VIRGINIA ECONOMIC DEVELOPMENT PARTNERSHIP

SECTOR OVERVIEWS SCANDINAVIA

DENMARK

- **MARITIME**
- **HEALTHCARE**

SWEDEN

- **DEFENSE**
- **HEALTHCARE**

April 2019

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Executive summary:

It is said that the Nordic countries are so alike that they can easily work together, yet so different that they can still learn a lot from each other!

A Dane, a Swede and a Norwegian might understand each other's language, and to non-Scandinavians the Nordic countries may look very similar due to their close cultural and historical ties. They are all advanced welfare states, with a large public sector and high level of taxes.

Due to small home markets, a high percentage of the Nordic manufacturers are also experts on global sales and the technology base is very high as is the level of digitization.

How to enter the Scandinavian markets is similar to many other export markets - the importance of careful preparation cannot be overstated. However, the Scandinavians are very receptive to foreign products and services as they are always looking to improve their competitive advantage.

The countries have few if any barriers to foreign trade and EU legislation applies in most industries.

Working with local distributors or collaborators can be a good way to penetrate a new market if your products or services do not sell directly info a public sector institution or municipality via tender procedures.

The main theme of the following sector reports is that both public and private organizations are preparing for major changes as a result of the technological development and implementation of digital solutions.

Internet of Things, Artificial Intelligence, Big Data, Apps solutions etc. will play a major role in the years to come and hence big changes are expected in all the industries/sectors researched.

SECTOR OVERVIEWS SCANDINAVIA

DENMARK

Maritime

Overview of market size and key players

The Danish maritime industry is one of Denmark's core industries.

As gatekeeper to the Baltic Sea, the geographic location has played a strong influential factor in the country's development into one of the world's leading maritime nations.

Surrounded by sea, a total coastline of over 7,000 km. and 400 islands have been the main factors for making maritime transport a vital source of income in Denmark, and Danes have been active in the shipping business since the Viking era.

The Danish maritime industry holds a strong position on the global market, especially due to highly technological and specialized products and solutions.

The Danish maritime cluster is referred to as **Blue Denmark** and consists of shipowners and shipping companies, ship brokers, ports and logistics companies together with shipyards, suppliers and designers of ships, maritime equipment, products and services.
In total approx. 110,000 people are employed by Blue Denmark (directly and indirectly) and the Danish maritime companies account for approx. 25% of the Danish exports. Blue Denmark is also very influential and is cooperating when developing policies, regulations and new solutions to the challenges of the future.
Blue Denmark holds a strong position within green shipping to ensure business that is sustainable in both economic and environmental terms.
An example of this is **Blue Inno+**, a cooperation project between the maritime industry, shipowners, universities and the authorities. A total of 14 green innovation projects have been launched to enhance growth and create more jobs.

Up to 87% of the companies within the Danish maritime industry have parent companies or subsidiaries in other countries.
More than 1000 maritime companies are based in Denmark and unlike many other industries, they are placed in all areas of the country.

The maritime industry is an old and traditional industry, which has succeeded in maintaining the leading position. Constant seeking common interest and bringing together unique knowledge has contributed to strong Danish positions within research, development and innovation – also within environment and climate.
As much as 45% of the companies within the Danish maritime industry are innovative, compared to 20% of the remaining part of the Danish industry.

The many successful companies within the Danish maritime industry ensure that the industry holds a strong position internationally, and continuous special efforts are required to maintain this position in the intensive global competition.

Facts and figures:

- *Blue Denmark* is the cluster for all maritime companies and operations in Denmark
- The Blue Denmark employs approx. 40,000 employees directly
- In 2015 the gross value-added growth in Danish maritime industry was approx. US$5 billion
- Today the Danish maritime industry holds a position as the 6th largest exporter of maritime technology and accounts for 2,5% of the total Danish exports.
- Danish shipowners transport approx. 10% of global trade
- Denmark has the 4th largest EU-flagged merchant fleet
- Danish shipping's largest export markets are China and USA

The *Danish Maritime* sectors and some key players:

- Shipyards
  - Fayard, Skagen, Assens, Hvide Sande, Hirtshals
- Maritime equipment manufacturers
  - ABB, C.C.Jensen, Caverion, Danfoss, Cobham SATCOM
- Maritime technology industries
  - C-Leanship,DESMI Ocean Guard, Alfa Laval
- Maritime service companies
  - Ericsson, CLIIN, MAN Prime Serv, ScanTech, Man Diesel & Turbo, Insatech
- Ship designers
  - FORCE Technology, Odense Maritime Technology, OSK ShipTech
- Maritime recycling companies
  - Uniscrap, H.J. Hansen

- *Danish Shipping* (Danish Shipowners Association) operates on behalf of 90 shipping companies and offshore companies, including key players such as Maersk Line, TORM, NORDEN, Maersk Tankers, DFDS, J. Lauritzen, Hafnia Tankers, Royal Arctic, Stena.

