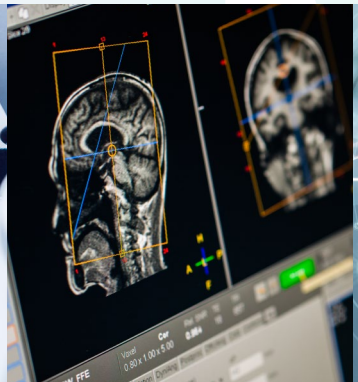
HealthTech Ireland
ASSOCIATION

The European Medical Technology Industry in figures 2020


HealthTech Ireland
ASSOCIATION

Providing **Diagnostics, Devices** and **Digital** solutions to help people live healthier lives.

MedTech Europe
from diagnosis to cure

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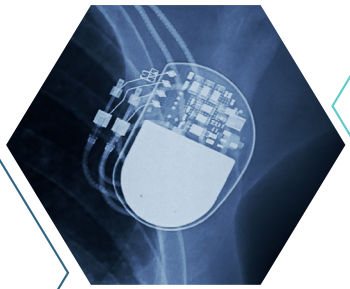
What is Medical Technology?

Medical technologies are products, services or solutions used to save and improve people's lives. In their many forms, they are with you all the time, from prevention, to diagnosis to cure.

There are three main categories of medical technologies:

- **Medical devices** (MDs) are products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical means.
- **In vitro diagnostics** (IVDs) are non-invasive tests used on biological samples (for example blood, urine or tissues) to determine the status of one's health.
- **Digital health** and care refers to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle.

For the sake of this document, medical technology refers to medical devices and in vitro diagnostics.



There are more than 500,000 medical technologies available in hospitals, community-care settings and at home.

Medical technology can be everyday objects such as sticking plasters, syringes, screening tests, or latex gloves. It could also be spectacles, wheelchairs, pregnancy tests or hearing aids.

Medical technologies also include total body scanners, gene mutation tests, implantable devices such as heart valves and pacemakers, and replacement joints for knees and hips.

You may not always notice medical technologies, but they are always there for you.

Medical technologies provide value in different ways. They allow people to live longer and better lives, thus empowering them to contribute to society for longer. At the same time, medical technologies improve the quality of care, and the efficiency and sustainability of healthcare systems.

Regulations

In the European Union, medical technologies are tightly regulated

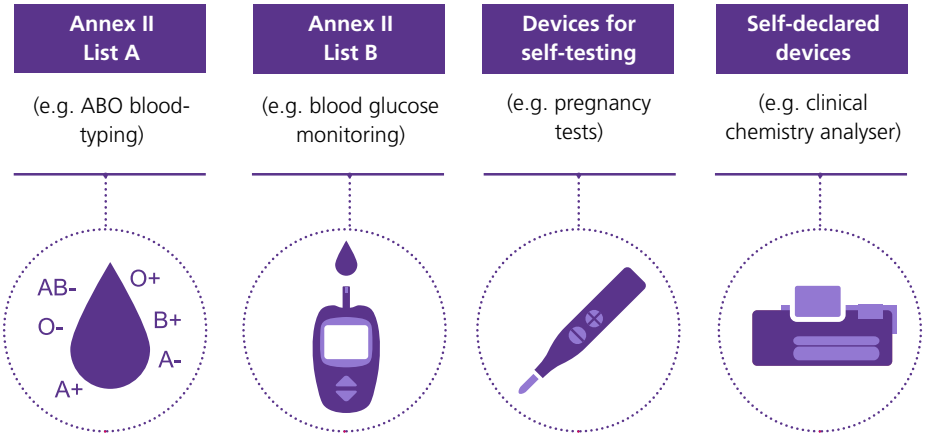
by laws that govern the safety and performance of devices across their lifetime, pre- and post-market. Over the next few years, the European medical technology sector will transition from being regulated under the current medical devices directives to two new regulations.

Classification of In Vitro Diagnostic Medical Devices

Today, the in vitro diagnostic (IVD) sector is regulated by Directive 98/79/EC. From 26 May 2022, the new Regulation 2017/746/EU will fully apply. Until this date, manufacturers can choose to comply with either the Directive or the Regulation.

Classification of IVDs is important as it determines the level of involvement by a third party (the "notified body") in assessing IVDs both pre- and post-market. This level of control is generally relative to the risk of an erroneous result from the assay.

Under the IVD Directive, IVDs are classified into four classes following a positive list approach:



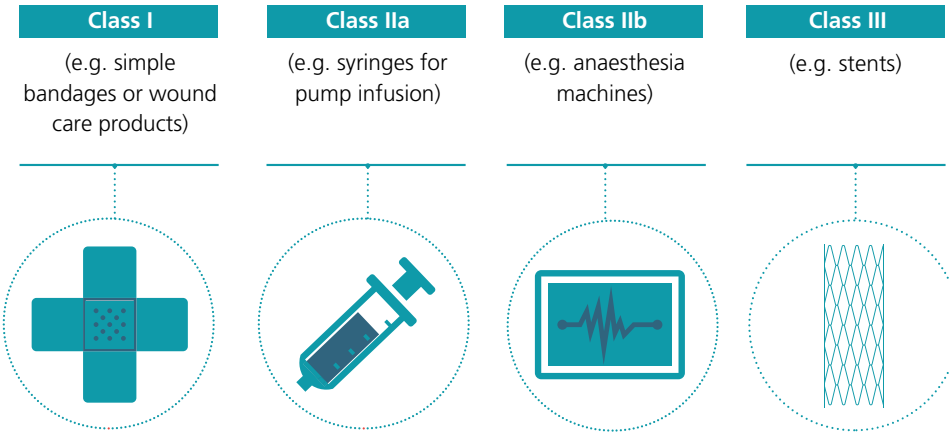
Under the IVD Regulation, all IVDs will be classified under a new risk-based classification system according to the risk the device poses to the health of the public and or an individual as a result of an incorrect test result. All IVDs will be classified under class A, B, C or D, with class D being the highest risk class.

Classification of Medical Devices

The medical device (MD) sector is regulated by Directives 93/42/EC and 90/385/EEC. From 26 May 2021, the new Regulation 2017/745/EU will fully apply. Until this date, manufacturers can choose to comply with either the Directives or the Regulation.

Classification of medical devices (estimated to be more than 500,000) drives many pre- and post-market requirements. Due to the large variety of products, the level of control made by a third-party (the "notified body") before placing them on the market depends on the level of impact on the human body that their use might imply. The same notified body, together with the Competent National Authorities, is involved post-market to ensure the continued safety and performance of medical devices.

