



## [Exporting syringes, needles and catheters to Belgium, the Netherlands and Luxembourg](#)

In the European market for syringes, needles and catheters, there is increasing demand for safe, cost- and time-effective solutions, as well as for products for minimally invasive surgery and customisable products. Imports to the Benelux reached €4.6 billion in 2015, of which 14% originated from developing countries. The main importing country in the Benelux is the Netherlands, while Belgium is leading in imports from developing countries.

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## 1 . Product description

Syringes, needles and catheters are medical disposables, and are products that are generally used only once. Medical disposables are usually low-technology products of high volume and low value.

This product group includes general-purpose devices of injection, suction, and drainage and infusion, as well as specialities such as spinal, soft tissue and bone biopsy needles or angiographic/angioplasty catheters.

Four CN codes have been selected for syringes, needles and catheters. See Table 1, which also shows the Prodcom codes used in the production statistics for syringes, needles and catheters.

Table 1: Selected products based on CN and Prodcom nomenclature

CN code	Prodcom code	Description
901831	32501311	Syringes, with and without needles used in medical, surgical, dental or veterinary science
90183210	32501313	Tubular metal needles, used in medical, surgical, dental or veterinary science
90183290	32501315	Needles for sutures, used in medical, surgical, dental and veterinary science
901839	32501317	Needles, catheters, cannula and the like, used in medical, surgical, dental or veterinary sciences (excl. syringes, tubular metal needles and needles for sutures)

Source: CN and Prodcom Nomenclature.

In this survey, syringes, needles and catheters refer to the product selection in Table 1, unless stated otherwise.

## Quality

Syringes, needles and catheters for the EU market including the Benelux must comply with the [Medical Devices Directive 93/42/EEC](#). For more information, see the “Additional requirements” below.

## Labelling

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

The label must state the following:

- name or trade name and address of the manufacturer. For devices imported into the EU for distribution in the EU, the label, the outer packaging and instructions for use must also include the name and address of the authorised representative if the manufacturer does not have a registered place of business in the EU;
- 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 with safety, expressed as year and month;
- where appropriate, an indication that the device is for single use. The manufacturer's indication 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 indication may be included in the batch or serial number;
- where applicable, method of sterilisation.

## Packaging

Medical devices require sterile packaging in compliance with EN868 (Part 1). Part 2 to 10 relate to the requirements and test procedures for 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 requirements and test procedures for packaging materials, and Part 2 on the validation requirements for 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. The EU also has requirements for [Wood packaging materials used for transport](#) (WPM), such as packing cases, boxes, crates, drums, pallets, box pallets and dunnage.

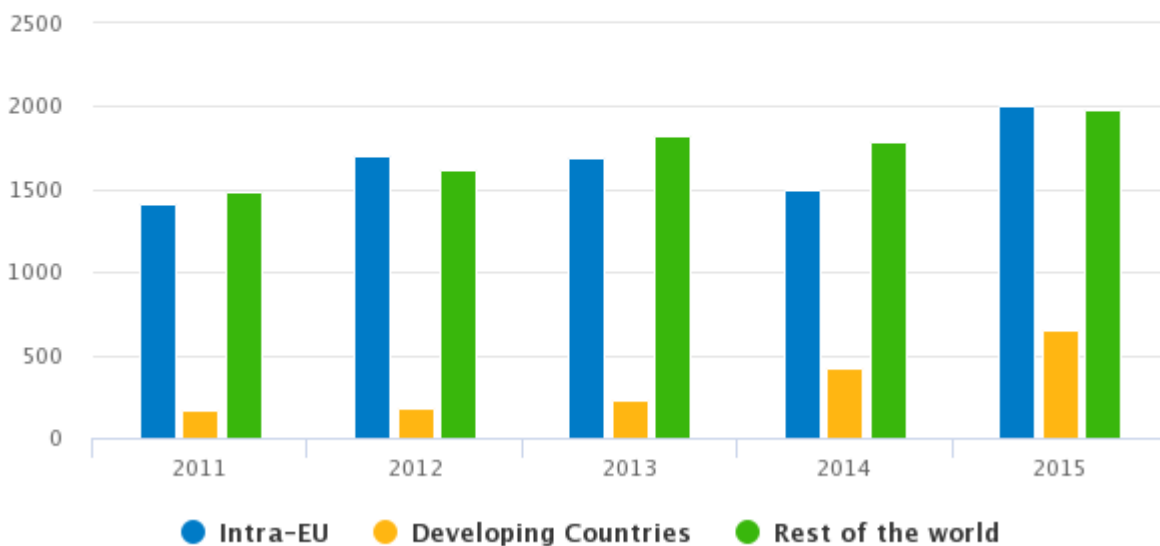
The International Trade Centre (ITC) provides additional information on [packaging for exporters](#).

