

Exporting embedded systems for telemedicine to the Netherlands

The Netherlands are a frontrunner in telemedicine. The development of telemedicine and the broader use of Information and Communication Technology (ICT) in health care are supported by the Dutch national infrastructure AORTA and by international pilot projects. Many Dutch companies use embedded systems in production processes.

Contents of this page

1. [Product definition](#)
2. [Product specifications](#)
3. [Which market opportunities for exporters of embedded systems does the Dutch market offer?](#)
4. [What trends on the Dutch market offer opportunities?](#)
5. [How do macroeconomic aspects impact the Dutch market?](#)
6. [What requirements should embedded systems comply with to be allowed on the Dutch market?](#)
7. [Common Buyer Requirements](#)
8. [What competition do I face on the Dutch market?](#)
9. [Through what channels can you get embedded systems on the Dutch market?](#)
10. [What are the end-market prices for embedded systems?](#)

1. Product definition

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 the Netherlands include [Advantech](#), [Intel](#), [Kontron](#), [DATA MODUL](#), [Micron Technology](#), [Congatec](#) and [Vertiv](#). Software and service providers specifically for e-health in the Netherlands include [TOPIC Embedded Systems](#), [Alphatron Medical Innovations B.V.](#), [Man & Machine Europe](#) and [Purekeys](#).

2. Product specifications

Quality:

High product quality and compliance with international and European standards on safety, as well as national legislation and practices, are key for 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"), Dutch 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 the Netherlands must be labelled in accordance with EU requirements and must provide product information as 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' possible injuries by avoiding the use of prohibited chemicals or materials.
- Packaging for products marketed in the Netherlands 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.

3. Which market opportunities for exporters of embedded systems does the Dutch market offer?

Telemedicine is emerging and offering growth potential

Despite the low production volume of embedded systems in the Netherlands compared to other EU countries,

thousands of Dutch companies are using embedded systems in their production processes. Emerging applications such as telemedicine are expected to foster market growth and open up more opportunities for high-tech hardware and software suppliers.

Production of embedded systems does not take place on a large scale (€29 million in 2015) in the Netherlands as compared to other countries. There are around 80 Dutch companies that specialise in the development of embedded systems, while another 150 companies use embedded systems as an integral part of their business.

These 230 companies can have a "gateway" function for many embedded system users across Europe. The Netherlands is exceptionally strong in innovation, ranked ninth in the WIPO Global Innovation Index 2016. Key Research and Development (R&D) spending areas include various industries such as high-tech.

The low production volume of embedded systems in the Netherlands opens up opportunities to exporters from developing countries, as the demand for high-tech embedded solutions is strong.

Tips:

Consider a go-to-market approach through an alliance with local developers of embedded systems in the Netherlands.

Find out who the leading market players are through local directories or associations such as [Embedded Systems Innovation](#).

Currently, the share of embedded systems used in telemedicine is 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:

Initially target the companies that are active in telemedicine, depending on your product offering.

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

Look for this information through specialised associations (for example, [Nictiz](#), the national competence centre for standardisation) or international trade fairs (for example, [Medica](#)).

The Netherlands benefits from being a trade hub

According to market experts, the ongoing trend of software and hardware separation, as well as the trend of increasingly outsourcing the production of hardware, will elevate the future significance of the international market. Exporters from developing countries will also benefit from the positioning of the Netherlands as a European trade hub. The seaport of Rotterdam is a key trade hub in Europe.

The share of imports of embedded systems from developing countries is 11.8% (2015), whereas nearly 67% of

embedded systems in the Netherlands are imported from other European countries. Imports from developing countries recorded an average decline of 6.2% between 2012-2015, while imports from Europe saw significant growth over the last four years (13.9% CAGR). Experts foresee that 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 once they improve their know-how.

Tip:

Work on minimising the entry barriers and maximising your competitiveness by presenting a value proposition, a product that complies with European quality standards, good knowledge of business English and a good understanding of European business culture.

In addition to China, some of the key exporters of embedded systems to the Netherlands are the Philippines, Malaysia, Thailand and India. Imports from Thailand, India and the Philippines saw the strongest growth between 2011-2015, probably benefiting from significant experience in embedded systems and the availability of skilled people in these countries.

Exporters with strong technical backgrounds and good reputations in the production of embedded systems have significant advantages.

Tip:

Work on continuous quality improvement, which is particularly critical in telemedicine applications.

The Netherlands is an important trade hub, exporting 92% of the total exports of embedded systems to the EU+EFTA. Exports of embedded systems to Belgium, Sweden, Poland and Estonia increased most significantly between 2011-2015, driven by a large growth of production activities in the relevant application industries in those countries. However, the total exports of embedded systems from the Netherlands only grew by 0.5% on average between 2013-2015.

