



[Exporting electro-diagnostic apparatus to Belgium, the Netherlands and Luxembourg](#)

The market for electro-diagnostic apparatus is relatively stable in the Benelux (Belgium, the Netherlands and Luxembourg). Nevertheless, there is an increasing demand for innovative, cost-effective mobile and/or non-invasive solutions. The three countries represented €474 million in imports of electro-diagnostic apparatus in 2015, of which 11% was from developing countries. The Netherlands is the main importer of electro-diagnostic apparatus in the Benelux. Both the Netherlands and Belgium import electro-diagnostic equipment from developing countries, making them equally interesting markets for exporters from developing countries.

Contents of this page

1. [Product description](#)
2. [Demand](#)
3. [Trends offering opportunities](#)
4. [Market requirements](#)
5. [Competition](#)
6. [Trade channels and market segments](#)
7. [Useful sources](#)

1 . Product description

Electro-diagnostic apparatus are used in surgical procedures to monitor a patient's physiological parameters. This equipment enables early detection and treatment of complications. Equipment includes glucose meters, urine tests, blood tests, blood pressure equipment and anti-thrombosis meters (INR value).

A single Combined Nomenclature (CN) code has been selected for electro-diagnostic apparatus. See Table 1, which also shows the Prodcom code used in the production statistics for electro-diagnostic apparatus.

Table 1: Selected products based on CN and Prodcom nomenclature

CN code	Prodcom code	Description
901819	26601280	Electro-diagnostic apparatus, including for functional exploratory examination or for checking physiological parameters (excl. electro-cardiographs, ultrasonic scanning apparatus, magnetic resonance imaging apparatus and scintigraphic apparatus)

Source: CN and Prodcom Nomenclature

In this survey, "electro-diagnostic apparatus" refers to the product selection in Table 1, unless stated otherwise.

Quality

Electro-diagnostic apparatus for the EU market including the Benelux must comply with the [Medical Devices Directive 93/42/EEC](#). For more information, see Requirements for the Benelux market below.

Labelling

The requirements for labelling medical devices for the European Union are set out in Annex I, Paragraph 13, of the [Medical Devices Directive 93/42/EEC](#).

The label must state the following:

- the name or trade name and address of the manufacturer. For devices imported into the European Union for distribution in the European Union, the label, the outer packaging and instructions for use must contain the name and address of the authorised representative if the manufacturer does not have a registered place of business in the European Union;
- information essential to identify the device and the contents of the packaging, especially for the users;
- where appropriate, the word STERILE;
- where appropriate, the batch code, preceded by the word LOT or the serial number;
- where appropriate, the date by which the device should be used, in safety, expressed in year and month;
- where appropriate, an indication that the device is for single use. The manufacturer's statement of single use must be consistent across the European Union;
- if the device is custom-made, the phrase “custom-made device”;
- if the device is for clinical investigations, the phrase “exclusively for clinical investigations”;
- any special storage and/or handling requirements;
- any special instructions for use;
- any warnings and/or precautions to be taken;
- year of manufacture for active devices other than those covered under (e). This may be included in the batch or serial number;
- where applicable, method of sterilisation.

Packaging

Medical devices require sterile packaging in compliance with European Standard EN868 (Part 1). Part 2 through 10 of EN868 relate to the requirements and test procedures for various packaging materials. These tests can be used to show that all requirements have been complied with.

There is an ISO standard for sterile packaging of medical products, [ISO 11607](#). This ISO standard is very similar to EN868 and has two parts: Part 1 on the requirements and test procedures for packaging materials; and Part 2 on the validation requirements of packaging processes. While EN868 is mandatory, ISO is a voluntary standard and is often requested by customers.

More general legislation applicable to medical devices packaging is the EU [Packaging and packaging waste](#) legislation. This legislation restricts the use of certain heavy metals and states other requirements. EU also has requirements for [Wood packaging materials used for transport](#) (WPM), such as packing cases, boxes, crates, drums, pallets, box pallets and dunnage.

