CBI Product Factsheet:

Anaesthesia equipment and accessories in Belgium, the Netherlands and Luxembourg
Introduction

After the financial crisis in 2009 and 2010, the market for anaesthesia equipment and accessories has recovered consistently in the Benelux (Belgium, the Netherlands and Luxembourg). This recovery was aided by the demand for innovative, technologically advanced and safe products. Benelux imports of anaesthesia equipment and accessories reached €358 million in 2014, of which 23% came from developing countries. Although the main importer of these products is the Netherlands, Belgium leads in imports from developing countries and is thus the most interesting country of these three countries in the Benelux region.

Product description

Anaesthesia equipment and accessories refer to instruments and devices used to study and to apply or administer anaesthetics to patients. These products also include medical oxygen masks and endotracheal tubes. The product group can be divided into inhalational and intravenous equipment. Anaesthesia equipment is often highly sophisticated because safety and quality are of the utmost importance.

One CN code has been selected for anaesthesia equipment and accessories referred to in this survey, unless otherwise stated. See Table 1 that also shows the Prodcom code used in the production statistics for anaesthesia equipment and accessories.

Table 1: Selected products based on CN and Prodcom nomenclature

<table>
<thead>
<tr>
<th>CN code</th>
<th>Prodcom code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>90189060</td>
<td>32501365</td>
<td>Anaesthetic apparatus and instruments</td>
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</table>

Source: CN and Prodcom Nomenclature

Quality

Anaesthesia equipment and accessories for the European market, which includes the Benelux, must comply with the Medical Devices Directive 93/42/EEC.

Labelling

The requirements for labelling medical devices for 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 EU for distribution in the EU, the label, the outer packaging, and instructions for use must also state the name and address of the authorised representative if the manufacturer does not have a registered place of business in the EU;
- Information required to identify the device and the contents of the packaging and particularly 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 the year and month;
- Where appropriate, an indication that the device is for single use. A manufacturer’s indication of single use must be consistent across the European Union;
- If the device is custom-made, the label must state custom-made device;
- If the device is for clinical investigations, the label must state exclusively for clinical investigations;
- Any special storage and/or handling requirements;
- Any special instructions on how to use;
- Any warnings and/or precautions to be taken;
- Year of manufacture for active devices other than those covered under (e). This information may be included in the batch or serial number;
- Where applicable, method of sterilisation.

Packaging

A key requirement for medical devices is sterile packaging in compliance with EN868 (part 1). Part 2 to 10 relate to the requirements and test procedures for the various packaging materials. These tests can be used to show that all requirements have been complied with.

There is also an ISO standard for sterile packaging of medical products, ISO 11607. This ISO standard is 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 for packaging processes. While EN868 is mandatory, ISO is a voluntary standard and is often requested by customers.
More general legislation also applicable to medical devices packaging is the EU Packaging and packaging waste legislation, which restricts use of certain heavy metals, as well as setting out 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.

**Demand**

**Imports**

**Figure 1: Imports of anaesthesia equipment and accessories to the Benelux, by main origin, € million, 2010-2014**

![Imports graph]

*Source: Trademap*

**Figure 2: Leading suppliers of anaesthesia equipment and accessories to the Benelux, € million, 2014**

![Leading suppliers graph]

*Source: Trademap*
Imports of anaesthesia equipment and accessories to the Benelux reached €358 million in 2014. Average annual growth in 2010-2014 was 20%, with a peak in 2011 of 46%.

Developing country share of Benelux imports increased from 14 to 23% in the same period. This growth is due especially to strong performance in Belgium and Luxembourg. The developing country share is forecast to be relatively stable for the foreseeable future.

Although most imports originate from sources in the rest of the world (53% of all imports), this is mainly due to the disproportionately high Dutch imports. Most imports to Belgium are from other European countries whereas imports to Luxembourg are mainly from developing countries.

The leading importer in the Benelux is the Netherlands (52%), followed by Belgium (38%) and Luxembourg (10%). Belgium leads in developing country imports, ahead of Luxembourg and the Netherlands. Growth in imports between 2010 and 2014 was also strongest in Belgium (€33 million) and Luxembourg (€23 million).

The import of anaesthesia equipment and accessories is expected to continue to show fairly strong growth in the next few years, in the range of 5 to 10%.

Leading suppliers

The leading suppliers of anaesthesia equipment and accessories to the Benelux vary. The top three suppliers are the USA, Mexico and Luxembourg itself.

The leading developing country suppliers are Mexico (€34 million), Costa Rica (€29 million), China (€11 million) and Malaysia (€7.9 million).