Under the MD Directive, MDs are classified into 4 classes following a risk-based classification system:



Under the new MD Regulation, the risk-based classification system contained in the current Directives has been maintained, although some changes/additions have been introduced. The principle is the same: to link the class of the device to the potential risk posed to the health of the public and an individual as a result of fault in the functioning. All MDs are classified under class I, IIa, IIb or III, with class III being the highest risk class.

Innovation

Medical technology is characterised by a constant flow of innovations, which are the results of a high level of research and development within the industry, and of close co-operation with the users. The average global R&D investment rate (R&D spending as a percentage of sales) is estimated to be around 8% in the medical technology sector[1]. Products typically have a lifecycle of only 18-24 months before an improved product becomes available.

In 2019, nearly 14,000 patent applications were filed with the European Patent Office (EPO) in the field of medical technology representing a 0.9% growth in patent applications compared to the previous year.[2] The medical technology field accounts for 7.7% of the total number of applications, second highest among all the sectors in Europe. In comparison, around 7,700 applications were filed in the pharmaceutical field and around 6,800 in the field of biotechnology. (Figure 2)

39% of all patent applications were filed from EPO countries (including EU27, UK, Norway and Switzerland) and 61% from other countries, out of which with the majority of applications filed from the US (40%).

Figure 1. Medical technology patent applications filed with EPO in 2019

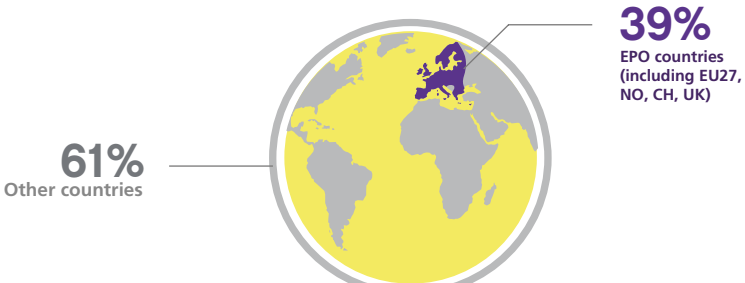
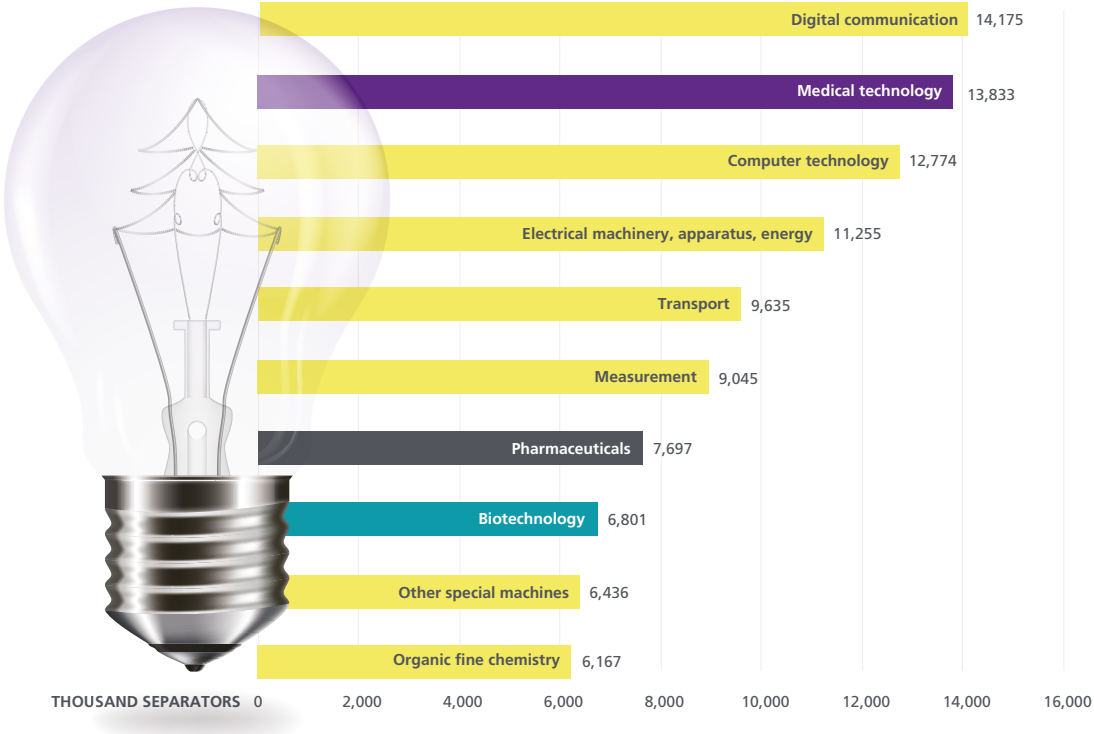


Figure 2 – Top 10 technical fields in patent applications

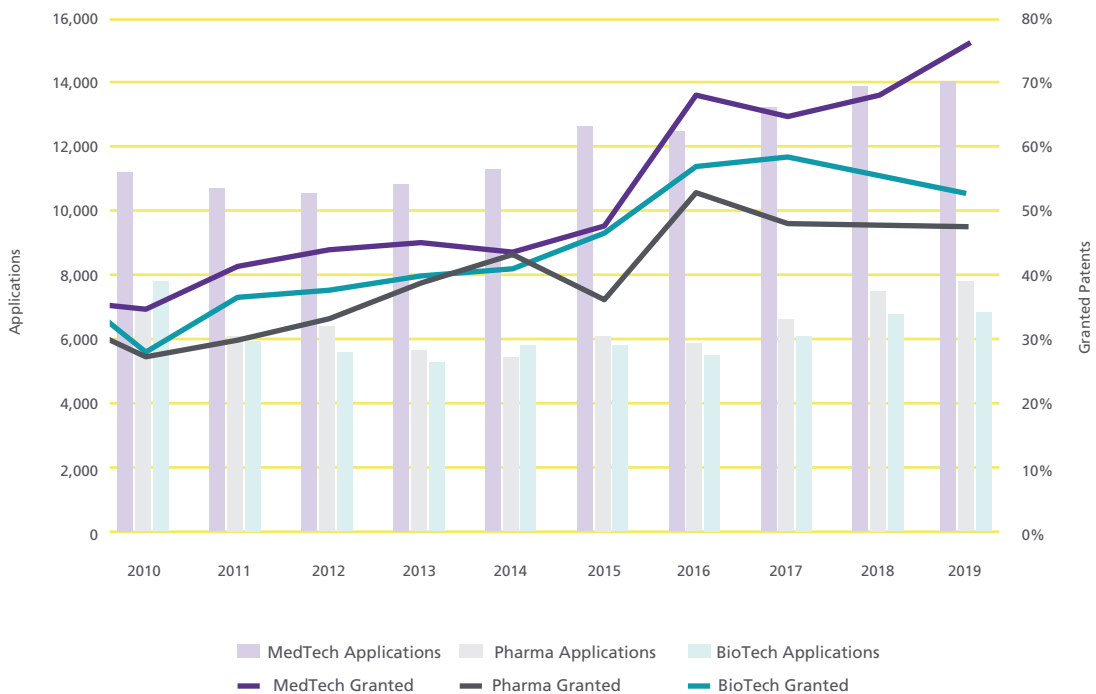
Number of patent applications filed with EPO, 2019 (ref. 2)