## 2 . Demand

### Imports

Figure 1: Benelux imports of syringes, needles and catheters by main origin

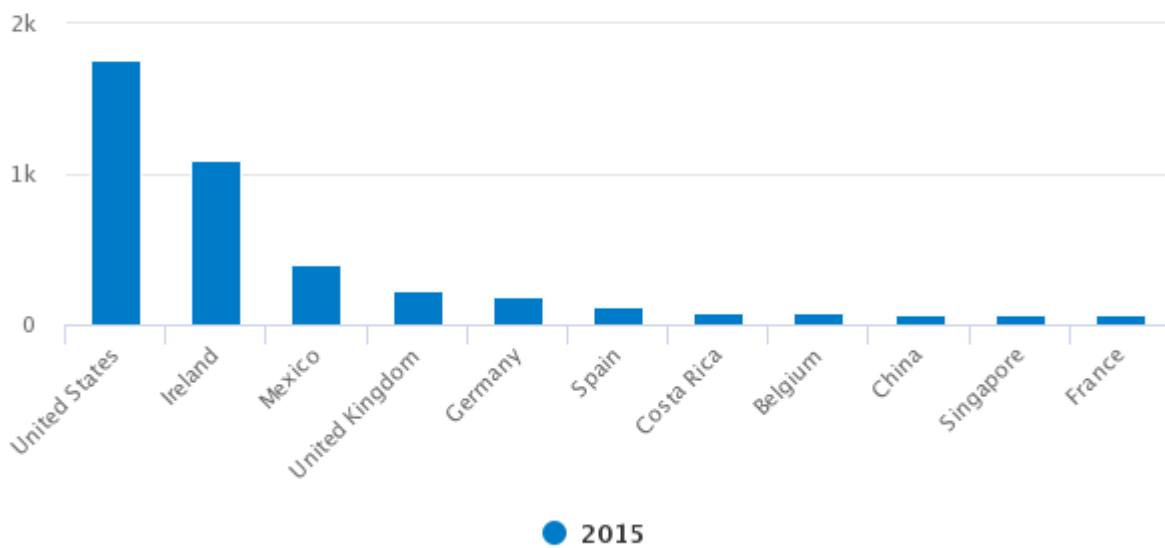
2011-2015, in € million



Source: Eurostat.