Tip:

Benchmark your company against your peers in Mexico, Costa Rica, China and Malaysia. 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 anaesthesia equipment and accessories per country is the ITC Trademap. Search on 901890 - Instruments and appliances used in medical or veterinary sciences.
Exports

Exports of anaesthesia equipment and accessories from the Benelux have increased considerably in the last four years, and amounted to €371 million in 2014. Average annual growth in the period 2010 to 2014 was 50% and mainly due to the impressive growth in Dutch exports of 330% (!) in 2011, mostly to destinations in Europe.

The developing country share in Benelux exports is 8.2%, as most exports (76%) are destined for countries in Europe. This also includes some re-exports of imports from developing countries. For the foreseeable future, developing country share is forecast to be stable.

The leading exporter is the Netherlands, accounting for 64%, far ahead of Belgium (29%) and Luxembourg (8%). This, combined with the Netherlands’ considerable imports, illustrates the country’s position as a European trade hub.

Of the total of €371 million, €61 million of Benelux exports go to France, with Germany in second position (€52 million) followed by the UK (€47 million).

Exports of anaesthesia equipment and accessories from the Benelux are expected to continue to show considerable growth in the next few years, in the range of 10 to 30%.
Production and apparent demand

Figure 6: Production of anaesthesia equipment and accessories in the Benelux, 2012-2014, € million

![Bar chart showing production in the Benelux from 2012 to 2014.](source: Eurostat Prodcom)

Figure 7: Main Benelux producers of anaesthesia equipment and accessories, 2014

![Pie chart showing production shares.](source: Eurostat Prodcom)

- Production in the Benelux totalled €342 million in 2014. No reliable data are available for the period before 2012. Luxembourg does not produce anaesthesia equipment and accessories.
- The Netherlands accounted for 69% (€236 million) of Benelux production in 2014, and Belgium for 31% (€105 million).

**Tip:**
- The presence of producers in the Netherlands and Belgium offers opportunities for subcontracting for developing country exporters. Links to databases of anaesthesia equipment and accessories can be found under Useful Sources below.
Figure 8: Apparent demand for anaesthesia equipment and accessories in the Benelux, 2012-2014, € million

Source: Eurostat Prodcom

- Apparent demand in the Benelux totalled €329 million in 2014. The Netherlands is the dominant producer of anaesthesia equipment and accessories at 56% and has the largest apparent demand. The rest of the Benelux demand is from Belgium (42%) and Luxembourg (2%).

Macroeconomic indicators

Figure 9: Real GDP, percentage change on the previous year

Source: OECD Economic Outlook 96 database
The major determinant of demand for anaesthesia equipment and accessories is spending in the medical sector. In turn, this demand is stimulated by economic growth and an ageing population (an ageing population needs more medical care). In each focus country, Gross Domestic Product (GDP) and the number of senior citizens are expected to show continued growth year-on-year in the foreseeable future. This is a good basis for estimating demand for and growth in imports in the coming years.

Profitability of imports of anaesthesia equipment and accessories is influenced by the euro/US dollar exchange rate, as many medical devices and disposables sourced globally are paid for in US dollars. While the euro/US dollar exchange rate was not forecast to go beyond 0.80 until 2020, the exchange rate was between 0.88 and 0.93 in the period March-October 2015. This has a large effect on the price level of imports. If this situation continues for several years, it will have a negative impact on European imports paid in US dollars versus local European production.

Tip:
- If the euro remains at approximately US$ 0.90, developing country producers should increasingly focus on cost reduction to remain competitive in the European market.

For more information, see CBI Trade Statistics for Medical and Laboratory Devices.

Trends offering opportunities

Replacement purchases are the main driver for buying anaesthesia equipment. Despite limited health care budgets and lengthy equipment replacement spans, there is growing demand for innovative, technologically advanced, and safe products. The demand is further driven by an increase in the number of surgical procedures, due to, for example, the ageing population.

Smart equipment

To optimise medication dosage and delivery, and to decrease the risk of drug error, smart infusion pumps are being developed. These pumps incorporate drug libraries and dose error reduction systems that intercept errors in, for example, rate, dosage and pump settings.

Safety

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

A trend in consumable anaesthesia accessories is to disposable rather than reusable products. These disposable products can be more cost- and time-effective than reusable products that need to be sterilised after each use. Examples include disposable anaesthesia masks and endotracheal tubes.

**Refurbished equipment**

Another cost-reduction trend is the purchase of refurbished anaesthesia equipment. As well as being cost-effective, refurbished equipment is familiar to anaesthetists, waiting periods are reduced and spare parts are readily available which helps to decrease downtime.