- *Danish Ferry Association* represents six ferry companies in Denmark (Molslinjen A/S, Scandlines Danmark A/S, HH Ferries Group, Danske Faerger A/S, Faergeselskabet Laesoe K/S, Smaaoernes Faergeselskaber)

Current trends and areas of opportunity

Thomas Knudsen, Chairman of Danish Maritime is hopeful that the maritime industry is heading towards brighter times because the market for newbuilds is improving and because many ships are about to install new equipment in order to meet new rules related to environment and climate.

The offshore wind industry is moving fast and have called for new international standards regarding specialized ships and structures. The access to the offshore wind market is important. However, decline of prices and inhomogeneous application of design and safety standards, makes it less attractive to ship builders to enter the market. The north-western European shipbuilding industry does not consider construction of offshore service craft, windfarm construction vessels or windfarm structures as priority products for the time being.

Poul Woodall, Environmental and Sustainability Manager at DFDS is concerned about energy optimization of ships and the climate objectives recently determined by IMO.
In general, it will be difficult for shipping to meet the targets set by IMO to obtain essential reductions of the discharges in 2030.

It is predicted that the coming 10 years will bring a total transformation of the sector of transport and logistics, e.g. introducing autonomous ships. Right now the industry is in the middle of a disruption of shipping and other businesses. Everything changes these years, and what happened to the farming sector will now happen to the maritime industry. Increased use of data, on ships and in containers, is one of the ways forward. Fortunately, there are many possibilities for innovation within Blue Denmark, for example by building test areas for autonomous ships.

According to the trade associations, the industry will focus on innovation and R&D to remain competitive. Also environmental friendly shipping, working environment and security are high on the agenda.

A new project ShippingLab will work on the “Smart ship of the Future” involving digital solutions, big data, IoT and equipment with measuring and control interfaces.

The Danish government launched a growth plan for the maritime sector in January 2018: Maritime Denmark 2018
https://www.dma.dk/Documents/Publikationer/DetBlaDanmark_A4%20_Indhold_UKpdf.pdf

The overall goal with plan is to ensure that Denmark maintain a leading role worldwide and several initiatives have been launched to help innovation and growth through closer cooperation between the industry and the Government.
Focus is to increase the competitiveness of the Danish maritime industry by developing and implementing new technology and digitization. Cyber security is high on the agenda and working closer together within EU to reduce administrative burdens.

With US companies being particularly strong in naval technology this would be very relevant for the Danish maritime industry.

Channels to market, approach and regulations

The Danish market is fully accessible with no restrictions or protectionism generally.

Standard approach would be directly to the relevant companies and introducing the products/services by mail initially.

The trade associations would also be interested in assisting with trade delegations and general information on their specific industry.

Trade associations

Danish Maritime
Business Association for Danish manufacturers of maritime equipment and ships
Symfonivej 18
DK-2730 Herlev
Tel. +45 3313 2416
www.danskemaritime.dk
cl@danskemaritime.dk

100 member companies

79, Rue du Cornet
B-1040 Bruxelles
Belgium

Danske Rederier
Danish Shipping (Danish Shipowners Association)
Amaliegade 33
DK-1256 Copenhagen K
Tel. +45 3311 4088
www.danishshipping.dk
info@danishshipping.dk

Danish Marine & Offshore Group
c/o TofKo Business Development A/S
Norremarksvej 27
DK-9270 Klarup
Tel. +45 9831 7711
www.offshore-denmark.com

Trade Shows & Conferences:

Danish Maritime Fair
13-14 May 2020
Bella Centre, Copenhagen
www.danishmaritimefair.dk

Mast NORTHERN COASTS
Conference & Exhibition (Northern Coasts 2019)
4-6 September 2019
Copenhagen
https://mastconfex.com/northerncoasts20197

