

# Exporting embedded systems for telemedicine to Germany

Telemedicine in Germany is seen as a segment with high potential. Driven by a large number of projects, the acceptance of telemedicine is growing, though large-scale growth of telemedicine will not take place in the short term.

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## 1. Product description

In telemedicine or e-health, the typical embedded systems used are motherboards, single board computers and system on module. The product range includes microprocessors (HS code 85421355), microcontrollers (HS code 85421360), microcomputers (HS code 85421966), digital signal processors (HS code 8541500), peripheral systems (HS code 85422161), network sub-systems (HS code 85421200), interfaces (HS code 85422970), memories and memory peripherals (HS code 8542320), memories for other uses (HS code 85421940) and other system solutions (HS code 8542500). In most cases, the embedded software is an integral part of the embedded hardware and is sold as one product.

Embedded systems are used in many applications, including telemedicine or e-health. The typical functions of embedded systems in telemedicine include storage of administrative and medical patient data, use of computers during consultations, the transfer of administrative patient data to reimbursing bodies, transfer of lab results from the laboratory, transfer of medical patient data to other carers and e-prescribing.

However, telemedicine is getting more complex every day. The new generation/evolving functions of embedded systems in telemedicine are real-time communication, adaptive scheduling, resource management, multitasking and the transfer of data from sensor to destination.

The major suppliers of embedded systems in Europe and in Germany include [Advantech](#), [Intel](#), [Kontron](#), [DATA MODUL](#), [Micron Technology](#), [Congatec](#) and [Vertiv](#). Software and service providers specifically for e-health in Germany are [CGM CompuGroup Medical Deutschland](#) as well as [Medavis](#), [Protec](#), [Bayerische TelemedAllianz](#), [Neat](#), [Ascom](#), [Deister Electronic](#).

## Product specifications

### Quality

High product quality and compliance with international and European standards on safety, as well as national legislation and practices, are key to European companies. Product safety is essential, since in many cases people's lives depend on the system, in particular in the e-health application.

In addition to ISO 9001, RoHS and REACH standards (see "Buyer requirements"), German customers expect a high level of reliability in embedded systems. They require product testing to be conducted by the supplier; Automated Optical Inspections (AOI) and In-Circuit Tests (ICT) are the most common tests, although more sophisticated testing methods are also used.

Although defect rates of 500 parts per million (ppm) might be acceptable for non-critical applications, defect rates of 50 ppm or less are expected for higher-quality suppliers. As these requirements are influenced by different factors, each supplier must negotiate the specific requirements with the customer.

Embedded systems are characterised by the interface, platform, peripherals and other tools. Embedded systems may also vary in terms of system complexity. Complex embedded systems may include connectivity to a network, a touch screen, real-time computing, etc. New-generation telemedicine requires real-time communication and adaptive scheduling.

Embedded systems are used in highly innovative environments/industries. The ability to offer a customised product design is a key driver in this product category. Customised solutions are required in telemedicine. Customisation may include integration or development of software for existing hardware assemblies, presenting cost benefits for exporters from developing countries because of easier/no shipping.

### Labelling

Products marketed in Germany must be labelled in accordance with EU requirements and must provide product information listed below.

The label information must also be electronically readable. Examples of suitable label technologies include:

- Bar Codes,
- Data Matrices,
- Radio Frequency ID.

Embedded systems are typically labelled with the description of content, including the following types of information:

- type of product,
- model type,
- quantity,
- net and gross weight (in kilograms),
- supplier/manufacturer name,
- supplier/manufacturer location,
- serial number,
- various environmental logos,
- country of origin based on assembly.

### Packaging

- Typically, the buyer defines the preferred type of packaging.
- Packaging must protect products from damage and protect consumers from possible injuries by avoiding the use of prohibited chemicals or materials.
- Packaging for products marketed in Germany must meet certain EU requirements. Make sure that your packaging has minimal weight and volume; has low levels of hazardous substances and materials in the packaging material; is recyclable.
- Embedded systems are typically packaged in plastic bags and cardboard boxes.

## **2. Which market opportunities for exporters of embedded systems does the German market offer?**

### **A positive business climate drives demand**

The embedded systems market has picked up around 2% growth, driven by the recovery of key application industries such as automotive or industrial automation. In addition to major industries, emerging applications such as telemedicine are also expected to foster market growth.