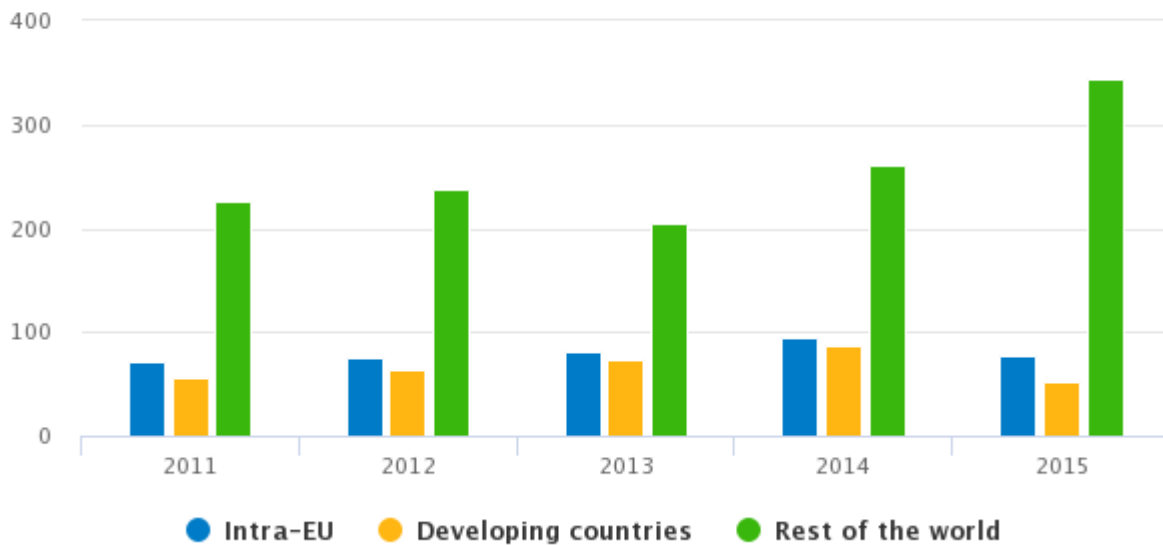
The International Trade Centre (ITC) provides additional information on [packaging for exporters](#).

2 . Demand

Imports

Figure 1: Benelux imports of electro-diagnostic apparatus by main origin, 2011-2015

in € million



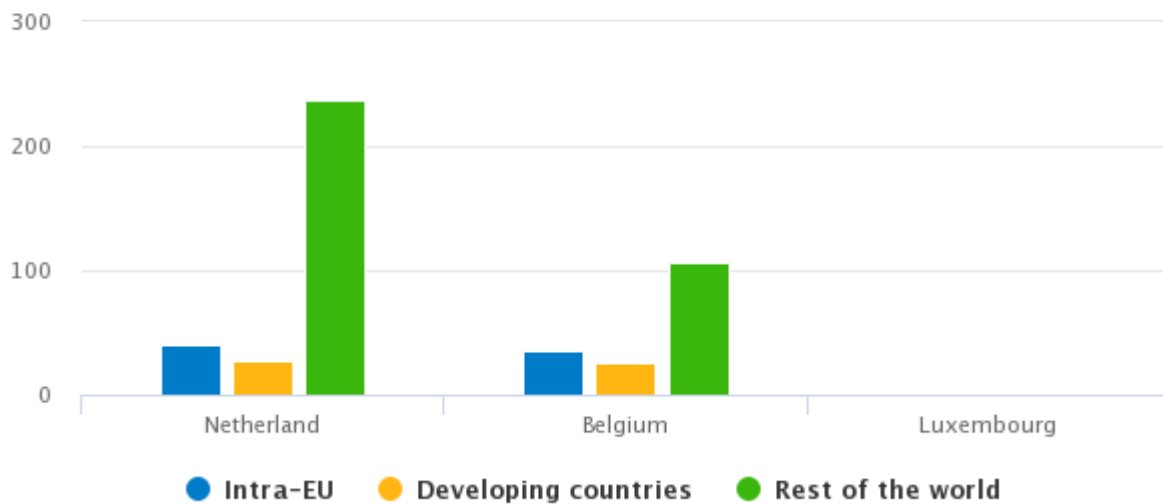
Source: Trademap.

Between 2010 and 2014, imports were marked by fluctuations within a slightly upward trend. In 2015, growth accelerated because of a strong increase in imports from developed countries outside Europe. The average annual growth in the period of 2011-2015 amounted to 8.0% and imports reached €474.2 million in 2015.

The share of developing countries in imports showed a mixed pattern. In 2012 and 2013, the share went up to reach 20.5%. It remained virtually stable in 2014, while it dropped to 11% in 2015. Most imports originate from developed countries outside the European Union (72%).