Relevant media:

www.soefart.dk
In Danish

https://shippingwatch.dk
In Danish & English

Media group Maritime Denmark

- Magazine Maritime Denmark
- Danish Maritime Magazine
- FiskerBladet (Fishing Magazine)

www.danishmaritimefair.dk

Sources:
Danish Maritime
Danish Shipping
Danish Maritime Authority www.dma.dk

Healthcare

Overview of market size and key players

Denmark is an international forerunner in the field of healthcare and renowned for increasing public satisfaction with healthcare services and improved productivity while also keeping the expenditures in check.
Healthcare in Denmark is funded by taxes and decentralized with responsibility placed in the 5 regions.
The demand for healthcare will continue to grow, primarily due to demographic reasons with an ageing population demanding better care, lower birthrates and a reduced workforce. Furthermore, the public sector has a wish to increase efficiency and reduce costs based on the technological innovation. Other benefits to be achieved are better life quality, better use of resources and a higher degree of self-reliance.

This report deals with medical devices and assistive/welfare technology.

In 2017/18 the government launched a new growth plan for Life Science in general and the industry is now implementing a number of new initiatives which will revitalize the industry focusing on digitalization, big data, efficiency and innovation.
The medical device industry represents 40% of the life science industry and include big players such as Danish Novo Nordisk, Coloplast, Ambu together with foreign players like Siemens Healthcare, Cook Medical, Johnson & Johnson and Medtronic.

There are close to 900 medical device companies in Denmark, and just under 50% are located around the capital of Copenhagen.
21 of the top 25 companies measured by turnover are based in the Copenhagen area.

The ten largest areas within the Danish medical devices market and examples of manufacturers (based in Denmark)

- **Diagnostics (In Vitro)**
  - Radiometer, Unisensor, Roche Diagnostics, Chemometec, Dako, Abbott
- **Diagnostic (Radiology)**
  - Philips Healthcare, Agfa Healthcare, BK Medical, Karl Storz
- **Gastroenterology**
  - Coloplast, ConvaTec, SCA Hygiene, BARD Norden, Paul Hartmann
- **Miscellaneous**
  - Adept Water Technology, Knudsen Plast, Novozymes, Sterigenics
- **Orthopedics**
  - BSN Medical, Convatec, Biomet, Johnson & Johnson, Boston Scientific
- **Cardiology**
  - Medtronic, Ambu, Acarix, Linvatec
- **Surgery**
  - BK Medical, Baxter, Covidien, Cook Medical, Ferrosan Medical Devices
- **Drug Delivery**
  - Medicom, Bang & Olufsen, Leo Pharma, Convatec, Ferrosan, Novo Nordisk
- **Vascular Surgery**
  - Medtronic, Cook Medical, St. Jude Medical, Vygon, BARD Norden
- **Wounds**
  - B Braun, Mölnlycke, Coloplast, Reapplix, KCI Medical, ConvaTec

Assistive and welfare technology:

Many assistive technologies are used daily by people who help the elderly or disabled persons with daily tasks. As an example, disabled and elderly people in Denmark have special access to medical aids provided by the local municipality whom also have an obligation to provide advice on options and costs according to the Social Service regulations, §112.

These aids are supplied by more than 300 assistive technology companies in Denmark of which 61% are involved in manufacturing and 27% are involved in trade only.
These products are divided into five main groups:

- Treatment and training
- Residences, housekeeping
- Communication
- Mobility and moving
- Personal care, clothes and shoes

Facts & Figures:

- The medical devices industry has an annual turnover of almost US$12 billion of which exports account for 33%
- The largest 20 companies account for approx. 75% of turnover
- 95% of the Danish medical device companies have less than 50 employees
- 40% of the companies cover more than one clinical area in their product range
- The assistive care industry has a turnover of US$635.000.000 per year of which exports account for 29%
- The assistive care industry consists of mainly small and medium-sized companies and Danish manufacturing companies

Current trends and areas of opportunities

Towards 2025 the regions are investing more than US$9,5 billion in 43 hospital projects in Denmark of which 6 are brand new hospitals.
Expenditure on medical equipment represent 5% of the total cost in Danish healthcare and the 5 regions are the largest buyer of medical equipment.

The Assistive Care industry work closely with the Danish Technology Institute (DTI). DTI have launched a national network for welfare technology (www.carenet.nu) using new technologies such as Virtual Reality, digital learning and augmented reality.

Within the assistive technology and welfare industry there is demand for digital solutions for the rehabilitation needs, and also physicals aids in general will be of interest.