Figure 2: Leading suppliers of syringes, needles and catheters to Benelux

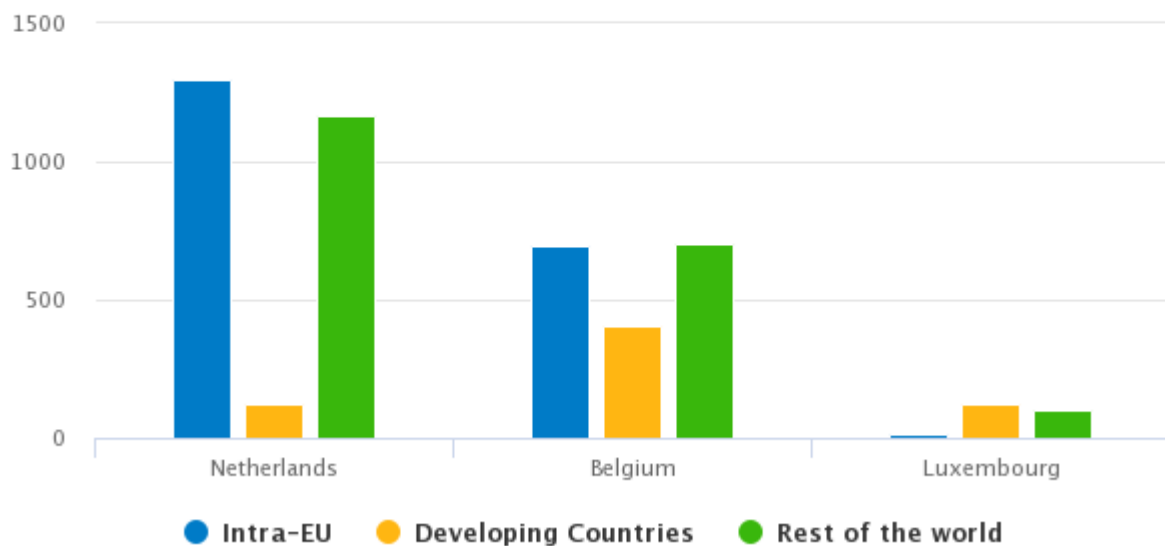
2015, in € million



Source: Trademap.

Figure 3: Imports of syringes, needles and catheters to Belgium, the Netherlands and Luxembourg by main origin

2015, in € million



Source: Eurostat.

Benelux imports of syringes, needles and catheters reached €4.6 billion in 2015. The average annual growth in the period 2011–2015 was 11%. The year 2014 showed a dip in imports because of reduced demand in that year, but both demand and imports recovered in 2015. In the coming years, the total imports are expected to be relatively stable.

The leading importing country in the Benelux is the Netherlands (56%), followed by Belgium (39%) and Luxembourg (5%). Belgium (€405 million) is importing more from developing countries than the Netherlands (€122 million) and Luxembourg (€124 million).

## Imports from developing countries

The share of imports from developing countries to the Benelux reached 14.0% in 2015. There was a clear increase in 2015, when the imports from developing countries grew by more than 50%. This development was caused by a strong increase in imports from Mexico. The share of developing countries is forecast to show significant growth in the next few years. Based on industry sources, growth is estimated at 3–5% per year. The reason is that production output in developing countries is expected to go up, as a result of growing investments in production in low-cost countries by the world's leading manufacturers.

## Leading suppliers

The leading suppliers of surgical instruments to the Benelux vary per country, but the USA, Ireland and Mexico are the top three suppliers for every country.

Of the developing countries, Mexico (€406 million), Costa Rica (€86 million) and China (€68 million) are among the leading suppliers. Other significant developing countries supplying syringes, needles and catheters to the Benelux are Malaysia, the Philippines, India, Thailand and Vietnam.

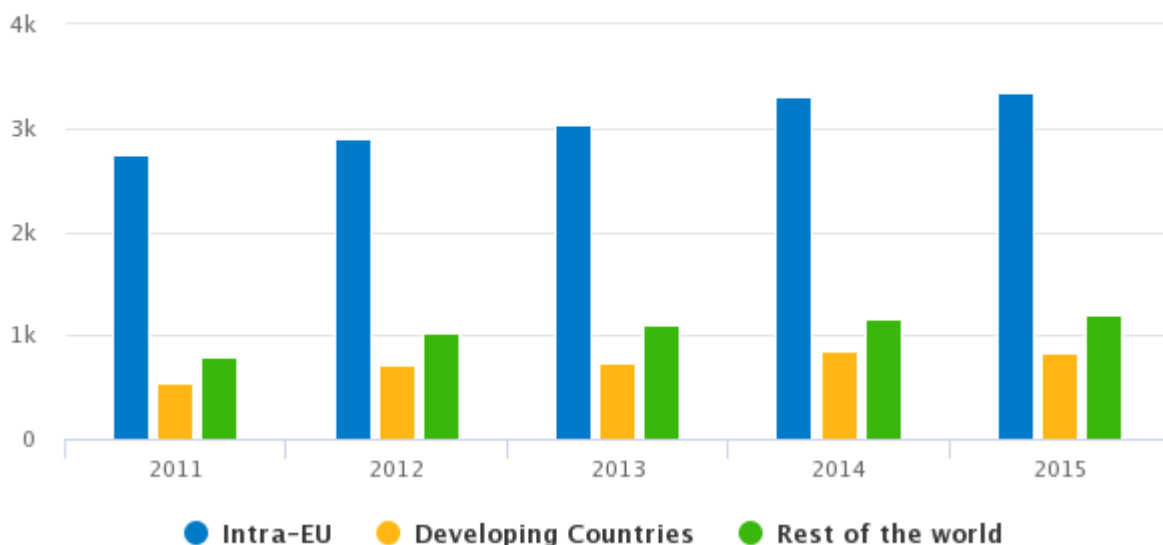
### Tip:

- Benchmark your company against your peers in Mexico, Costa Rica, China, Malaysia, the Philippines, India, Thailand and Vietnam. 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 syringes, needles and catheters per country is the [ITC Trademap](#).