The share of embedded systems used in telemedicine is still small, but the importance of this application is growing. Telemedicine applications require more complex solutions, often with two processors in one interface. Telemedicine is seen as a segment with high potential, driving the demand for more complex embedded solutions.

### **Tips:**

Start by targeting companies that are active in telemedicine, depending on your product offering.

Carry out internet research, find out which products companies are supplying to this emerging industry and consider offering your products and/or services to them.

Look for this information through specialised associations for medical companies (for example, [Spectaris](#)) in Germany or trade fairs (for example, [Medica](#)).

Germany is the leading producer and consumer of embedded systems in Europe. The market accounts for nearly 30% of embedded systems manufactured Europe-wide and 20% of the European consumption of embedded systems. In the period 2011-2015, the production of embedded systems was growing at a Compound Annual Growth Rate (CAGR) of 1%, while consumption was growing at the same pace. Due to the positive economic climate, in-country production and consumption of embedded systems will pick up, though production will focus on highly sophisticated models.

### **Tips:**

Target Germany as the leading market for embedded systems in various industrial applications.

Consider a go-to-market approach through an alliance with local manufacturers of embedded systems (software or hardware) in Germany.

Find out who the leading market players are through local directories or associations such as [ZVEI](#), the main association for electronics in Germany as well as Europe.

## **Hardware and software separation is a growth driver**

After less favourable market development in 2012 and 2013, the international trade in embedded systems is expected to benefit from the trend of software and hardware separation as well as the currently increasing tendency toward outsourcing the production of hardware.

The share of imports of embedded systems from developing countries is 10.1% (2015), whereas 70.1% of embedded systems in Germany are imported from other European countries. Imports from developing countries declined between 2011-2015 by 2.5% on average, while imports from Europe grew by nearly 2.1% CAGR over the same period. However, the trend of separating software and hardware, as well as the trend of increasingly outsourcing the production of hardware overseas, will elevate the future importance of developing countries in the supply chain, keeping in mind that developing countries are in the process of increasing their technological capabilities. In the long term, the reshoring trend in embedded systems may cause a slowdown in international trade, because German companies will build up production in Germany again as automation is causing costs to drop.

Exporters from developing countries that are located close to Europe will probably have geographical advantages; however, exporters with a technical background and a good reputation in the production of embedded systems have more significant advantages.

### **Tips:**

Work on minimising the entry barriers and maximising your competitiveness. Knowing requirements of buyers and complying with standards are key aspects of this approach.

Ensure that you have a value proposition, a product that complies with European quality standards, knowledge of German and/or outstanding business English, and a good understanding of German business culture.

Work continuously on quality improvement. This is particularly critical in telemedicine applications, regardless of your geographical position.

Germany exports amount to about 73% of the total exports of embedded systems to the EU+EFTA (European Union plus European Free Trade Area including Iceland, Norway, and Switzerland). Exports to EU+EFTA declined by 1.3% on average between 2011-2015. Exports of embedded systems to the Czech Republic, Denmark, France and the Netherlands increased the most between 2011-2015, mainly driven by a significant growth of production activities in relevant application industries such as automotive, medicine and other sectors.

Through the cooperation with German suppliers of embedded systems, you will indirectly be able to reach out to other significant European markets that are supplied by German manufacturers.

## **3. What trends on the German market offer opportunities?**

The European telemedicine market is estimated to grow by over €5 billion per year from 2015 onwards. However, the market is not yet developing on a large scale and there are only a few good examples of solution transfer across health-care centres. The growing usage of telemedicine services, including the interaction between doctors and patients, is an opportunity for both patients and manufacturers in related industries. In Germany, the use of Information and Communication Technology (ICT) in health care, including embedded systems, is above the European average:

- All health-care practices are equipped with computers, and nearly two thirds are equipped with Internet access.
- The use of computers during consultations is above average.
- Electronic Medical Data Storage is above average.
- The use of ICT for decision support is above average.
- The exchange of medical and administrative data is rare, partly due to strict data protection laws.
- The electronic transfer of laboratory results is slightly more frequent than in the rest of Europe.

There are some challenges in promoting telemedicine in Germany:

- The German code of conduct for doctors hinders remote treatment unless the doctor has seen the patient at least once in person.
- The quality of the Internet connection in some areas is lagging.
- There is a lack of knowledge of telemedicine advantages and possibilities.