**Tips:**
- Invest in R&D to develop innovative, cost-effective solutions.
- Focus on disposable alternatives in consumable anaesthesia accessories.
- An interesting option would be to offer bundled solutions of anaesthesia equipment and accessories sold as a package.

For more information on general trends in the sector, see [CBI Trends for Medical and Laboratory Devices](#).

**Market requirements**

**Mandatory**

Anaesthesia equipment and accessories for the European market, including the Benelux, need CE Marking. To obtain this, your products need to comply with the [Medical Devices Directive 93/42/EEC](https://www.eea.europa.eu/legislation-and-policy/medical-devices-directive-93-42-ee). This directive ensures 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](http://www.iso.org/iso/iso_catalogue/catalogue_ singleproduct/13485eed.htm)).

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:**
- Consult the European Commissions [Blue Guide](http://ec.europa.eu/enterprise/policies/innovation/innovation-policy/blue-guide_en), 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](http://ec.europa.eu/enterprise/policies/innovation/innovation-policy/blue-guide_en) to assist stakeholders in implementing directives related to medical devices.
- Keep up-to-date with the [revision of the Medical Devices Directives](http://ec.europa.eu/enterprise/policies/innovation/innovation-policy/blue-guide_en).

Depending on the specific product, your anaesthesia equipment and accessories may also have to comply with the [Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU](http://ec.europa.eu/environment/waste/waste-electrical-and-electronic-equipment-wwee/index_en.htm). This aims to increase the recycling and/or re-use of waste of electrical and electronic equipment.

**Tip:**

**Additional requirements**

Complying with voluntary standards, such as [IEC/EN 60601](http://www.iec.ch) could help you obtain CE Marking for your product.

Other voluntary standards provide organisational (such as, [ISO 13485](http://www.iso.org/iso/iso_catalogue/catalogue_ singleproduct/13485eed.htm)), environmental and social (labour) 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.

The concept of Corporate Social Responsibility (CSR) has become more important in the medical device sector. Buyers are increasingly selecting suppliers on their ethical and social responsibility measures.

For anaesthesia equipment and accessories, no duty is levied on imports to EU Member States from outside the EU.

**Tips:**

- For more information on access to the European market, see:
  - 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 Organisation.
  - Consult the Frequently Asked Questions (FAQ) on the Ecodesign Directive.
  - Provide products for which you can prove the environmental benefits, such as recyclability and reusability.
  - Use sustainable materials in your products, such as biodegradable, bio-based and recycled plastics.
  - Consult the Frequently Asked Questions (FAQ) in Green Public Procurement.
  - Have your CSR policy in order and advertise it clearly, for example on your website and in brochures, preferably using quotes from your CE audit report.

**Competition**

As competition for anaesthesia equipment and accessories 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.

**Trade channels and market segments**

As market channels for anaesthesia equipment and accessories do not differ significantly from the Medical and Laboratory Devices sector in general, 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
- Heyer Benelux - distributor
- Hospithera - distributor
- Medec Benelux - manufacturer
- Omega Medical - distributor
- Romed - distributor

**Netherlands**

- AdQuipment - distributor
- All Medical - manufacturer/distributor
- De Koningh Medical Systems - manufacturer
- Delta Medic - distributor
- EmdaMed - distributor
- Medeca - distributor
- Medi Medeco - distributor
- MedSupport Systems - distributor
- Philips Healthcare - manufacturer
- Stöpler - manufacturer
Luxembourg

- Centermed - distributor

**Useful sources**

- Finding prospects: ESTA Healthcare, FHI, Medassort, Qmed
- Benelux associations: Association for Anaesthesia and Resuscitation of Luxembourg, Belgian Association for Regional Anesthesia, Dutch Association for Anaesthesia Professionals, Dutch Association for Anaesthesiology, Dutch Association for Regional Anesthesia, Luxembourgian Association for Anaesthesia and Reanimation Nurses, Nefemed, Society of Anaesthesia and Resuscitation of Belgium, UNAMEC
- European associations: Medtech Europe (Eucomed), European Association of Cardiothoracic Anaesthesiologists, European Hospital and Healthcare Federation, European Society of Regional Anaesthesia & Pain Therapy, European Society for Paediatric Anaesthesiology, European Society of Anaesthesiology
- Trade fairs: Euroanaesthesia (UK), Healthcare Expo (Belgium), MEDICA (Germany), Medtec Europe (Germany), Zorgtotaal (Netherlands)

For more information, see CBI Finding Buyers in the Medical and Laboratory Devices sector.
CBI Market Intelligence

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This survey was compiled for CBI by Globally Cool – Creative Solutions for Sustainable Business in collaboration with CBI sector expert Leendert Santema.

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