CBI
Ministry of Foreign Affairs

CBI Product Factsheet:

Endoscopy devices in Germany, Austria and Switzerland

Introduction

The market for endoscopy devices is growing in Germany, Austria and Switzerland. There is increasing demand for innovative, cost-effective solutions. Imports of endoscopy devices to Germany and Austria reached €528 million in 2014. The share of imports from developing countries is small at 2.5%, and is forecast to show small growth. The leading importer is Germany, with a considerable market for imports from developing countries, making it the most interesting country of these three German speaking and neighbouring countries.

Product description

Endoscopes are used in diagnostic medical procedures to assess the interior surfaces of an organ. The instrument may have a rigid or flexible tube and provides an image for visual inspection and photography, and enables biopsies and retrieval of foreign objects. Products comprise a rigid or flexible tube, a light delivery system to illuminate the object under inspection, a lens, and an optical fibre system.

Because only a small incision is required, the use of endoscopy devices enables minimally invasive surgery (keyhole surgery). This helps patients to recover more quickly.

One CN code has been selected for endoscopy devices. See Table 1 that also shows the Prodcom code used in production statistics for endoscopy devices.

Table 1: Selected products based on CN and Prodcom nomenclature

CN code	Prodcom code	Description
90189020	32501335	Endoscopes

Source: CN and Prodcom Nomenclature

In this survey, endoscopy devices refer to the products in Table 1, unless stated otherwise.

Quality

Endoscopy devices for the European market must comply with the Medical Devices Directive 93/42/EEC. For more information, see Market Requirements below.

Labelling

The requirements for labelling medical devices in 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 also include 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. 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 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 also 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 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. EU also has requirements for Wood packaging materials used for transport (WPM), such as packing cases, boxes, crates, drums, pallets, box pallets, and dunnage.

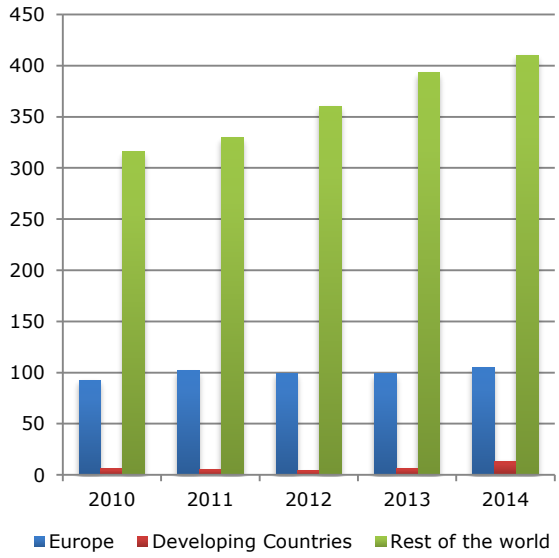
The International Trade Centre (ITC) provides additional information on packaging for exporters.

Demand

No statistics are available on endoscopy devices for Switzerland. The data here are for Germany and Austria.

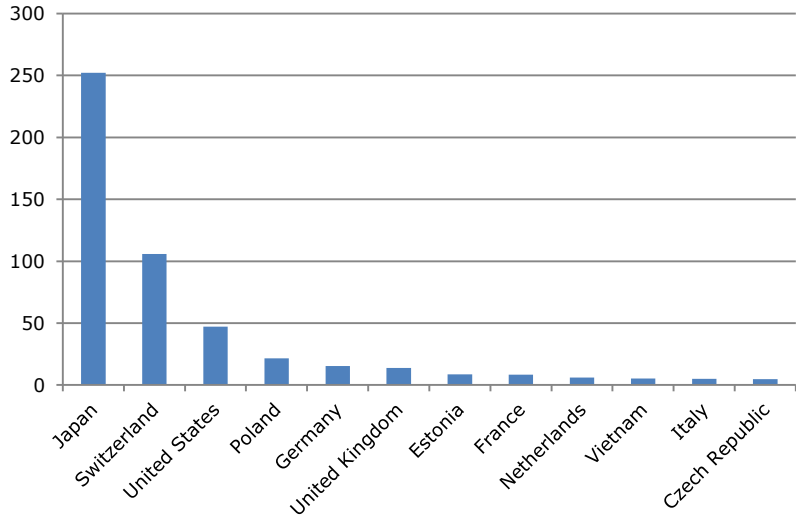
Imports

Figure 1: Imports of endoscopy devices to Germany and Austria by main origin, € million, 2010-2014