The import of electro-diagnostic apparatus is expected to show a small increase in the foreseeable future, estimated to be in the range of 1 to 3%. The share of developing countries is also forecast to grow and reach a level between 16 and 24%. To a large extent, this figure depends on the output (growth) from production facilities in developing countries owned by the world's leading manufacturers of medical devices.

Figure 2: Imports of electro-diagnostic apparatus to Belgium, the Netherlands and Luxembourg by main origin 2015
in € million

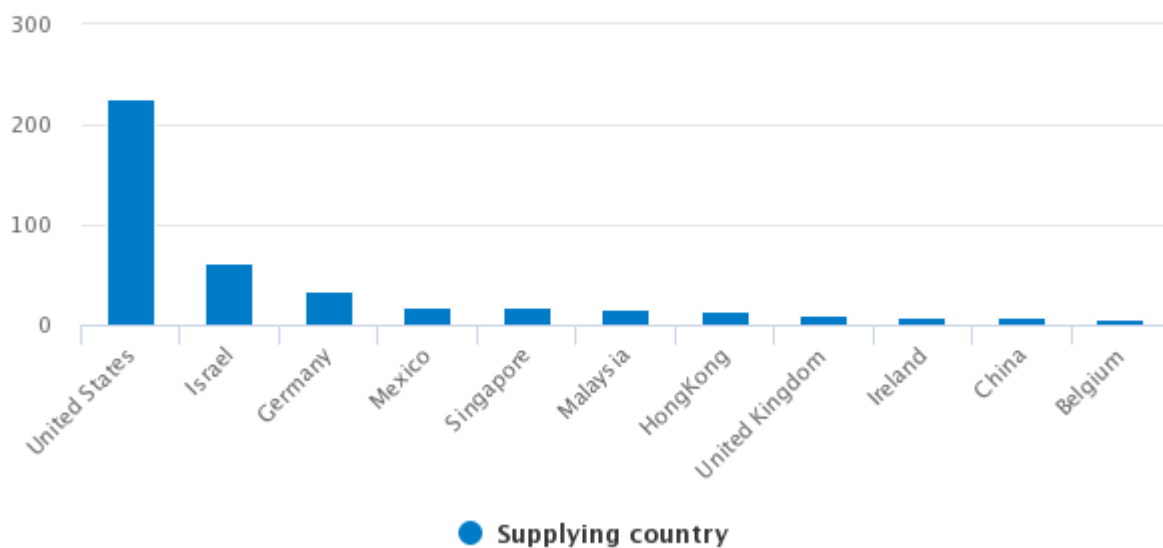


Source: Trademap.

The leading importing country is the Netherlands (64%), followed by Belgium (36%) and Luxembourg (0.4%). Imports to both the Netherlands and Belgium from developing countries amount to more than €25 million per year, although the share of imports from developing countries in the Netherlands is much lower than in Belgium. The growth in imports was stronger for Belgium (by 15% per year) than for the Netherlands.

Leading suppliers

Figure 3: Leading suppliers of electro-diagnostic apparatus to the Benelux, 2015
in € million



Source: Trademap.

Around 45% of the total import of electro-diagnostic apparatus to the Benelux comes from the United States. This import is dominated by the supply of parts and accessories for electro-

diagnostic apparatus for functional exploratory examination. Israel is the second-largest supplier. The leading supplier of electro-diagnostic apparatus from developing countries to the Benelux is Mexico, followed by Malaysia and China.

Among the largest suppliers of electro-diagnostic apparatus to the Benelux, the highest annual import growth in the period under review was recorded by Hong Kong (by 126.5%), Malaysia (45.5%) and the United States (13.4%).