While over the last decade the number of EPO filings in the field of medical technology has doubled, pharma and biotech patent applications were relatively stagnant. Furthermore, the ratio of granted patents to patent applications in the medtech sector has been continuously growing in the past years reaching 76% in 2019. In comparison, this ratio is around 50% in the pharmaceutical and biotechnology field. (Figure 3)

Figure 3 – Evolution of European patents by technical field

(ref 2.)



Employment

The European medical technology industry employs directly more than 730,000 people[3]. Germany had the highest absolute number of people employed in the medical technology sector, while the number of medical technology employees per capita is highest in Ireland and Switzerland. In comparison, the European pharmaceutical industry employs around 765,000 people[4].

The jobs created by the medical technology industry account for around 0.3% of total employment in Europe.[5] These jobs are also highly productive, as the value added per employee is estimated to reach €160,000 per employee. These indicators show that the medical technology industry has an important economic and societal impact in Europe.

Figure 4 – Top 10 European countries with highest medtech employment

Direct employment in the medical technology industry in 2018, or latest year available (ref. 3)

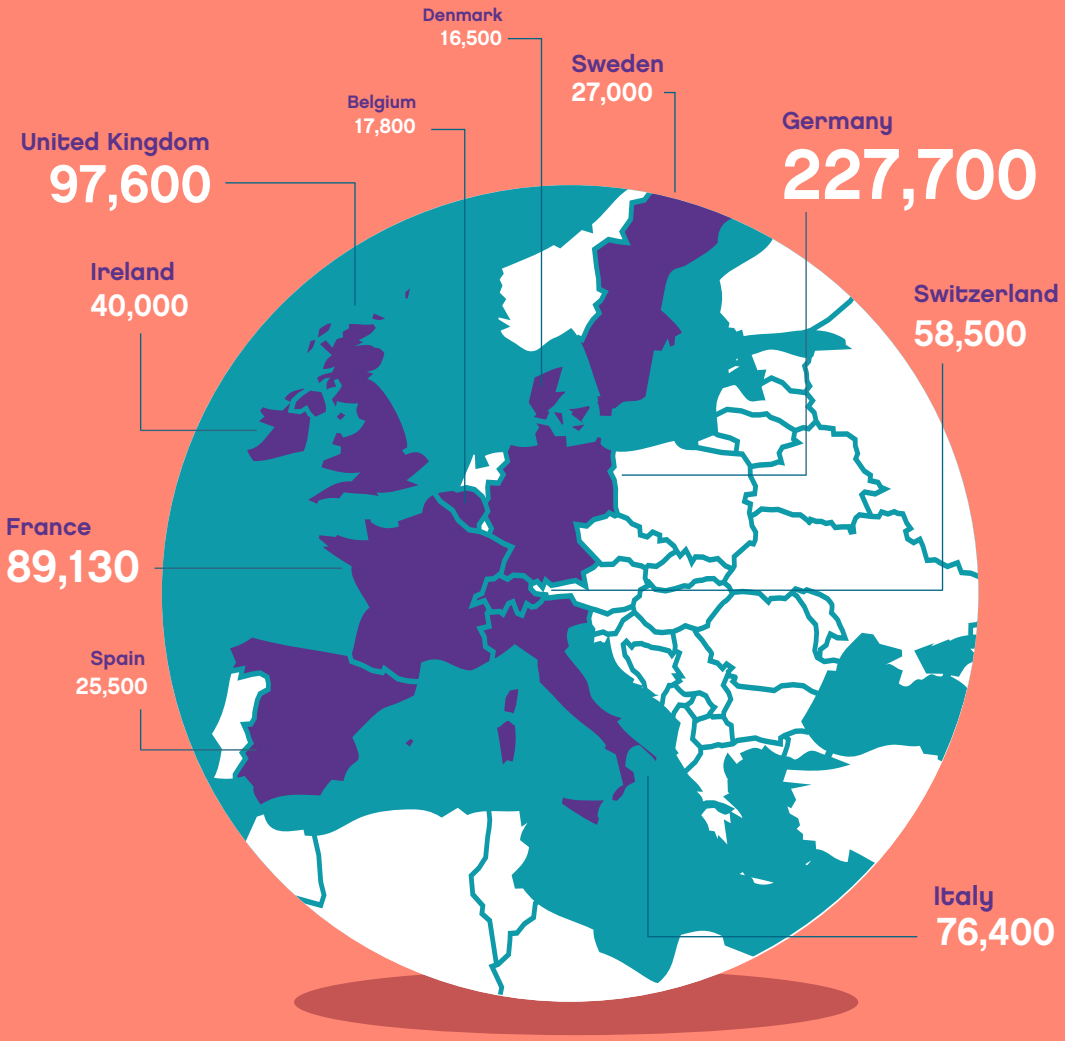
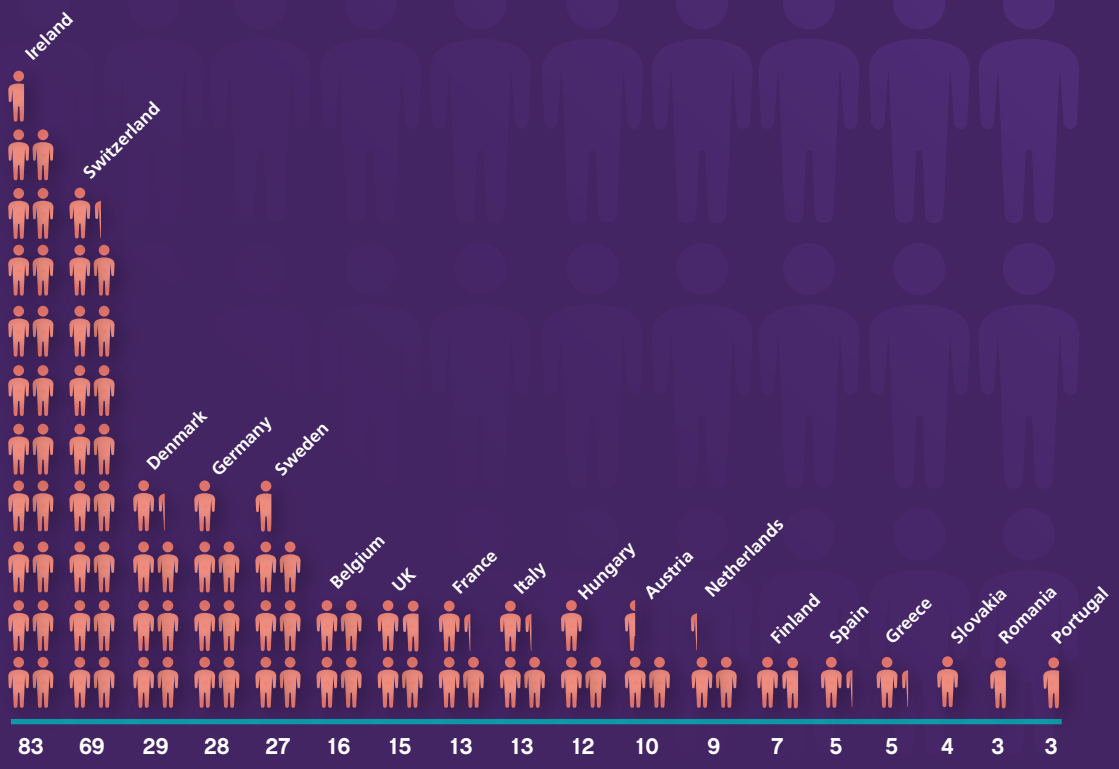
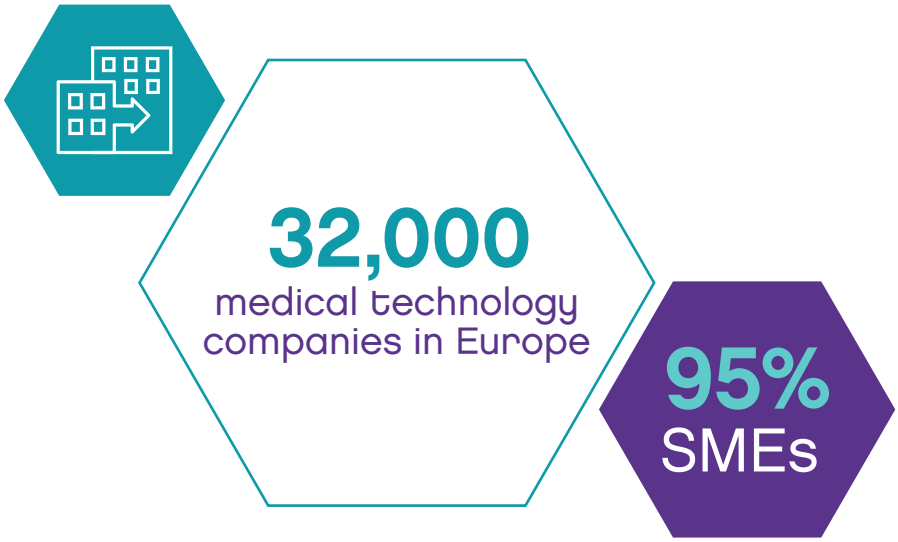