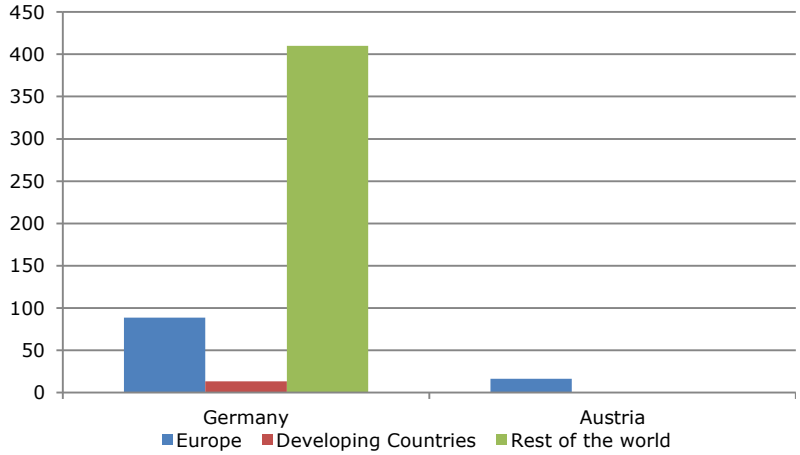
Source: Trademap

Figure 2: Leading suppliers of endoscopy devices to Germany and Austria, € million, 2014



Source: Trademap

Figure 3: Imports of endoscopy devices to Germany and Austria by main origin, € million, 2014



Source: Trademap

- Imports of endoscopy devices to Germany and Austria reached €528 million in 2014. Average annual growth in the period 2010 to 2014 was 6.3%.
- The developing country share of imports is very small at 2.5%. Most imports originate from developed countries outside the EU (78%). In the foreseeable future, small growth in the developing country share is forecast in the range of 0 to 3%.
- The leading importer is Germany (97%) with Austria responsible for 3%. Germany also leads in imports from developing countries imports while Austria imports almost no endoscopy devices from developing countries.
- The imports of endoscopy devices are expected to grow moderately in the foreseeable future, in the range of 3 to 6%.

Leading suppliers

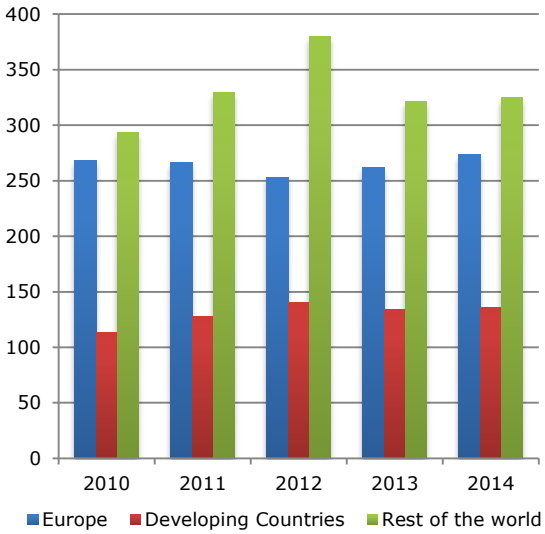
- Most leading suppliers of endoscopy devices to Germany are developed countries, with the top 5 suppliers being Japan, Switzerland, USA, Poland and Germany itself.
- Vietnam exported €5.2 million in 2014 and is the only developing country on the list of leading suppliers.
- Other developing countries exporting endoscopy devices to Germany are China (€3.3 million), Thailand (€3.1 million) and Pakistan (€0.5 million).

Tip:

- Benchmark your company against your peers in developed countries, Vietnam, China, Thailand and Pakistan. 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 endoscopy devices per country is the ITC Trademap.