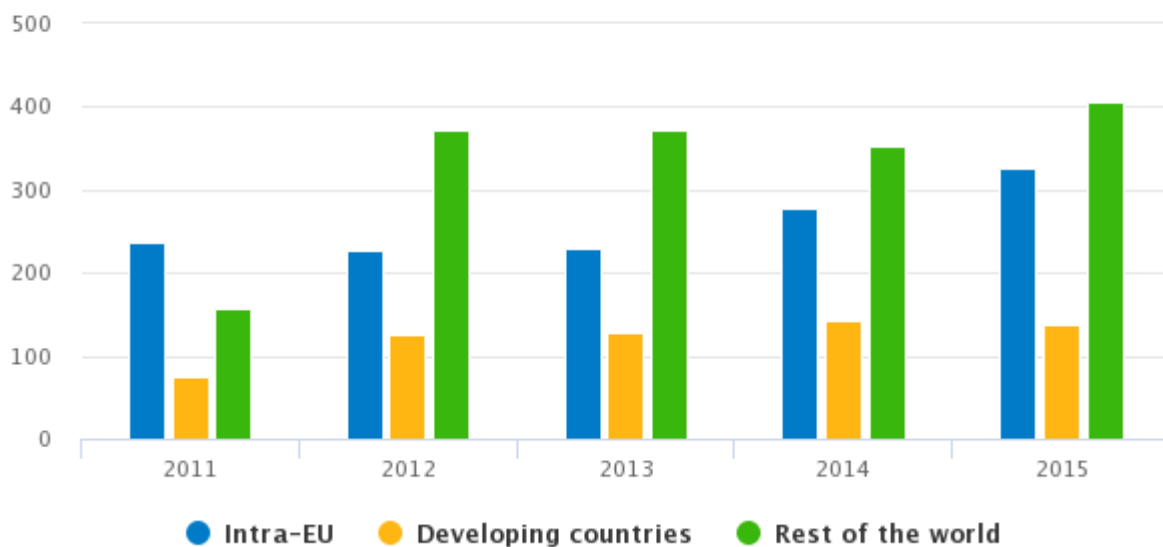
Tip:

- Benchmark your company against your peers in developed countries, Mexico, Malaysia and China. Several factors can be taken into account, such as market segments served, perceived price and quality level, and countries served. A useful source to find exporters/producers of electro-diagnostic apparatus per country is the [ITC Trademap](#).

Exports

Figure 4: Benelux exports of electro-diagnostic apparatus by main destination, 2011–2015

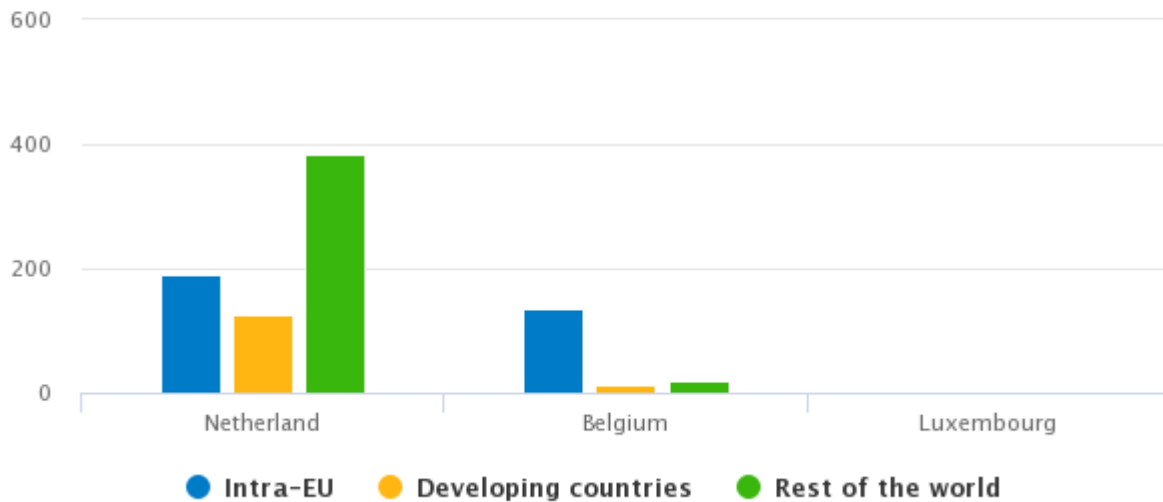
in € million



Source: Trademap.

Figure 5: Exports of electro-diagnostic apparatus to Belgium, the Netherlands and Luxembourg by main destination, 2015

in € million



Source: Trademap.

Exports of electro-diagnostic apparatus from the Benelux have shown a strong upward trend in the last four years, amounting to €866.5 million in 2015. The average annual growth was 17%.

The leading exporter in the Benelux is the Netherlands, accounting for 81% of the total Benelux exports, far ahead of Belgium (19%). This fact, together with the considerable imports to the Netherlands, illustrates the country's position as a European trade hub. Luxembourg has virtually no exports of electro-diagnostic apparatus.