## Exports

Figure 4: Benelux exports of syringes, needles and catheters by main destination

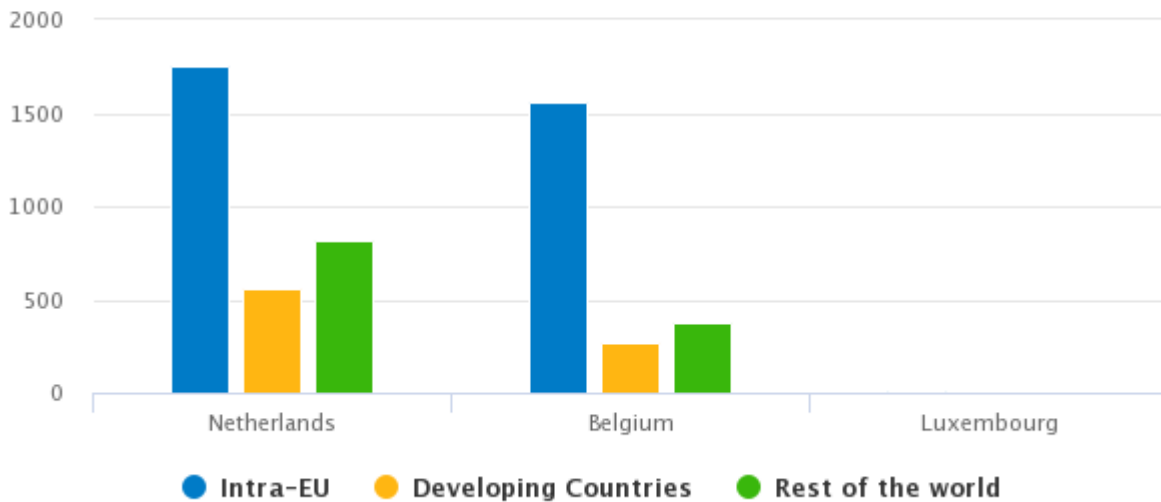
2011–2015, in € million



Source: Eurostat.

Figure 5: Exports of syringes, needles and catheters to Belgium, the Netherlands and Luxembourg by main destination

2015, in € million



Source: Eurostat.

Exports of syringes, needles and catheters from the Benelux showed an upward trend in the last four years, amounting to €5.4 billion in 2015. The average annual growth in the period 2011-2015 was 7.0%.

After some fluctuations, the share of exports to developing countries reached 15% in 2015. Most exports are destined for countries in Europe (62%), including some re-exports of imports originally coming from developing countries. For the foreseeable future, the share of developing countries is forecast to show small growth in the range of 0.5 to 3%.

The leading exporter in the Benelux is the Netherlands, accounting for 58% of the region's total. It is followed by Belgium (41%) and Luxembourg (0.3%).

Of the total export amount of €5.4 billion, €769 million goes to Germany. France is in second position (€553 million), followed by the United Kingdom (€541 million).

Benelux export destinations for syringes, needles and catheters with the most significant annual growth in the last five years are Japan (by 28%) and China (32%).