Figure 5 – Number of people directly employed in the medical technology industry per 10,000 inhabitants

2018 or latest year available (ref. 3)

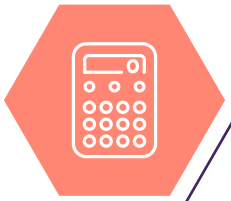


Companies



There are more than 32,000 medical technology companies in Europe.
The highest number of them are based in Germany, followed by Italy, the UK, France and Switzerland. Small and medium-sized companies (SMEs) make up around 95% of the medical technology industry, the majority of which employ less than 50 people (small and micro-sized companies)[3].

Expenditure on Medical Technology



€225

Expenditure on medical technology per capita in Europe

In Europe, an average of approximately 10% of gross domestic product (GDP) is spent on healthcare. Of this figure, around 7.4% is attributed to medical technologies, i.e. less than 1% of GDP. The spending on medical technology is estimated to vary significantly across European countries, ranging from around 5% to 12% of the total healthcare expenditure. Expenditure on medical technology per capita in Europe is at around €225 (weighted average).*

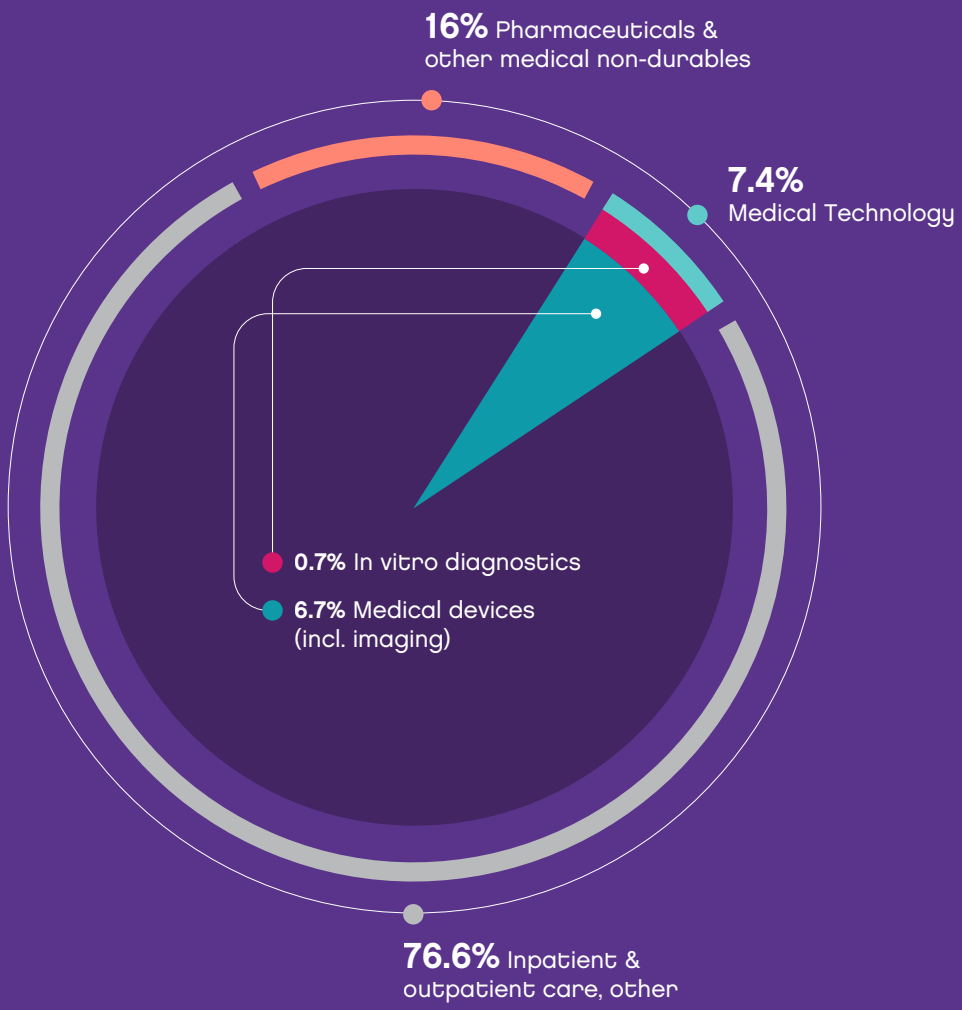
10%

of GDP spent on healthcare

* *Medtech Europe calculation based on sources 4-8.*

Figure 6 – Breakdown of total healthcare expenditure in Europe

2018 (ref. 4–8)




CYTOSINE
GUANINE
ADENINE
THYMINE
Cardiovascular diseases
Pulmonary disease
Diseases of the digestive system
Liver disease
Diseases of the musculoskeletal system
Neurological diseases

MedTech Market in Europe

€120
billion market

The European medical technology market is estimated at roughly €120 billion in 2018.[7,8]

The biggest medical device markets in Europe are Germany, France, the United Kingdom, Italy and Spain. The same group of countries form the top 5 IVD markets in Europe. (Figures 7 and 8)

Based upon manufacturer prices the European medical device market is estimated to make up 27% of the world market. It is the second largest medical device market after the US (around 43%).[8]

27%
of the world market

2nd
largest market after US

Figure 7 – European medical device market by country

2018 (ref. 8)

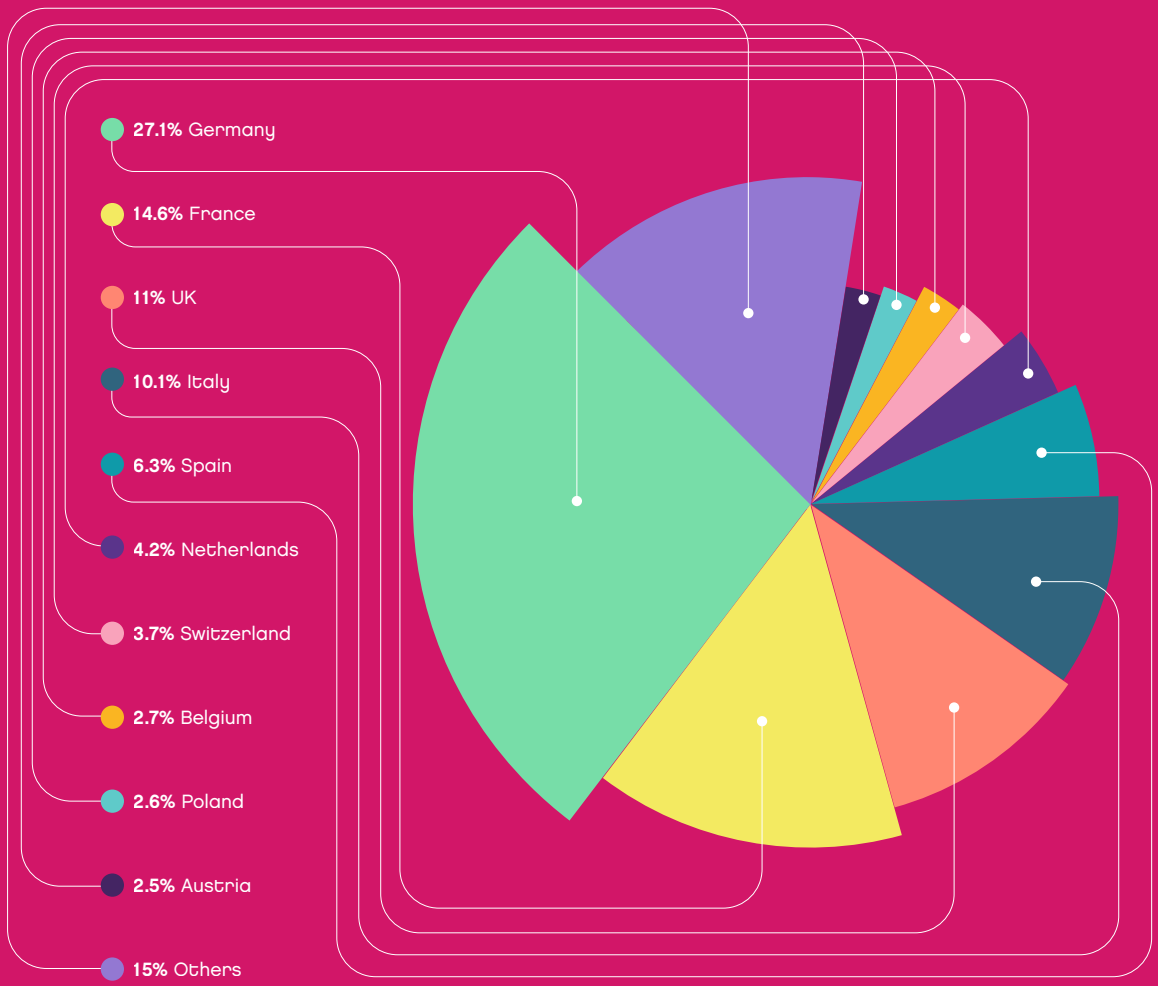


Figure 8 – European IVD market by country

2018 (ref. 7)