Of the total Benelux exports, 15% go to Germany. France takes second position (13%), followed by the United Kingdom (12%).

Benelux exports of electro-diagnostic apparatus are expected to show moderate growth in the next few years, estimated to be in the range of 2 to 4%.

The share of exports to developing countries in the total Benelux exports reached 16% in 2015. This figure also includes some re-exports of imports from developing countries. For the foreseeable future, the share of developing countries is forecast to show a small increase, estimated at 1 to 3%.

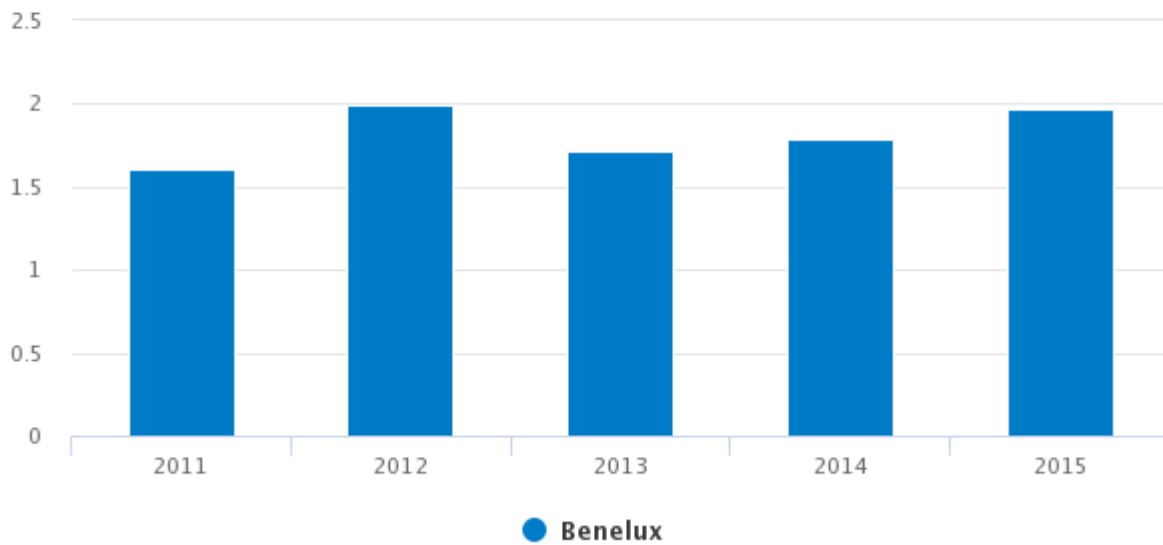
Tip:

- Learn more about your competitors in our study of [Competition in medical and laboratory devices](#).

Production and apparent demand

Figure 6: Production of electro-diagnostic apparatus in the Benelux, 2011-2015

in € million



Source: Eurostat Prodcorn.

Production in the Benelux amounted to nearly €2.0 billion in 2015, following an average annual increase of 5.1% in the period of 2011-2015. Production showed a peak in 2012.

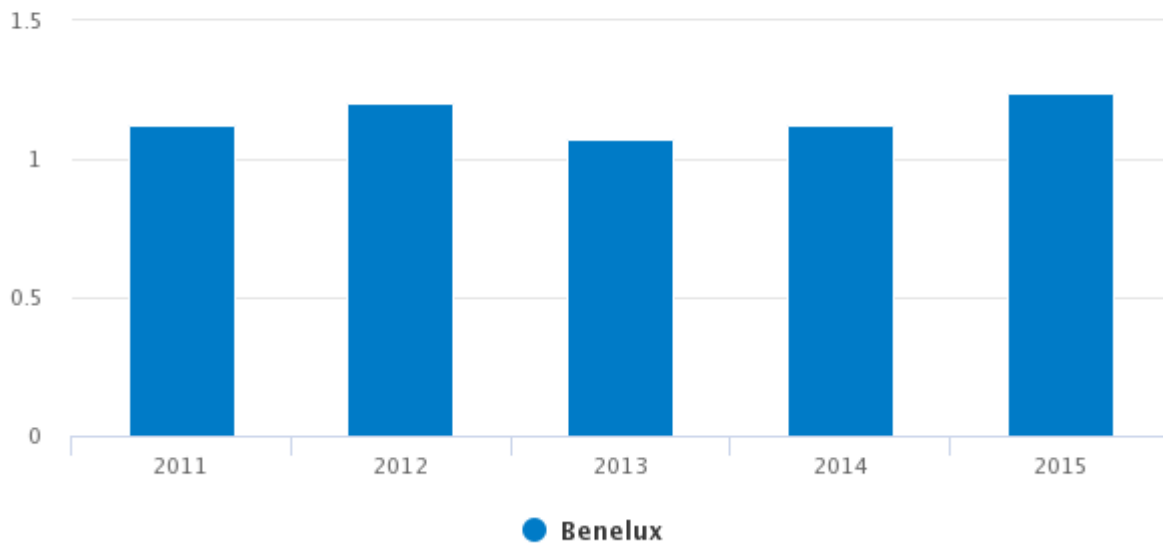
The Netherlands (€1.7 billion) accounted for 88% of the Benelux production in 2015, with Belgium (€229 million) representing 12%. Luxembourg does not produce electro-diagnostic apparatus.