Numerous European and German projects have been set up to further the acceptance of telemedicine and work

on the limitations of other challenges in telemedicine solutions. There are 240 identified telemedicine projects in 100 cities and communities in Germany, suggesting that the acceptance of telemedicine is continuously growing. More information on telemedicine projects can be found through the [German Society for Telemedicine](#).

### Tips:

Pursue the opportunities within the growing acceptance of telemedicine in Germany through a value proposition to local manufacturers of telemedicine devices.

Approach the local manufacturers of telemedicine devices at international trade fairs (for example, [Medica](#)) or other venues. Consider sharing your knowledge and taking part in pilot projects.

Check buyers' websites to find out which projects they are currently working on.

Familiarise yourself with the current telemedicine projects and consider offering your support, if the relevant experience and capacity are in place. The [German Society of Telemedicine](#) is a hub for information.

See [our study of trends in the Electronics and Electrical Engineering sector](#) for more information.

## 4. How do macroeconomic aspects influence the German market?

When cooperating with German companies, exporters from developing countries can mitigate the financial risks in investments via partnerships. Germany is one of the leading economies in Europe with a strong historic development and growth forecasts above the European level.

Germany is the largest market in Europe with a share of the total European Growth Domestic Product of around 20% and a share of the total European manufacturing of around one third, respectively. The country is expected to have a GDP growth rate of 1.2% in 2017 and around 1.6% in 2018.

The population of the EU was estimated at 510 million in 2016, with Germany contributing 16% to the total EU population (approximately 82 million).

## 5. What requirements should embedded systems comply with to be allowed on the German market?

To assure durability and safety, products *must* comply with relevant EU regulations and standards. Compliance with 1) *must* requirements and 2) *common* requirements is a basic necessity for *all exporters* in the electronics and electrical engineering sector, while 3) *niche* requirements are applicable if you plan to operate in a niche. Below, you will find all the standards that apply to embedded systems. Familiarise yourself with guidelines on the application of all *must*, *common* and *niche* requirements.

### 1. CE marking

For intra-European trade, all embedded systems must be marked with the CE mark. This shows that the product was assessed before commercialisation and that it meets EU safety, health and environmental protection requirements. For embedded systems, the most important Directives on CE marking are:

- Electromagnetic compatibility (EMC Directive 2004/108/EC),
- Low-voltage equipment (LVD 2006/95/EC),
- Eco-design of energy-using products (Directive 2009/125/EC), which are not standards but implementing measures,
- RoHS (see below). For software used in medical devices, the following Directive on CE marking is important:

- Medical device (Directive 93/42/EEC).

[The European Commission page on CE marking](#) is a useful starting point to find out how the legislation on CE marking is relevant to you; it illustrates the key steps that you need to take in order to comply with and obtain CE marking for your products.

### Tips:

Comply with the CE marking requirements for all your products before approaching potential customers in Germany.

Familiarise yourself with the [LVD](#) and [EMC](#) standards that apply to embedded systems.

Apply for the CE marking for software that is used in medical devices.

## 2. Chemicals

Use of certain chemicals is restricted by the EU and is regulated through several Directives and Regulations.

Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

The Directive sets maximum levels for lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE) in electronic equipment (0.01% by weight for cadmium and 0.1% for the other substances). The [Directive](#) covers all embedded systems, with the exception of the products mentioned in [Annex III](#) to the Directive. Since 2013, CE marking has been required in relation to RoHS compliance of final products. This includes technical documentation and a declaration of conformity.

REACH Regulation

This legislation restricts the use of certain dangerous chemicals (as per [Annex XVII of the Regulation](#)) and sets requirements on indicating information about the chemicals used. Manufacturers are required to provide information to their buyers on the properties of chemical substances used.

### Tips:

List all chemicals, including raw materials and additional materials, used in your production process.

Check the candidate list of [Substances of Very High Concern](#).

Fill out this information in the form required by your EU buyer, for example, by providing information in Material Safety Data Sheets (MSDS) or software in which you declare the chemical content of your product (for example, [BOMcheck](#) – a collective data system developed by a group of large electronics companies to collect chemical composition information from suppliers).

Provide the EU buyer with technical documentation and a declaration of conformity for the products supplied.