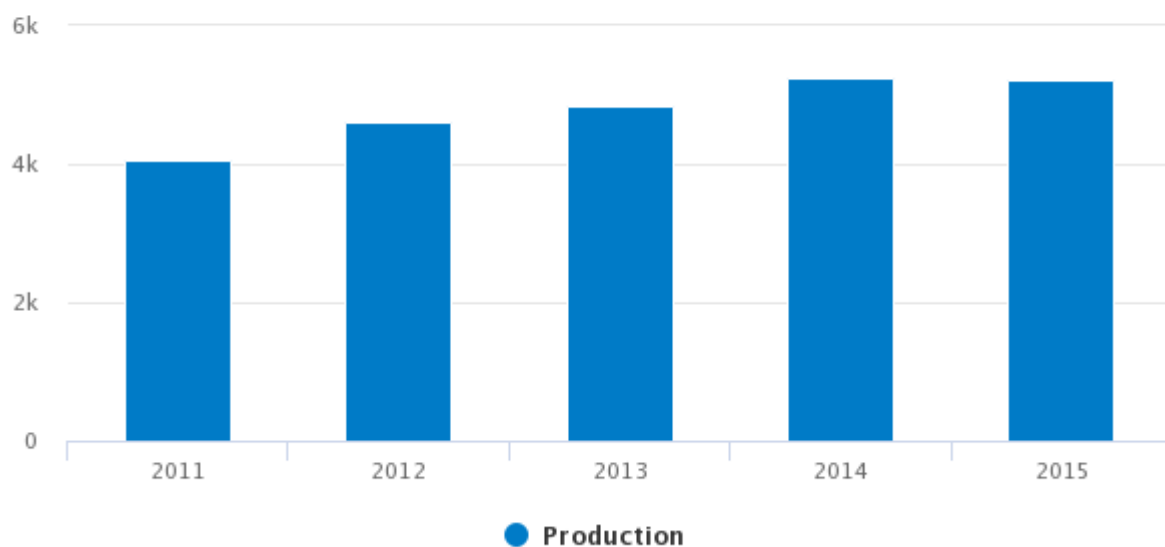
European exports of syringes, needles and catheters are expected to show moderate growth in the foreseeable future, estimated at 2-4%.

### Tips:

- Learn from European exporters and find opportunities in other growing markets such as Japan or China.
- Learn more about your competitors in our study of [Competition in medical and laboratory devices](#).

## Figure 6: Production of syringes, needles and catheters in the Benelux

2011-2015, in € million



Source: Eurostat Prodcom.

The total production in the Benelux amounted to €5.2 billion in 2015, following an average annual increase of 6.5% in the period 2011-2015.

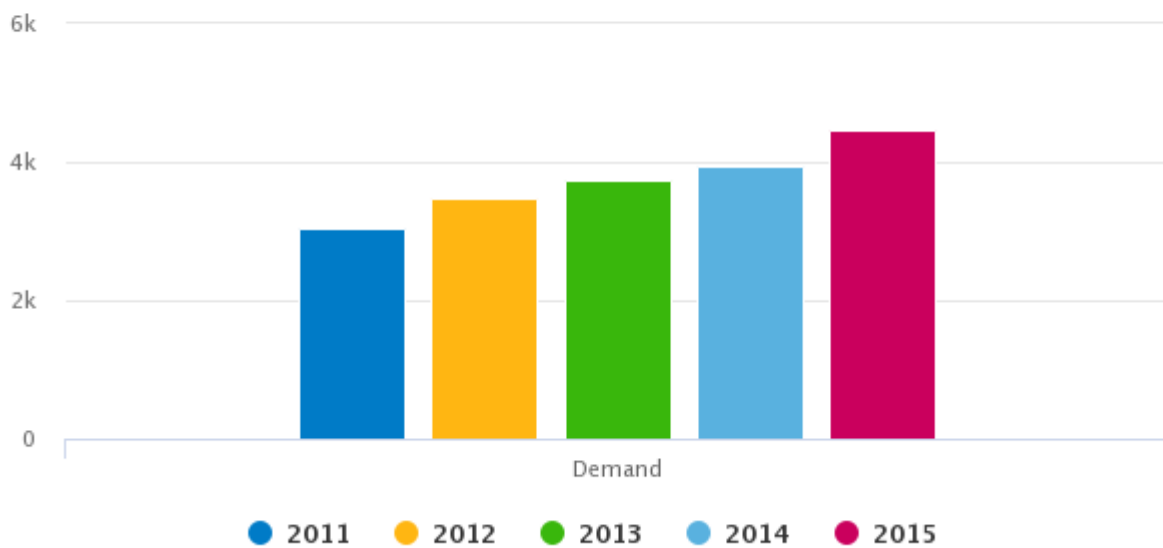
The Netherlands (€3.0 billion) accounted for 59% of the total Benelux production in 2015, with Belgium (€2.2 billion) representing 41%. Luxembourg does not produce syringes, needles and catheters.

