required to pay the VAT on import immediately. The VAT can then be paid when you file your VAT return. In order to do this, you will need an Article 23 permit. As non-EU manufacturer, you are not able to apply for an Article 23 permit yourself. However you can engage a tax representative for this purpose. This representative can apply for a permit for you.

If you do use a tax representative, then you will not need to register with us. The tax representative will declare the VAT that you are required to pay on the VAT return for that period. The representative will deduct this VAT as input tax on the same VAT return. Then you will not be required to pay this VAT in advance on import.

GrowthImports can act as your European fiscal representative and support with reclaiming your VAT in the European Union

Get your free importer and fiscal scan here

12. Discovering MedTech hubs in Europe

Europe is known for its innovations and high-quality solutions as well as being open for cooperations. The clusters will allow OEMs to identify and partner regionally with top innovative European MedTech OEMs. It can provide the opportunity to become part of a key network that will give access to new partnerships such as universities, research organizations, funding and new business opportunities.

Here are some key points of why these medical clusters are important nowadays:

- Creating awareness and a professional brand for you as a manufacturer to partner with leading innovative medtech clusters
- Collaboration and Knowledge exchange
- Resource Sharing such as working with universities, funding and more Talent Pool
- Regulatory Expertise
- Investment Opportunities
- Increase Global Competitiveness by partnering with these clusters

One of the most known MedTech cluster hubs in Europe are Medicon Valley in Denmark and Sweden, MedTech West in Germany and MedTech Strasbourg in France.

We made an overview of all the major MedTech hubs across European markets. The overview includes their members, their events, industries and information on their capabilities and size.

The overview can be found by going

growthmedics.com/european-medtech-clusters-overview

13. Medical tradeshows in Europe in 2024

The importance of attending and exhibiting at congresses and trade shows in Europe cannot be overstated for medical device companies looking to enter or expand in the European market.

These events offer unparalleled opportunities for market insight, networking, brand exposure, and staying abreast of industry and regulatory developments. The trend towards more hybrid, health-conscious, and sustainable event models is likely to continue shaping how these trade shows are attended in the future.

We've listed 40 tradeshows in the B2B healthcare industry across European countries taking place in the year 2024.

To download the full PDF click here:

Growth MEDICS

Interested to learn more?

Get in touch with us Book a meeting with us here:

Learn more about our 3 Months Market Acceleration Program

Check out our case-studies here

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