Tip:

- Discover opportunities to supply to producers in the Netherlands and Belgium. Links to databases of producers of electro-diagnostic apparatus can be found under Useful Sources below.

Figure 7: Demand for electro-diagnostic apparatus in the Benelux, 2011-2015

in € million



Source: Eurostat Prodcom.

Apparent demand (production + imports - exports) in the Benelux was fairly stable at around €1.1-1.2 billion in the period of 2011-2015, with a slight peak in 2015.

The Netherlands is the dominant market for electro-diagnostic apparatus in the Benelux at 82%. Most of the remaining demand comes from Belgium (17%), with only a very small share for Luxembourg (0.2%).

3 . Trends offering opportunities

M-health

A major trend in the medical devices sector is the development of mobile health technology. When patients can use electro-diagnostic devices at home rather than at a health-care facility, collecting patient data such as blood pressure and glucose levels moves from inpatient to outpatient care. This is convenient for the patient and means a significant decrease in costs for the healthcare facility. Because mobile monitoring technology can give patients instant feedback, it is also a powerful tool to facilitate changes in behaviour to improve health.

Implantable devices

A specific type of mobile health technology is the development of implantable devices for continuous, real-time monitoring of, for instance, blood pressure and glucose levels. These devices can export measurements directly to a mobile device and health-care providers, so that the patient can be notified immediately if their measurements need to be addressed.

Non-invasive diagnostics

Invasive methods such as blood tests are often used to measure a patient's vital signs and lab values. Non-invasive diagnostics are now being developed. With innovative techniques, glucose levels can be measured from saliva, earwax, tears and even skin. As well as being painless for the patient, these techniques are generally cost-effective and provide easy monitoring of glucose levels wherever, whenever. Other examples of non-invasive diagnostics are acoustic sensor technology to monitor the respiratory rate and non-invasive haemodynamic monitoring systems.

Tip:

- Invest in R&D to develop cost-effective mobile and/or non-invasive solutions.

For more information, see [CBI Trends for Medical and Laboratory Devices](#).

4 . Market requirements

Mandatory

Electro-diagnostic apparatus for the EU market including the Benelux require CE marking, including the reference code of the Notified Body. To obtain this, your products must comply with the [Medical Devices Directive 93/42/EEC](#) on the safety and performance of medical devices. The requirements include a quality system for design, manufacture, and final product inspection and testing (such as [ISO 13485](#)).

In 2012, the European Commission presented a proposal to replace the three [European medical devices directives](#) with two European regulations to “achieve a suitable, robust, transparent and sustainable regulatory framework” for the development of safe, effective and innovative medical devices. On 5 October 2015, the Ministers of the European Union countries agreed on a general approach to the package. The new regulations are expected to be implemented by 2018–2020.

Tips:

- See our study of [Buyer Requirements for Medical Devices](#) for more information.
- Consult the European Commission’s [Blue Guide](#), which sets out how to implement the EU product rules on medical devices.
- For more information on the Medical Devices Directive, see the accompanying [guidance documents](#) to assist stakeholders in implementing directives related to medical devices.
- Keep up to date with the [revision of the Medical Devices Directives](#).

Depending on the specific product, your electro-diagnostic apparatus may also have to comply with the [Waste Electrical & Electronic Equipment \(WEEE\) Directive 2012/19/EU](#). This directive aims to increase recycling and/or reuse of waste of electrical and electronic equipment.