Exports

Figure 5: Exports of endoscopy devices from Germany and Austria, by main destination, € million, 2010-2014

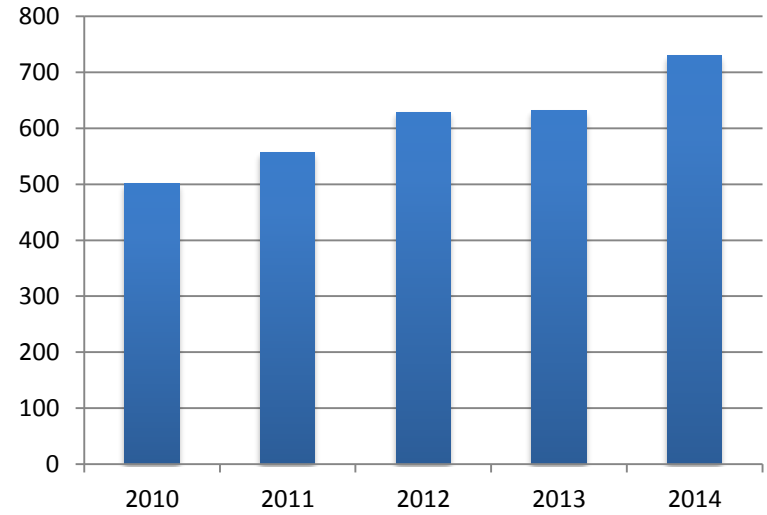


Source: Trademap

- After peaking in 2012 (€774 million), exports of endoscopy devices amounted to €734 million in 2014. Average annual growth in 2010-2014 was 2.1%.
- The developing country share in exports is 19%, as most exports are destined for countries in Europe (37%) and other (44%) countries, including some re-exports of imports from developing countries. For the foreseeable future, the developing country share is forecast to show small growth in the range of 0 to 3%.
- Germany is responsible for practically all exports, with Austria accounting for 0.2%.
- Of the total of €774 million, €185 million is to the USA with France in second position (€ 61 million) followed by Switzerland (€32 million).
- Small growth is expected in European exports of endoscopy devices in the foreseeable future, in the range of 2 to 4%.

Production and apparent demand

Figure 7: Production of endoscopy devices in Germany and Austria, 2010-2014, € million



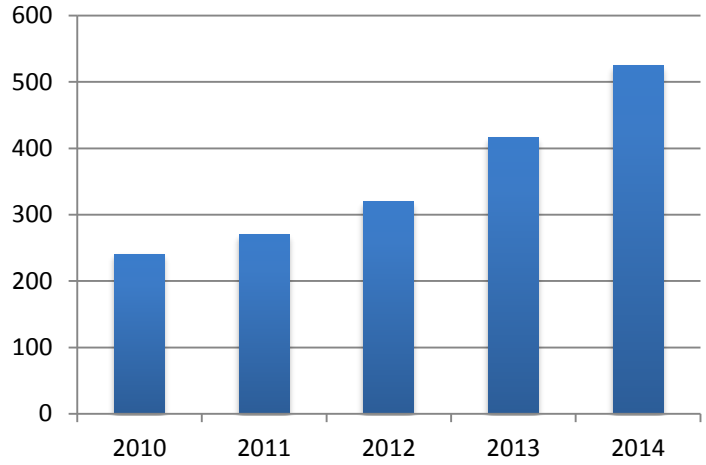
Source: Eurostat Prodcom

- Production in Germany totalled €729 million in 2014, after an average annual increase of 9.8% in the period 2010-2014. Austria did not produce endoscopy devices in this period.

Tip:

- The presence of producers in Germany offers opportunities for subcontracting for developing country exporters. Links to databases on producers of endoscopy devices can be found in Useful Sources below.