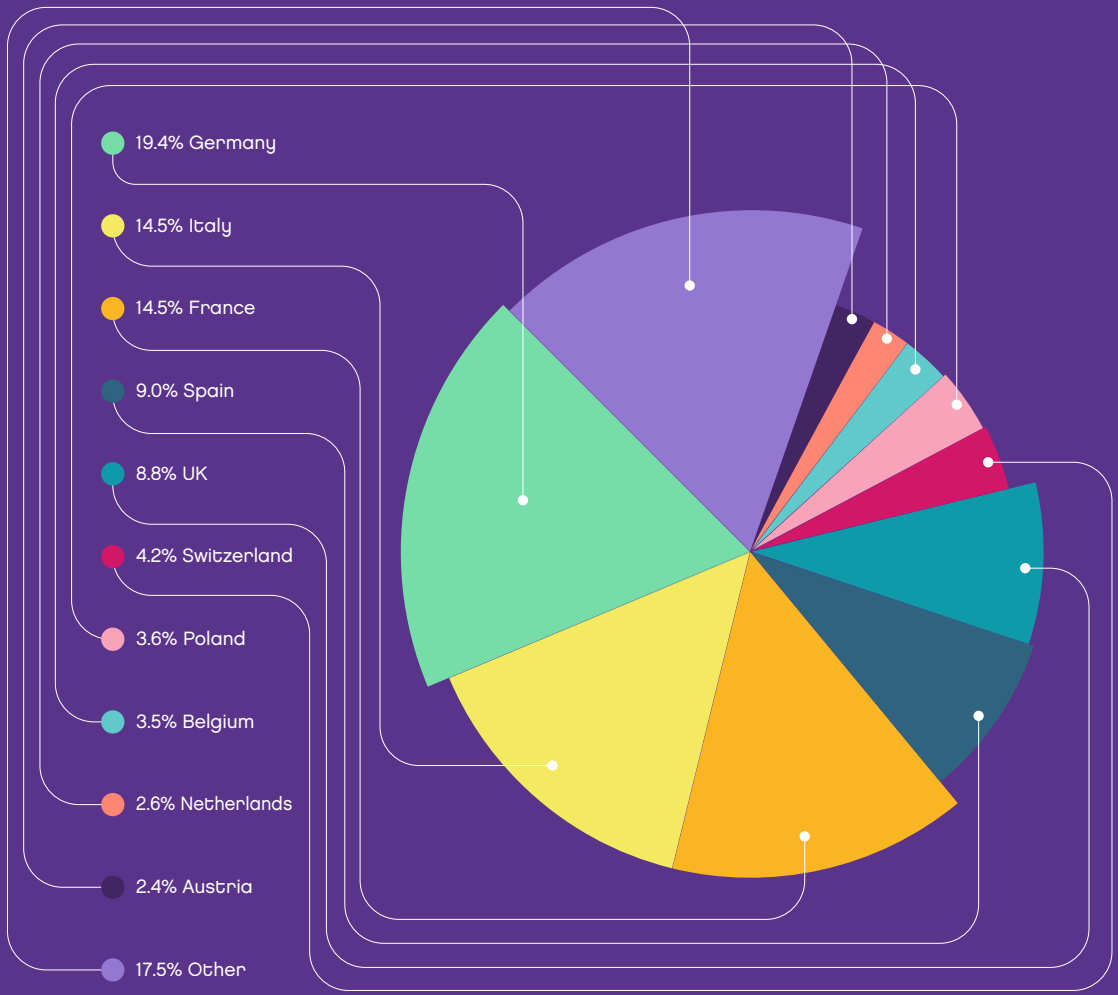


Figure 9 – Europe in the global medical device market

2018 (ref. 8)

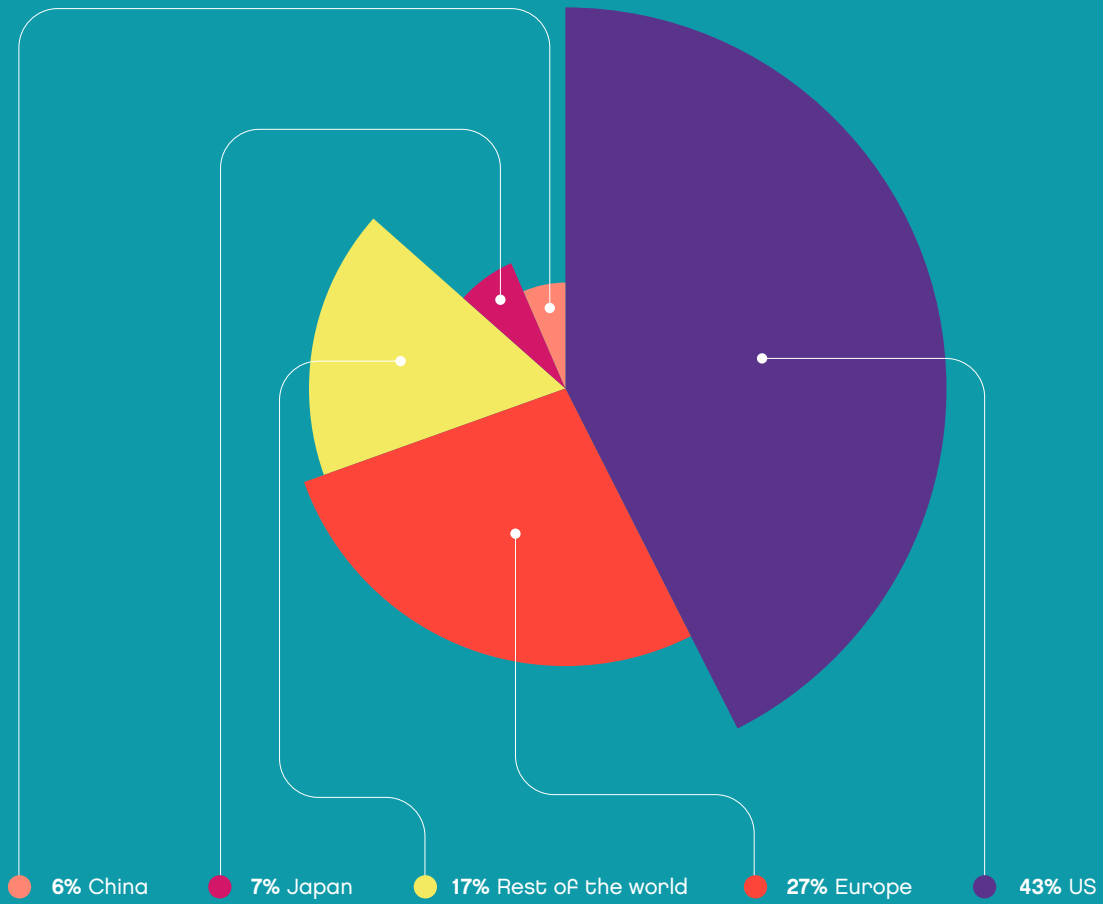
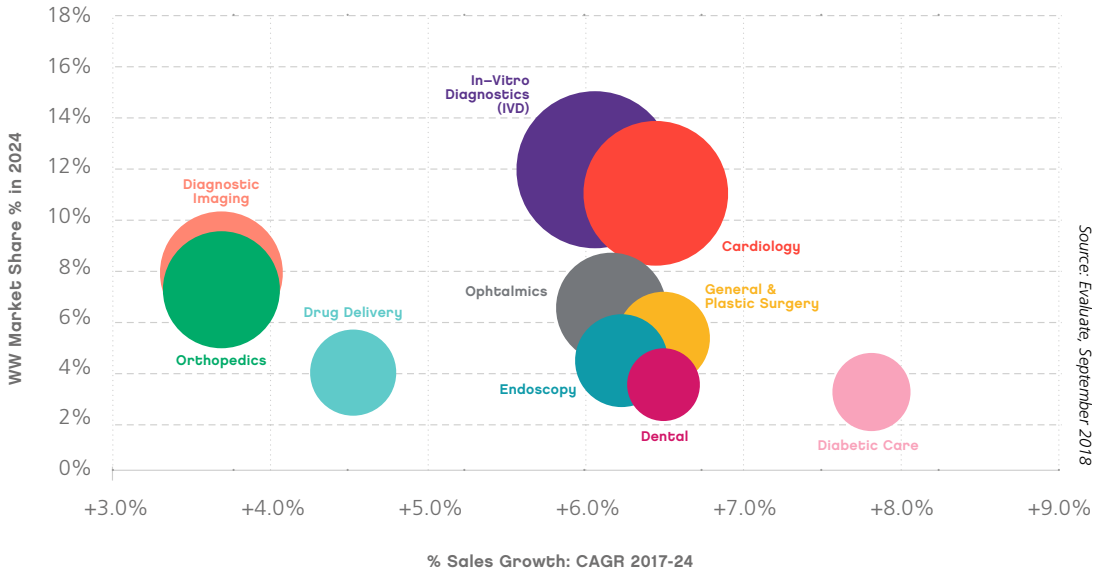