Channels to market and approach

The Danish public healthcare system is organised in 2 main sectors; primary health care which is administered by the 98 municipalities and the hospital sector administered by the 5 regions in Denmark.

In January 2016 Denmark obtained a new Public Procurement Act in line with EU legislation, so for the health- and care sector a public tender is required for purchases of services and goods over DKK 1.5 million. For orders under this threshold, there is no formal requirement for public tender processes, however, the procurer has to ensure that the procurement process is carried out on market conditions, e.g. offers from three potential suppliers.

SKI is the Purchasing Service organization in charge of the public sector's procurement needs. They have framework agreements with suppliers on specific goods or services.

Other providers include private operators (distributors) and caregivers using medical devices and assistive technology.

The Danish trade associations recommend access through distributors who are already familiar with the Danish system.

Regulations:

The Danish Medicines Agency (https://laegemiddelstyrelsen.dk) forms part of the Danish Ministry of Health and they monitor medical devices available in Denmark.

As a member of the EU, Denmark is obliged to implement the EU directives on medical devices into Danish legislation. They have been implemented into the Danish Act on Medical Devices and the related executive orders on medical devices.

On 5 April 2017, 2 new Regulations on medical devices were adopted, and they entered into force on 25 May 2017. These replace the existing Directives.

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

The new rules will apply after a transitional period. Namely, 3 years after entry into force for the Regulation on medical devices (spring 2020) and 5 years after entry into force (spring 2022) for the Regulation on in vitro diagnostic medical devices.

The two new regulations are Medical Device Regulation and In Vitro Diagnostic Device Regulation, and they are expected to lead to higher product quality and better patient safety in the European markets.

The new Regulations contain a series of extremely important improvements to modernize the current system. Among them are:

- stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- the reinforcement of the criteria for designation and processes for oversight of Notified Bodies
- the inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations
- the introduction of a new risk classification system for in vitro diagnostic medical devices in line with international guidance
- improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification
- the introduction of an "implant card" containing information about implanted medical devices for a patient
- the reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations
- the strengthening of post-market surveillancerequirements for manufacturers
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance

Manufacturers of medical devices outside EUEA shall have a contract with an authorised representative inside the EU/EEA (article 11). The obligations of the representatives, importers and distributors are described also (article 13 and 14) in the MDR(2017/745/EU) and IVDR (2017/746/EU)

Fact sheets for manufacturers of medical devices are available and further details can also be found here:
http://ec.europa.eu/growth/content/new-eu-rules-medical-devices-enhance-patient-safety-and-modernise-public-health-0_en

Medical devices are classified according to risk into Classes I, IIa, IIb and III.

Additional Danish registration requirements only concern companies that are headquartered in Denmark.

All products must be CE approved.

Relevant trade associations

Medicoindustrien (trade association for the medical devices)
Forskerparken Scion DTU
Agern Allé 13
DK-2970 Hoersholm
Tel. +45 4918 4700
medico@medicoindustrien.dk
www.medicoindustrien.dk

200 member companies/organizations

Danish Care (trade association for Assistive Technology)
Handicaporganisationernes Hus
Blekinge Boulevard 2
DK-2939 Taastrup
Tel. +45 3254 2425
info@danish.care
www.danish.care.dk

85 member companies/organizations

https://hmi-basen.dk (AssistData)
Website for products and suppliers of the assistive technology
Approx. 1000 suppliers present more than 60.000 assistive products
(Danish and English)

Trade Shows

Health & Rehab Scandinavia
12.-14. May 2020
Bella Center Copenhagen
www.health-rehab.dk

Last show in 2018:
8.500 visitors from Denmark/Scandinavia
220 exhibitors
240 seminars, conferences and events

Conference:
Wellfare Technology anno 2019
3. September 2019
(In Danish)

Sources:
Medicoindustrien
Dansk Teknologisk Institut
Danish.Care
Healthcare Denmark
Danske Regioner, Nordic Guide Healthcare,Tænketanken Mandag Morgen
ec.europa.eu

SECTOR OVERVIEWS SCANDINAVIA

SWEDEN

Defense

Overview of market size and key players

Sweden has, in relation to its population, a defense and security industry that from an international perspective is very competent and competitive.

The Swedish government has decided to substantially increase its defense budget for the first time in two decades, with significant expenditure being directed towards the purchase of advanced defense systems, international peacekeeping missions, and research and development initiatives.