Figure 8: Apparent demand for endoscopy devices in Germany and Austria, 2010-2014, € million

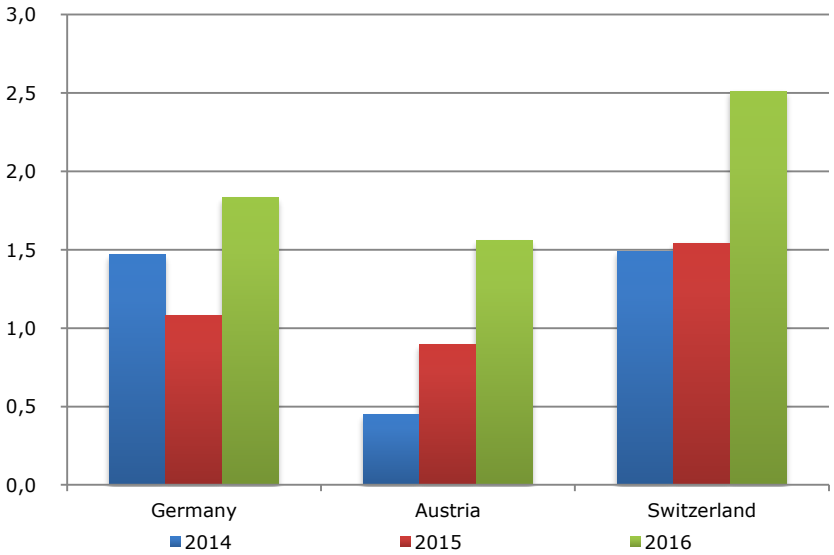


Source: Eurostat Prodcom

- Apparent demand in Germany and Austria totalled €524 million in 2014, after an average annual increase of 22% in the period 2010-2014. This growth is mainly due to the relatively low value in 2010, resulting from the negative impact of the financial crisis in 2009 and 2010.
- Germany is the dominant endoscopy devices producer at 97%, and has the largest apparent demand. Only 3% of demand comes from Austria.

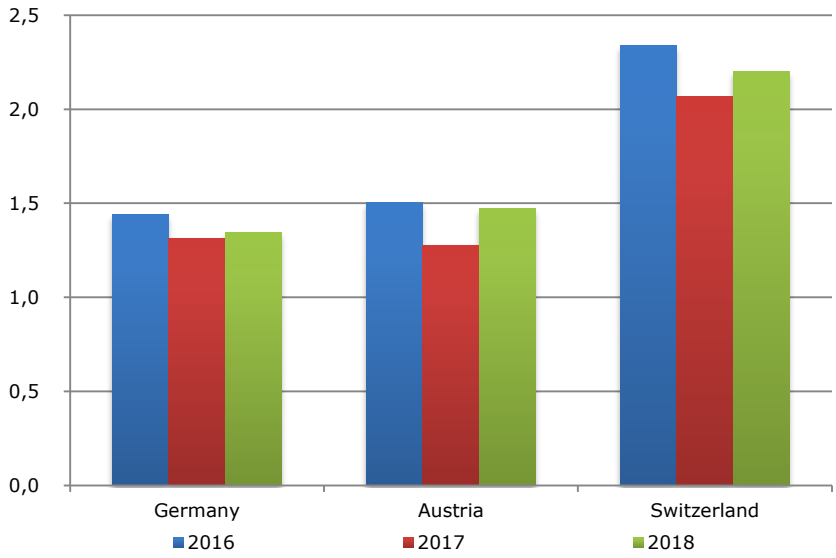
Macroeconomic indicators

Figure 9: Real GDP, percentage change from previous year



Source: OECD Economic Outlook 96 database

Figure 10: Number of senior citizens (65+), percentage change on the previous year



Source: Eurostat EUROPOP2013

- The major determinant of demand for endoscopy devices 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 endoscopy devices imports is influenced by the euro/US dollar exchange rate because many medical devices sourced globally are paid 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 remains the situation for some years, it will have a negative impact on European imports paid in US dollars versus local European production.

Tip:

- If the euro stays 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

Growing preference for non-surgical options

The market for endoscopy devices is fuelled by the growing replacement of conventional open surgeries with minimal invasive procedures. Surgical endoscopy can offer these minimal invasive procedures and fits well with the trend to robot-assisted surgery and single incision surgery. Major benefits include reduced trauma to the surgical site, less blood loss, shorter hospital stays, faster recovery, reduced risk of long-term surgical scarring, and superior patient outcomes.