Figure 10 – World medical technology market by area and sales growth

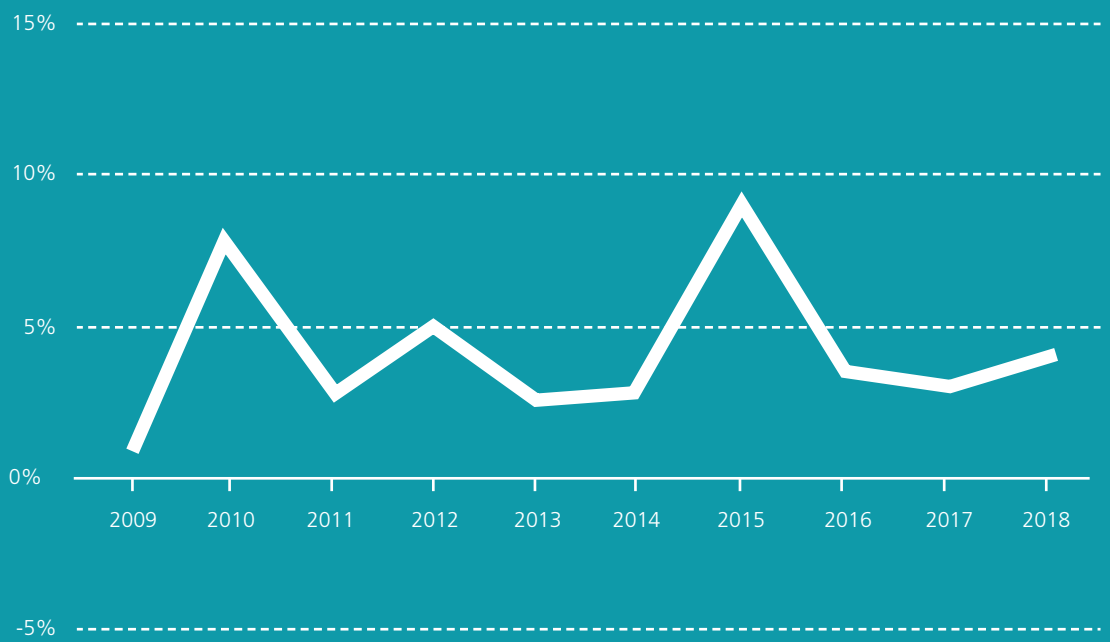
2017-2024 (ref. 1)



Medical technology offers solutions for many disease areas. On a worldwide perspective, in vitro diagnostics (IVD) are the largest sector, followed by cardiology and diagnostic imaging.[1]

Figure 11 – European medical device market growth rates

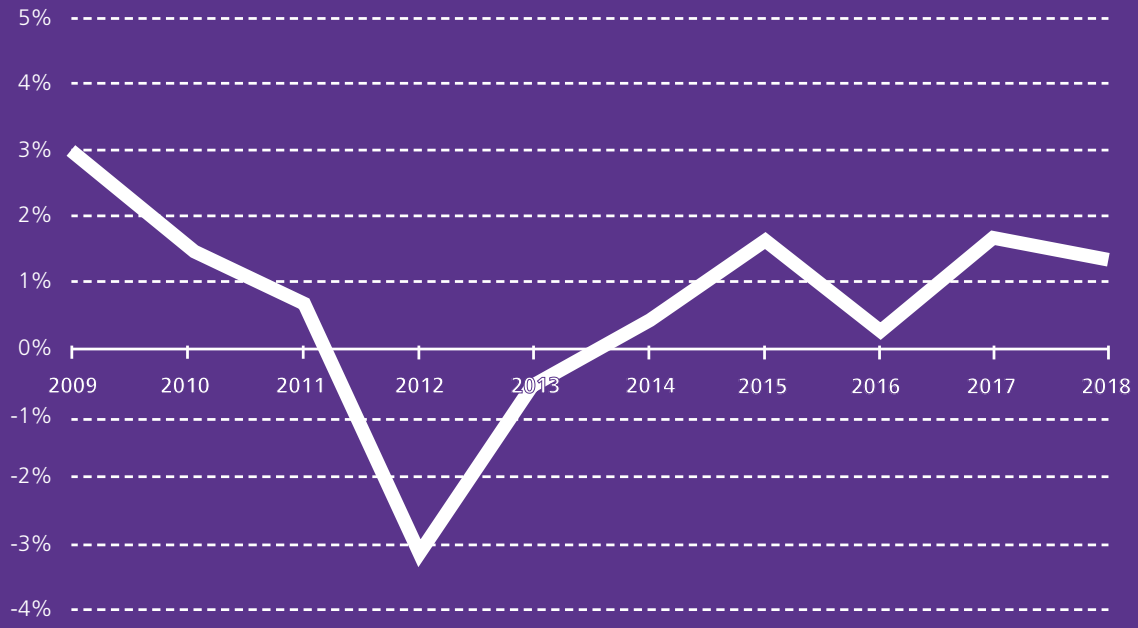
2009-2018 (ref. 8)



The European medical device market has been growing on average by 4.2% per annum over the past 10 years. Demand fell in 2009 due to the economic crisis, resulting in a growth rate of only 1%. The market recovered in 2010, since then the annual growth rate has varied between 2.6 and 9.3% in the European medical device market.[7]

Figure 12 – European IVD market growth rates

2009-2018 (ref. 7)



The European IVD market growth has been slowing down until 2013, while annual growth rates in the pre-crisis period were at around 2-4%. In 2013 the European market started to recover and the annual growth rate in 2018 was around 1%.