## 3. Waste of Electrical and Electronic Equipment (WEEE)

If you want to export embedded systems to Germany, be aware that your EU buyers are obliged to participate in product take-back schemes. This does not directly affect exporters from developing countries, but specific requirements on the design may be set in order to facilitate the reuse and recycling set out by WEEE.

### Tip:

Familiarise yourself with information published in [the EU Export Helpdesk](#) to have a better understanding of [WEEE requirements](#).

## Common Buyer Requirements

Quality management systems (QMS)

If you plan to export to Germany, all products must meet buyers' quality demands. ISO 9001 and 14001 are designed to make sure that the manufactured and/or exported products to Europe meet customer needs. Compliance with [VDE](#) (a European standard with several variations) is often also required by German buyers.

### Tips:

Apply for [ISO 9001](#) as quickly as possible and plan for [ISO 14001](#).

Familiarise yourself with VDE requirements. The latter standard is particularly important when entering the German market.

Consider forming a Quality Assurance team within your company that will ensure the high product quality required by EU buyers.

Corporate Social Responsibility (CSR)

German buyers increasingly look for products that have been manufactured with due respect for human rights, labour conditions and the environment. Bigger EU companies even develop their own CSR policies and require the suppliers to conform to these requirements. In particular, workers' health and safety are sensitive topics in Europe and buyers want to avoid reputation loss.

### Tips:

Understand what CSR policies are required by your customers by checking websites of electronic companies in Germany.

Consider implementing Occupational Health and Safety (OHS), which deals with aspects related to labour conditions. These requirements are not mandatory, but they will definitely give you an advantage over other competitors who do not apply them.

## 6. What competition do I face on the German market?

See our study of [competition in the Electronics and Electrical Engineering sector](#) for more information.

## 7. Through what channels can you get embedded systems on the

## German market?

The importance of authorised distributors is growing in Europe. Original Equipment Manufacturers (OEMs) are increasingly shifting the multi-partner cooperation approach to a single provider or to Electronics Manufacturing Services (EMS). Germany has launched an EMS initiative supporting local EMS companies. An EMS supplier typically provides value-added services that include:

- resolving complex logistics problems,
- providing local support services,
- sourcing hard-to-find components,
- providing small-volume procurement,
- minimising costs and saving time for OEMs/Original Design Manufacturers (ODMs).

### Tips:

Consider supplying EMS providers in Germany as an alternative to direct contact with manufacturers of telemedicine devices.

Look for local EMS suppliers in Germany through local directories, trade fairs such as [Medica](#) and [EmbeddedWorld](#) (look for lists of participants), or specialised associations (for example, [ZVEI](#)).

Internet blogs are a new sales channel for embedded systems suppliers who want to attract high-end customers. Manufacturers use these blogs to showcase their expertise by posting technical topics and discussing them. This enables direct interaction with a customer's design team. This approach has proven successful in many markets.

### Tips:

Consider specialised internet blogs in demonstrating your professional skills and experience.

Strive to keep overall production costs significantly lower than in Germany in order to compete with domestic manufacturers.

Work on production process optimisation and delivery time reduction.

Minimise the risk of damage during production and meet customer requirements in terms of product quality and delivery time.

## 8. What are the end-market prices for embedded systems?

Embedded systems have a wide price range from €50 to €1300 in Europe, depending on the specifications and application. Suppliers that are present in several European countries have harmonised their prices; any differences in pricing may occur because of the different logistics, taxes and other local costs.



**Table 1: Prices of embedded systems**

Embedded Systems	Original equipment manufacturer volume price range, in €
Motherboards	50-150
Single board computer	75-900
System on module	250-1300


Be aware of different costs and value chain margins that add up to the product price. Production and administration costs of the manufacturer usually make up 47-54% of the end price (OEM volume price). Production and administration costs should include all raw material costs, development, labour, and other fixed and administration costs. To develop a unique selling proposition, exporters from developing countries will have to understand their own costs, liabilities and responsibilities, and analyse product market price levels.


**Table 2: Breakdown of prices**


Original equipment manufacturer (OEM) volume price breakdown	Margin
Production and administration costs	47-54%
Freight to Europe and other related costs	6%
Import and other costs (for example, VAT, financing)	5%
Marketing costs in Europe	7-10%
Importer margin	5-7%
Distributor margin	10-20%

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