### Tip:

- Discover opportunities to supply to producers in the Netherlands and Belgium. Links to databases of producers of syringes, needles and catheters can be found under "Useful sources".

Figure 7: Demand for syringes, needles and catheter in the Benelux

2011-2015, in € million



Source: Eurostat Prodcom.

- Apparent demand in the Benelux amounted to a total of €4.5 billion in 2015, following an average annual increase of 9.9% in the period 2011-2015.
- The Netherlands is the dominant market for syringes, needles and catheters in the Benelux with a 55% market share, followed by Belgium (40%) and Luxembourg (5%).

### 3 . Trends offering opportunities

#### Safety

Innovative techniques and products are constantly being developed to further increase patient safety. Such innovations include a regional anaesthetic delivery system that mitigates the risk of nerve injuries and an actuating device that reduces needle misplacement errors.

#### Minimally invasive surgery

There is continual innovation in minimally invasive surgery. Compared to regular procedures, minimally invasive surgery involves smaller incisions, lower risks of infection and a shorter recovery time. This type of surgery offers benefits to the patient; for instance, minimal blood loss, skin scarring, duration of hospital stay and trauma. It can increase the number of operations in day surgery and a faster turnaround of patients, while reducing costs. These increasingly demanding applications require high-quality devices such as balloon catheters and vascular catheters.

#### Customisation

To accelerate the R&D process and optimise cost- and time-effectiveness, manufacturers are introducing online customisation of catheters with a variety of specialised components. Customisation is contributing to meet the needs of specialist clinical and research at minimal time and cost.

#### Tips:

- Invest in R&D to develop safe, cost- and time-effective solutions.
- Also include products in your product range especially suited for minimally invasive surgery.



- Consider opportunities for the customisation of your products.

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

## 4 . Market requirements

### Mandatory

Syringes, needles and catheters for the EU market, including the Benelux, require CE marking. To obtain this, your products must comply with the [Medical Devices Directive 93/42/EEC](#) on the safety and performance of medical devices, including disposables. The requirements include a quality system for design, manufacture, and final product inspection and testing (such as [ISO13485](#)).

In 2012, the European Commission presented a proposal to replace the three [European medical devices directives](#) with two EU 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 [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](#).

### 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 becoming increasingly aware of sustainability issues. The concept of [Corporate Social Responsibility](#) (CSR) has also become more important in the medical device sector. Buyers are increasingly selecting suppliers based on their ethical and social responsibility measures.

For syringes, needles and catheters, [no duty](#) is levied on EU imports from outside the EU.

### Tips:

For more information on gaining access to the European market, see the following sources.

- [EU Export Helpdesk](#) for requirements, tariffs, statistics and preferential arrangements;
- [ITC Market Access Map](#) for technical standards;

- [ITC Standards Map](#) for voluntary standards.
- In the [ISO Catalogue](#), click on TC 76, 84, 194 and 210 for an overview of ISO standards.
- Search EN norms in the [online shop of the British Standards Institution](#).
- Use sustainable materials in your products, such as biodegradable, bio-based and recycled plastics.
- 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 competition for syringes, needles and catheters does not differ significantly from the Medical and Laboratory Devices sector, see [CBI Competition for Medical and Laboratory Devices](#) and [CBI Top 10 Tips for Doing Business with European Buyers](#) for an overview.

## 6 . Trade channels and market segments

As market channels for syringes, needles and catheters 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
- [Be medical](#) - distributor
- [Cantaert Medical](#) - distributor
- [Dermat Medical Supplies](#) - distributor
- [OptiMed](#) - distributor
- [Romed](#) - distributor

Netherlands

- [Almeva](#) - distributor
- [Daxtrio](#) - distributor
- [Instamed](#) - distributor
- [MedSupport Systems](#) - distributor
- [Stöpler](#) - distributor
- [Wijgergangs Medical](#) - distributor

Luxembourg

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

Benelux distributors often represent key international players in the USA, the UK and Germany, such as [Arrow International](#), [B. Braun](#) and [BD](#).

## 7 . Useful sources

- Finding prospects: [ESTA Healthcare](#), [FHI](#), [Medassort](#), [Qmed](#)
- Benelux associations: [Nefemed](#), [UNAMEC](#)
- European associations: [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)

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