Through the cooperation with Dutch suppliers of embedded systems, you will indirectly be able to reach out to other significant European markets that are supplied through the trade hub.

4. What trends on the Dutch 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 solutions transfer across health-care centres. The growing usage of telemedicine services in the Netherlands, including the interaction between doctors and patients, is an opportunity both for patients and manufacturers in related industries.

The Netherlands is one of the frontrunners in the use of Information and Communication Technology (ICT), including embedded systems. ICT in the following services is particularly strong:

- Storage of administrative and medical patient data,

- Use of a computer during consultation,
- Use of a Decision Support System,
- Transfer of lab results from the laboratory,
- E-prescribing.

The acceptance of e-health in the Netherlands is very high, driven by the national e-health strategy that is focused on improving the affordability, accessibility and quality of health care through an optimal usage of ICT.

The Netherlands uses keystone technologies such as the [Electronic Health Record](#) (EHR) to promote a broader use of ICT in health care. The Dutch national infrastructure [AORTA](#) has been introduced to support a better exchange of data between health-care providers. AORTA contains an eID authentication system and allows the safe, controlled transfer of health data across the Netherlands through a central hub.

The electronic exchange of information is strictly regulated, as the AORTA hub guarantees privacy and encompasses a comprehensive access rights management framework.

Aside from the national efforts, large-scale pilots have also contributed to the growing acceptance of telemedicine in recent years, as well as to the introduction of EHR and other e-health solutions.

Tips:

Pursue the opportunities in the telemedicine segment in the Netherlands – one of the frontrunners in e-health Europe - 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 the buyers' websites to see 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.

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

5. How do macroeconomic aspects impact the Dutch market?

The Netherlands is a small European country, but it has a strong economy. The Netherlands has demonstrated a solid historic development (except for the economic slowdown in 2012 across most European countries) and positive growth forecasts.

The Netherlands had a 2.4% Compound Annual Growth Rate (CAGR) of the Gross Domestic Product (GDP) between 2011-2016 and forecasts expect a growth of 1.8% in 2018, whereas Europe grew by 2.2% in 2015.

The Netherlands holds a 5% share of the total European GDP and a 4% share of the total manufacturing, respectively. The population of the EU was estimated at 510 million in 2015, with the Netherlands contributing 3% to the total EU population (approximately 17 million).

6. What requirements should embedded systems comply with to

be allowed on the Dutch 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 standards that apply to embedded systems.

Tip:

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 the Netherlands.

Check the information for relevant standards and guidelines on the application of [LVD](#), [EMC](#) and [Ecodesign](#) related to embedded systems.

Read more about CE marking for low-voltage equipment and electromagnetic compatibility in the EU Export Helpdesk.

Check the conformity of your products with the [Directive](#) if your target customer industry is medical devices. Apply for the CE marking for software that is used in medical devices.

2. Chemicals

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

Tip:

Exporters of electronics and electronic components have to meet the requirements under both RoHS and REACH.

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.

Tips:

Make sure that you provide the EU buyer with all information required in relation to chemicals used in embedded systems. 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.

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](#).

3. Waste of Electrical and Electronic Equipment (WEEE)

If you want to export embedded systems to the Netherlands, 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.

7. Common Buyer Requirements

Quality management systems (QMS)

If you plan to export to the Netherlands, 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 German standard with several variations) is often also required by Dutch buyers.

Tips:

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

Familiarise yourself with VDE requirements.

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

Corporate Social Responsibility (CSR)

Dutch 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 suppliers to conform to these requirements. In particular, workers' health and safety are sensitive topics in Europe and buyers want to avoid reputation loss.

An important initiative for the electronics sector is the [EICC Code of Conduct](#). Most large electronics companies have implemented this code and require their suppliers to act in accordance with it.

[SA 8000](#) is a certification standard for social conditions. Although this certification is not a requirement, the standard is publicly available, so you may want to be aware of the most important issues.

Tips:

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

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 exporters from developing countries.

8. What competition do I face on the Dutch market?

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

9. Through what channels can you get embedded systems on the Dutch 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 Electronic Manufacturing Services (EMS). 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 the Netherlands as an alternative to direct contact with manufacturers of telemedicine devices.

Look for local EMS suppliers through local directories and international trade fairs such as [Medica](#) and [EmbeddedWorld](#) (look for lists of participants).

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.

Use these intelligence centres in order to introduce your company and your ideas, as an added benefit.

10. 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

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.

Tip:

Be aware of different costs and value chain margins that add up to the product price.

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%

Tips:

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


Work on production process optimisation and delivery time reduction.

Make the production process more efficient and flexible by introducing a modular production approach and using different technologies.


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

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