Sweden is expected to invest US$34.7 billion cumulatively in strengthening its armed forces over the next 4-5 years. Despite a considerable increase in the country's total defense budget, military expenditure as a percentage of GDP is predicted to maintain an average of 1.01% during the next few years.
The arms procurement, with an increased focus on aircraft, anti-submarine warfare equipment, and submarines, is to be the driving factor in increasing the capital expenditure

The Swedish Armed Forces are about to finalize their 2020-2035 strategy.
General Major Michael Claesson is heading up the strategy work, converting political decisions into military reality.
According to a recent study by the Armed Forces, Sweden have disarmed since the fall of the Berlin wall in 1989 and the solution of the USSR in 1991.
However, with recent incidents with Russia acting more aggressively with the attack on Ukraine and the takeover of the Crimea peninsula, the Swedes are aware that a military conflict in the area will affect them too.
According to Mr. Claesson, the technology will change a lot, but conventional warfare will continue to apply in all the traditional areas; air, sea and field.
There is also a need for more staff, in fact the analysis suggests a doubling of the armed forces in 2035 compared to the current level, and this is alongside the technological development.

A future environment of conflict, according to Mr. Claesson, is likely to be “grey-zone” conflicts where involved states use methods which are not clearly military. Threats to the digitized society are already reality. Hence the military tasks must be part of a total defense solution in cooperation with other authorities with adjacent tasks.

The Swedish legislation distinguish between 2 military categories of military equipment: equipment for combat purposes (products with a destructive effect) and other military equipment. In addition the defense market also consists of products with dual-use and non-classified products.

During the past, the average allocation for capital expenditure was 36.5% of the total defense budget, which is expected to increase to 36.6%. This is primarily due to the overhaul and modernization of fighter aircraft, and the procurement of helicopters, transport aircraft, frigates, nuclear submarines, C4ISR platforms, and missile defense systems.

Additionally, the government is also expected to increase its focus on cyber security and the procurement of drones to enhance aerial surveillance.

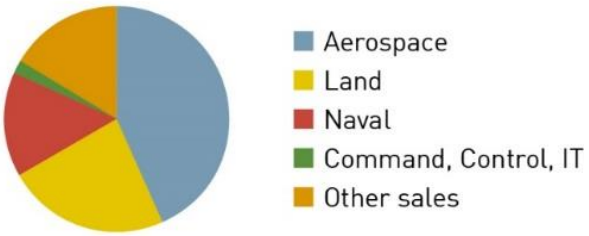
The main sectors in Sweden's defense industry:

- *Network-based command and control systems*
- *Telecommunications systems, including electronic countermeasures*
- *Combat aircraft; manned and unmanned*
- *Aircraft Engines*
- *Command and control systems for land, naval and air applications*
- *Systems for exercise and training*
- *Electronic warfare systems; passive and active*
- *Camouflage and deception systems; UV, VIS, NIR, TIR and radar*
- *Surface vessels and submarines built with stealth technology*
- *Combat vehicles, tracked vehicles*
- *Short and long-range weapons systems; land, sea and air*
- *Air, sea and airborne radar and IR systems*
- *Small and large calibre ammunition*
- *Smart artillery ammunition*
- *Propellants, explosives and other pyrotechnical substances*
- *Support systems for operation and maintenance*
- *Ranges for test and evaluation*

Facts & Figures:

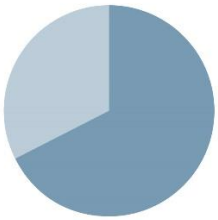
- Sweden spend 1,1% of GDP on defense (22,2% on material and 3,4% on RDT&E)
- No companies in the Swedish defense industry is owned by the state
- The SOFF members (Swedish Security and Defence Industry Association) represent a total turnover of approx. US$3,3 billion and 33.000 employees
- Exports account for almost 70% of the total turnover
- The Swedish defense industry invests 18% of their turnover in R&D

MEMBER COMPANIES' SALES DIVIDED INTO SEGMENTS (2015)

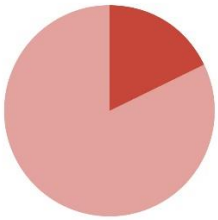


SOFF

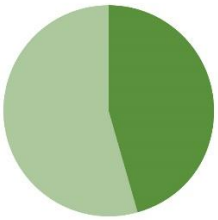
SHARES OF MEMBER COMPANIES' REVENUES (2016)



68 %
Export as share of total defence market sales



16,1 %
R&D share of revenue



43,1 %
Sales of non-classified products to civil customers

SOFF

Current trends:

There is a trend towards fewer, but larger procurements, which have positive consequences for the defense industry as they promote competition, efficiency, economies of scale and cost reductions.