Tip:

- Consult the Frequently Asked Questions (FAQ) on the [WEEE Directive](#).

Additional requirements

Complying with voluntary standards such as [IEC/EN 60601](#) could help you obtain CE marking for your product.

Other voluntary standards address organisational (such as [ISO 13485](#)), environmental and social/labour requirements.

Governments, industries and consumers are increasingly aware of sustainability issues. The [Ecodesign Directive 2009/125/EC](#) helps to improve the energy efficiency of products and is complemented by the [Energy Labelling Directive](#) for labelling requirements.

In 2014, the European Commission published the [Green Public Procurement \(GPP\) criteria for Electrical and Electronic Medical Devices \(Healthcare EEE\)](#). This is a voluntary instrument with clear, verifiable, justifiable and ambitious environmental criteria, based on a life cycle approach and scientific evidence.

Recently, the concept of [Corporate Social Responsibility](#) (CSR) has become more important in the medical devices sector. Buyers are increasingly selecting suppliers based on their ethical and social responsibility measures.

For electro-diagnostic apparatus, [no duty](#) is levied on EU imports from countries outside the EU.

Tips:

1. For more information on gaining access to the European market, see the following sources:
2. [EU Export Helpdesk](#) for requirements, tariffs, statistics and preferential arrangements;
3. [ITC Market Access Map](#) for technical standards;
4. [ITC Standards Map](#) for voluntary standards.
5. In the [ISO Catalogue](#), click on TC 76, 84, 194 and 210 for an overview of ISO standards.
6. Search EN norms in the [online shop of the British Standards Institution](#).
7. Consult the Frequently Asked Questions (FAQ) on the [Ecodesign Directive](#).
8. Provide products for which you can prove the environmental benefits, such as recyclability and reusability.
9. Use sustainable materials in your products, such as biodegradable, bio-based and recycled plastics.
10. Consult the Frequently Asked Questions (FAQ) on [Green Public Procurement](#).
11. Keep your CSR policy in order and advertise it clearly; for instance, on your website and in brochures, preferably using quotes from your CE audit report.

5 . Competition

As the competition for electro-diagnostic apparatus does not differ significantly from the Medical and Laboratory Devices sector, see [CBI Competition for Medical and Laboratory Devices](#) and [CBI's study of how to do business with European buyers](#) of Medical Devices and Laboratory Equipment for an overview.

6 . Trade channels and market segments

As market channels for electro-diagnostic apparatus do not differ significantly from the Medical and Laboratory Devices sector, see [CBI Market Channels and Segments for Medical and Laboratory Devices](#) for an overview.

Potential trading partners include:

Belgium

- [Acertys Healthcare](#) - distributor
- [Cantaert Medical](#) - distributor
- [Dermat Medical Supplies](#) - distributor
- [OptiMed](#) - distributor

The Netherlands

- [Almeva](#) - distributor
- [AdEquipment](#) - distributor
- [Daxtrio](#) - distributor
- [Delta Medic](#) - distributor
- [Instamed](#) - distributor
- [MedSupport Systems](#) - distributor
- [Meekers Medical](#) - manufacturer and distributor
- [Philips Healthcare](#) - manufacturer
- [Schnabel](#) - distributor
- [Wijgergangs Medical](#) - distributor

Luxembourg

- [Hospilux](#) - distributor
- [Centermed](#) - distributor
- [Meditec](#) - distributor

Benelux distributors often represent important international players from - for instance - the US, UK and Germany, such as [Heine Optotechnik](#).

7 . Useful sources

- Finding prospects: [ESTA Healthcare](#), [FHI](#), [Medassort](#), [Qmed](#)
- Benelux associations: [Nefemed](#), [UNAMEC](#)
- European associations: [COCIR European Trade Association representing the Medical Imaging, Radiotherapy, Health ICT and Electromedical Industries](#), [Medtech Europe \(Eucomed\)](#), [European Hospital and Healthcare Federation](#)
- Magazines and news: [Medical Device and Diagnostic Industry](#)
- Trade fairs: [Health&Care Expo](#) (Belgium), [MEDICA](#) (Germany), [Medtec Europe](#) (Germany), [Zorgtotaal](#) (the Netherlands)

For more information, see [CBI Finding Buyers](#) in the Medical and Laboratory Devices sector.

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