Developments in endoscopic visualisation devices

Visualisation equipment is the fastest growing segment in endoscopic devices, growing with a CAGR of 4.4% (source, Medica). Improved visualization techniques enhance the quality and opportunities for endoscopic treatments. Endoscopy is becoming the primary technique for detection and treatment of chronic and acute gastrointestinal disorders and other ailments, driven by its unique capability to reach hard-to-reach areas in the body. This trend fuels the market for endoscopy devices.

Endoscopy devices used for early diagnosis

In Western Europe, there is a rise in incidence of cancer and gastrointestinal diseases. As early diagnosis can substantially increase the survival rate for this type of cancer, demand for early diagnosis and screening has increased significantly.

Disposable endoscopes

Endoscopy has been done with re-usable instruments that take a long time to decontaminate, and have high maintenance costs. Single-use, disposable endoscopes are more time- and cost-efficient. As disposable endoscopes are sterile, they also lower the risk of patient infection.

Other technological inventions

Several other technological inventions increase the potential for endoscopy devices, for instance, application of capsule endoscopy in colon cancer screening and 3D printing for endoscopy. 3D printing can be used to manufacture the overtubes used by endoscopies. 3D printing enables doctors to adjust instruments more precisely to the patient and the operational area, which reduces the risk of injury.

Tips:

- Many trends in endoscopy devices are linked to improving time- and cost-efficiency. If you are considering developing new endoscopy devices, make sure they exceed the current options on time- and cost-efficiency.
- You can greatly improve your competitiveness if you focus your export marketing on reducing maintenance costs for potential buyers.

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

Market requirements

Mandatory

The European Union has a Mutual Recognition Agreement (MRA) with Switzerland covering the recognition of conformity assessments irrespective of the origin of products including medical devices. This means that certificates issued in the European Union, in accordance with European legislation, are equivalent to those issued in Switzerland, in accordance with Swiss legislation.

Endoscopy devices for the EU market 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 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:

- Consult the European Commission Blue Guide that 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 endoscopy devices may also have to comply with the

- Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU. This directive aims to increase recycling and/or re-use 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 provide organisational (such as, ISO 13485), environmental and social (labour) requirements.

Governments, industries and consumers are becoming increasingly awareness 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, with 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 device sector. Buyers are increasingly selecting suppliers based on their ethical and social responsibility measures.

For endoscopy devices, no duty is levied on EU imports from countries outside the EU.

Tips:

- For more information on gaining 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 of 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) on Green Public Procurement.
- Ensure 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.

Competition

As competition for endoscopy devices 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.

Trade channels and market segments

As market channels for endoscopy devices do not differ significantly from the Medical and Laboratory Devices, see CBI Market Channels and Segments for Medical and Laboratory Devices.

Potential trading partners include:

Germany
- B. Braun - manufacturer
- ENDO-FLEX - manufacturer and distributor
- Endo Passion - manufacturer
- Endomed - manufacturer and distributor
- KARL STORZ - manufacturer
- MGB - manufacturer
- RAUMEDIC - manufacturer
- Richard Wolf - manufacturer

Austria
- allomed - distributor
- Mositech - distributor
- Reinhard Di Lena - distributor
- Zeppelin - manufacturer and distributor

Switzerland

- Andromis - manufacturer
- Anklin - distributor
- Desopharmex - distributor
- Endotec Medical Systems - manufacturer and distributor
- Marcel Blanc - distributor
- Treier - distributor

Useful sources

- Finding prospects: ESTA Healthcare, MedicalExpo, Qmed
- National associations: Austrian Association of Medical Device Manufacturers and Suppliers, Austrian Society of Gastroenterology, Federation of Swiss Medical Devices Trade and Industry, German Medical Dealers Association, German Medical Technology Association, German Society for Endoscopy and Imaging, German Society of Gastroenterology, SPECTARIS Trade Association Medical Technology, Swiss Society of Gastroenterology
- European associations: Medtech Europe (Eucomed), European Society of Gastrointestinal Endoscopy, European Hospital and Healthcare Federation, United European Gastroenterology
- Magazines and news: Devicemed, Medical Device and Diagnostic Industry
- Trade fairs: MEDICA (Germany), Medtec Europe (Germany)

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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