Societal security is challenged by numerous threats and risks and the market is still relatively immature. The Swedish market has currently a growth rate of approx. 8% and 2/3 of the enterprises within this sector expect it to grow more than 10% annually over the next 10 years.

The Swedish defense and security industry face a number of challenges

- falling R&D investments in Europe
- protectionism
- increased competition from new industrial players
- deterioration in security-political development in surrounding geographical areas

and within technological development:

- Systems of systems
- Remotely-operated weapons
- Command and Control systems
- Sensors and radars
- Autonomous system
- Artificial intelligence
- Internet of Things
- Big data
- Cyber defense
- Unmanned, in-flight refueling, satellite communication

Security threats from Russia and the deployment of troops in overseas peacekeeping missions, the Swedish government is expected to concentrate on procuring advanced land defense systems, communication systems, and sophisticated air defense equipment.
Sweden's homeland security (HLS) expenditure is projected to increase in the coming years, driven by investments to counter the rise of organized crime within the nation, and threats from global terrorist organizations such as ISIS and Al-Qaeda.

The MoD is expected to invest in multirole aircraft, artillery systems, corvette modernization, engineering support vehicles, mine sweeper vessels, transport aircraft, training aircraft, anti-ship missiles, maritime patrol and anti-submarine warfare assets among others.

Channels to market and approach:

Special market mechanisms are at work in the defense industry, it is a sector with special characteristics as the only customers are governments and protectionist practices allow barriers which causes uneven competition.

Due to the sophistication of Swedish industry, about 90 percent of all military equipment acquisitions is met by Swedish contractors, of which only about 15 percent is handled by foreign subcontractors.
An organization known as FMV, the Defense Material Administration, is responsible for procurement, maintenance, and storage of equipment for the Swedish Armed Forces.

FMV with approx. 3,400 employees utilizes more than 2,000 different suppliers within domestic and foreign industry.
Being a public procurement authority, there are rules and principles that FMV has to follow. The main framework is the Public Procurement Act (LOU) that applies to all public organizations. FMV also complies with the law for the procurement of defense and security (LUFS).

The public procurement system in Sweden is characterized by a high performing public procurement system, which is fairly advanced in its strategic dimension, including green, innovation and social criteria.

Irregularities and corruption are not a significant issue in Sweden, largely as a result of its highly developed and well-resourced legal and institutional frameworks.

Act on defence and sensitive security procurement (2011:1029) (LUFS). LUFS is largely based on Directive 2009/81/EC on defence and sensitive security procurement (Defence Procurement Directive). It regulates procurement of military equipment or services, or militarily sensitive equipment or services.

American companies interested in pursuing opportunities in Sweden are recommended to make contacts with various Swedish companies, in order to establish a market presence and access existing networks through partnerships, as entering the market individually can prove challenging.

Most Swedish defense companies are members of the Association of Swedish Defense Industries (SOFF)
It is important to point out that a company looking to do business through the FMV procurement process is not required to have a Swedish partner or agent. All defense materials imported for the Swedish Armed Forces are duty-free. Goods imported for the manufacturing or maintenance of products for Swedish military use are also duty-free.

The Transatlantic Link between Sweden and the USA is a close and fruitful cooperation between the two nations. US technology is essential to many Swedish products and the US market is extremely important to many Swedish companies.

Trade Associations

SOFF
Swedish Security and Defence Industry
Storgatan 5
S-114 85 Stockholm
Tel. +46 8 782 08 50
info@soff.se
www.soff.se

90+ members

FMV
Swedish Defence Material Administration
S115 88 Stockholm
Tel. +46 8 782 40 00
Mail: registrator@fmv.se
www.fmv.se

Civil authority under the Ministry of Defence
FMV provides defence logistics to the Swedish Armed Forces.
FMV procures complex weapon systems such as helicopters and submarines. FMV repair and maintain combat vehicles, aircraft and ships, they keep stock, and transport everything from weapons and uniforms, to tents and shovels.

3.400 employees

Swedish Armed Forces
www.forsvarsmakten.se

Trade Shows & Conferences:

UDT
Undersea Defence Technology
13-15 May 2019
Stockholmsmässen
www.udt-global.com

Electronic Warfare Europe
13-15 May 2019
Stockholmsmässen
www.eweurope.com

ITEC
Training and education technologies for the defence and civil protection communities
14-16 May 2019
Stockholmsmässen
www.itec.co.uk

The **4th biannual European Conference of Defence and the Environment (ECDE) Stockholm, May 14th - May 16th, 2019.**
The conference is organized by the **Swedish Defence Sector** and is supported by **DEFNET**, an informal, expert-level, group comprising mainly of environmental focal-points and specialists from the Ministries of Defence (MODs) of EU Member States, and Nordic-Baltic Defence Estates, which is a cooperation forum for building and construction organizations of defence administrations in the Nordic and Baltic countries.
www.ecde.info

NORDIC DEFENCE FORCES
THE 7TH ANNUAL ADL CONFERENCE MAY 14TH – 16TH 2019
NORDEFCO ADL conference in Norway.
The conference has in recent years grown from a national Norwegian conference to a joint Nordic ADL event with international attendees and speakers.
https://nordicadl.com/archive/adl-conference-2019/

In the spirit of the Nordic cooperation, the NORDEFCO ADL Forum of Experts has decided to make this conference a roving event. The conference will be organized by Norway in 2019 followed by Sweden in 2020.

Sources:
SOFF
ec.europe.eu/
www.konkurrensverket.se
Government Offices of Sweden
Extracts from Swedish Defense Industry Report 2018:Market Attractiveness, Competitive Landscape and Forecasts to 2023. (available at www.researchandmarkets.com)

Healthcare

Overview of market size and key players

Like their Danish neighbors, healthcare in Sweden is largely tax-funded and decentralized as the responsibilities lie with the county councils.

Sweden's municipalities are responsible for care for the elderly in the home or in special accommodation. Their duties also include care for people with physical disabilities or psychological disorders and providing support and services for people released from hospital care as well as for school healthcare.
In spite of a relatively limited market size of 10 million people, the healthcare spending is high and therefore very interesting to exporters worldwide.

The variation of medical devices includes advanced technologies with invasive treatment methods to items used for daily care such as bandages or test strips and even IT-systems. Effects of medical devices are generally reached without the aid of pharmaceutical, immunological or metabolic substances.
The market for medical devices is growing and the current number of products available in Sweden is estimated to be approximately 900.000 and is a rapidly growing industry.

The medical device manufacturing industry is relatively small in Sweden and consist of small to medium-sized companies and many multinational subsidiaries.

The medical device market is expected to grow overall through 2019.

Facts and figures:

- In 2016 the medical device market was valued at US$2.2 billion
- Number of medical device companies in Sweden is approx. 640 with 5 or more staff and net sales over a million SEK plus a great number of companies with 1-4 employees.
- Government spending on health and medical care, including dental US$7,3 billion (2017)

Current trends and areas of opportunities

Many of the challenges facing Swedish healthcare are seen in many countries, and include issues of access, quality and funding.

The population is aging and the average life span is now 84 years for women and 81 years for men. As a result the local healthcare industry is receptive to innovative technologies for treating and mitigating chronic and age-related diseases.

There is also a demand for diabetes products, user-friendly home care, orthopedic and implantable devices, non-invasive equipment and especially e-health products.

Like other Scandinavian countries there is a high focus on and an increasing demand for new technology using digitalization, IoT, big data etc.

Sweden has launched e-Health with a vision to become the best in the world in 2025 using the opportunities offered by digitization to improve the health and welfare of the Swedish population.

Channels to market and approach

In Sweden the healthcare providers consist of many actors.
Sweden has 21 county councils that provide healthcare to the inhabitants in the county. Other healthcare providers include 290 municipalities, a number of private operators, and caregivers who use medical devices.
Each year, healthcare providers in Sweden invest large sums on medical devices, and this amount increases each year as the range of products continues to grow.

All medical devices to be purchased by the governmentally funded healthcare providers must be procured via a tendering process. Nevertheless, healthcare providers have no common process for this.
The county councils in Sweden sometimes work together in small groups to purchase certain product types. The most common is, however, that each county council manages its own contracts. Some counties also have decentralized procurement.
In Stockholm County Council, for example, each hospital has its own purchasing unit, and procurement has so far not been synchronized between hospitals within the county. In addition to county councils, there are also the 290 municipalities and many private operators and caregivers who use medical devices. Municipalities must, like county councils, procure the medical devices to be used via a tendering process. The same does not apply to private operators and caregivers.

Regulations:

The Swedish Medical Products Agency (www.lakemedelsverket.se), a body under the Ministry of Health, is the responsible national authority for regulation and surveillance of the development, manufacturing and sale of drugs and medical devices.

Sweden has brought its legislation in line with the safety requirements in force within the EU concerning testing, certification and labelling of medical devices.

Each medical device placed on the market must comply with the requirements in the Swedish Medical Devices Act, irrespectively of how the device is to be used and risks associated with its use.
As a member of the EU, Sweden is obliged to implement the EU directives on medical devices into Swedish legislation.

On 5 April 2017, 2 new Regulations on medical devices were adopted, and they entered into force on 25 May 2017. These replace the existing Directives.

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

The new rules will apply after a transitional period. Namely, 3 years after entry into force for the Regulation on medical devices (spring 2020) and 5 years after entry into force (spring 2022) for the Regulation on in vitro diagnostic medical devices.

The two new regulations are Medical Device Regulation and In Vitro Diagnostic Device Regulation, and they are expected to lead to higher product quality and better patient safety in the European markets.

The new Regulations contain a series of extremely important improvements to modernize the current system. Among them are:

- stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- the reinforcement of the criteria for designation and processes for oversight of Notified Bodies
- the inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations
- the introduction of a new risk classification system for in vitro diagnostic medical devices in line with international guidance
- improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification
- the introduction of an "implant card" containing information about implanted medical devices for a patient
- the reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations
- the strengthening of post-market surveillancerequirements for manufacturers
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance

Manufacturers of medical devices outside EUEA shall have a contract with an authorised representative inside the EU/EEA (article 11). The obligations of the representatives, importers and distributors are described also (article 13 and 14) in the

Fact sheets for manufacturers of medical devices MDR and IVDR are available and further details can also be found here:
http://ec.europa.eu/growth/content/new-eu-rules-medical-devices-enhance-patient-safety-and-modernise-public-health-0_en

Medical devices are classified according to risk into Classes I, IIa, IIb and III.

All Swedish manufacturers and authorized representatives of the following products shall sign up for registration with the Swedish Medical Products Agency:

- in vitro diagnostic products
- medical devices in class I, Is and Im
- custom-made medical devices
- module and procedure packs
- national medical information systems (NMI)

Trade associations

Swedish Medtech (Association for Medical Technology)
Sveavägen 63
S-103 59 Stockholm
Tel. +46 8 586 246 00
Info@swedishmedtech.se
www.Swedishmedtech.se

180 members

Swedish Labtech
Trade organization for companies selling diagnostics, laboratory supplies and tools for analysis and biotechnology.
http://www.swedishlabtech.se/

75 member companies

SwedenBIO
The national organization working for the benefit of the entire life science sector in Sweden and it is a member driven, non-profit organization.
https://swedenbio.se/

250 members

Trade Shows:

Leva & Fungera – Showcase for assistive technologies
Svenska Massen, Gothenburg
13-15 April 2021 (every two years)
14.000 visitors and 200 exhibitors
https://levafungera.se/

Swedental
Stockholm International Fairs
13-15 November 2019
13.000 visitors and 200 exhibitors
www.swedental.org

Principal fair in Scandinavia for the dental industry.

Conferences:

Vitalis – eHealth event, conference and exhibition
https://en.vitalis.nu/
21-23 May 2019
The Swedish Exhibition & Congress Centre
Gothenburg

Sources:
TLV, Sweden (The Dental and Pharmaceutical Benefits Agency)
www.sweden.se
Government Offices of Sweden
Swedish Medtech
Business-Sweden.se
www.nordic-guide.org
(healthcare guide for the Nordic countries)

Further reading:

Danish Maritime:

- Danish Maritime Industry, Facts & Figures 2018
- The Danish Government, Maritime Denmark, A global, maritime power hub
- Danish Shipping, Facts & Figures, June 2018
- Members of Danish Maritime
- Offshore Wind Industry Standards, 2017
- Employment and Production in Blue Denmark, 2015

Danish Healthcare:

- Danish Care Information 2018
- Guide to the Nordics 2018, the health and care sector (Nordic Business & Living Lab)

Swedish Defense:

- Facts, Swedish Security and Defence Industry Association, 2014
- Defence Innovation Technologies, case studies 2016
- State sponsored cyber attacks, SOFF, 2018

Swedish Healthcare:

- Nordic Smart Digital Health, Nordic Innovation
- Economic evaluation of medical devices 2015, TLV