Trade in Europe

€11.7 billion

Estimation of Europe's trade surplus in 2018

Europe has a positive medical devices trade balance of €11.7 billion (2018). Compared to the previous years, the main European medical device trade partners remain the same: the US, China, Japan and Mexico.[9]

Medical devices trade balance of individual countries varies a lot across Europe as shown in Figures 15 and 16. Based on export and import values including European intra-community trade, the international trade balance indicator is highest in Ireland and Germany followed by Switzerland and the Netherlands.

Figure 13 – Top export destinations of the European medical devices market

2018 (ref. 9)

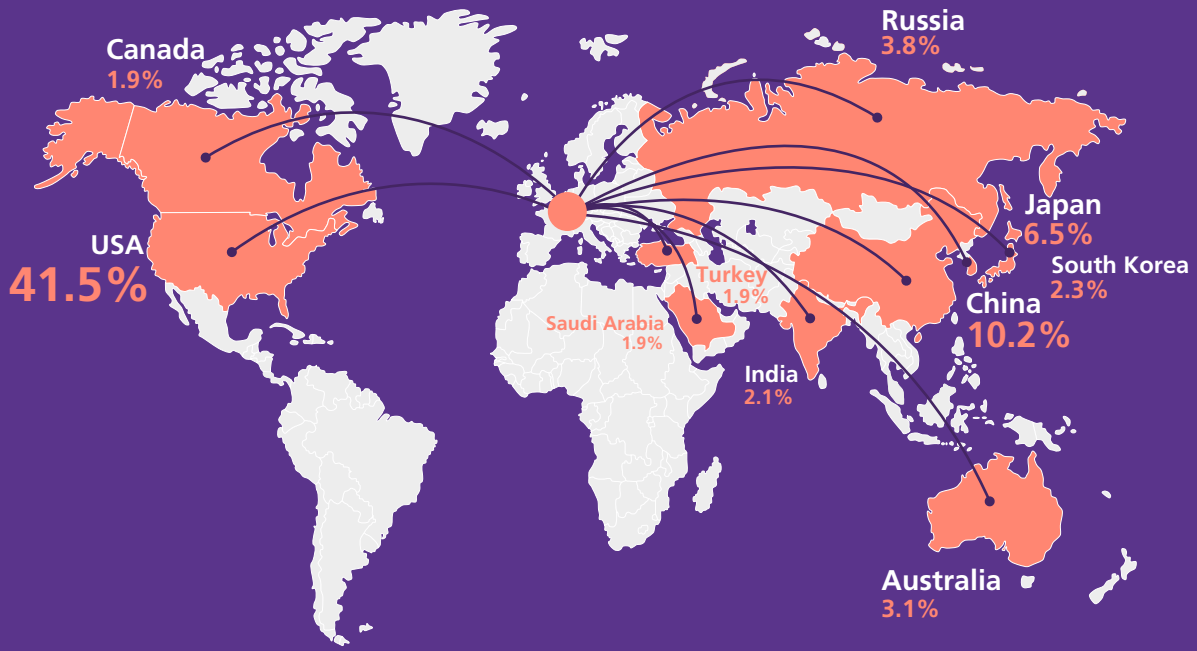


Figure 14 – Top import suppliers to the European medical devices market

2018 (ref. 9)

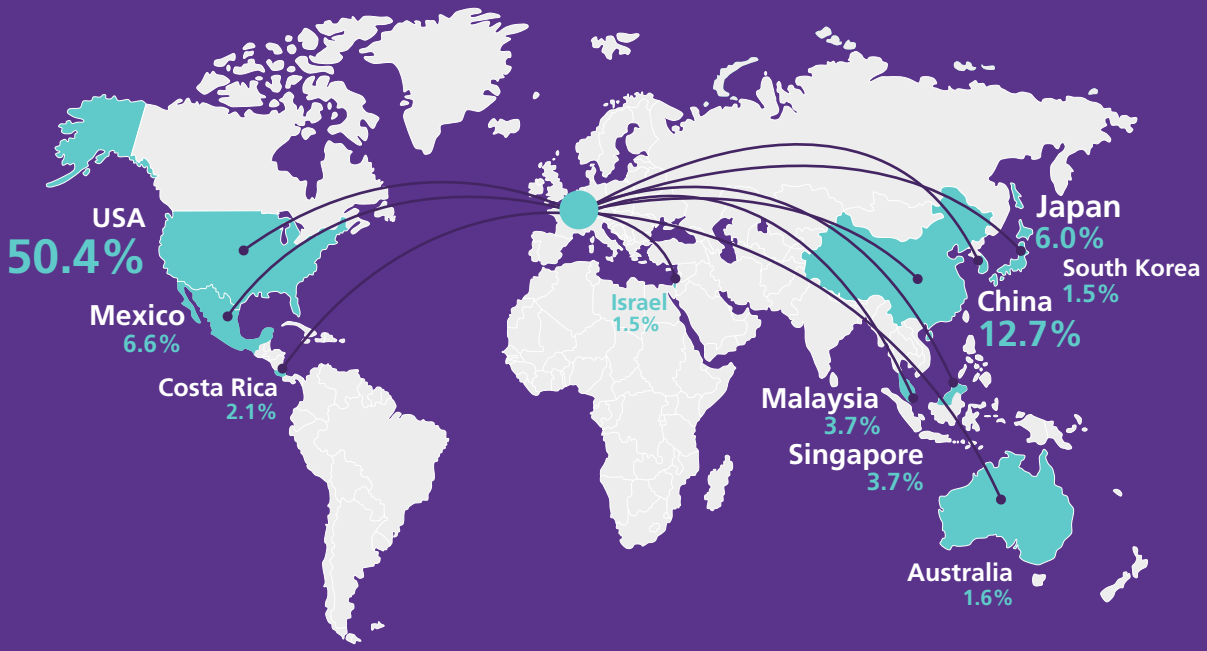


Figure 15 – Export and import of medical devices by country

Including intra-community trade, million euros, 2018 (ref. 9)

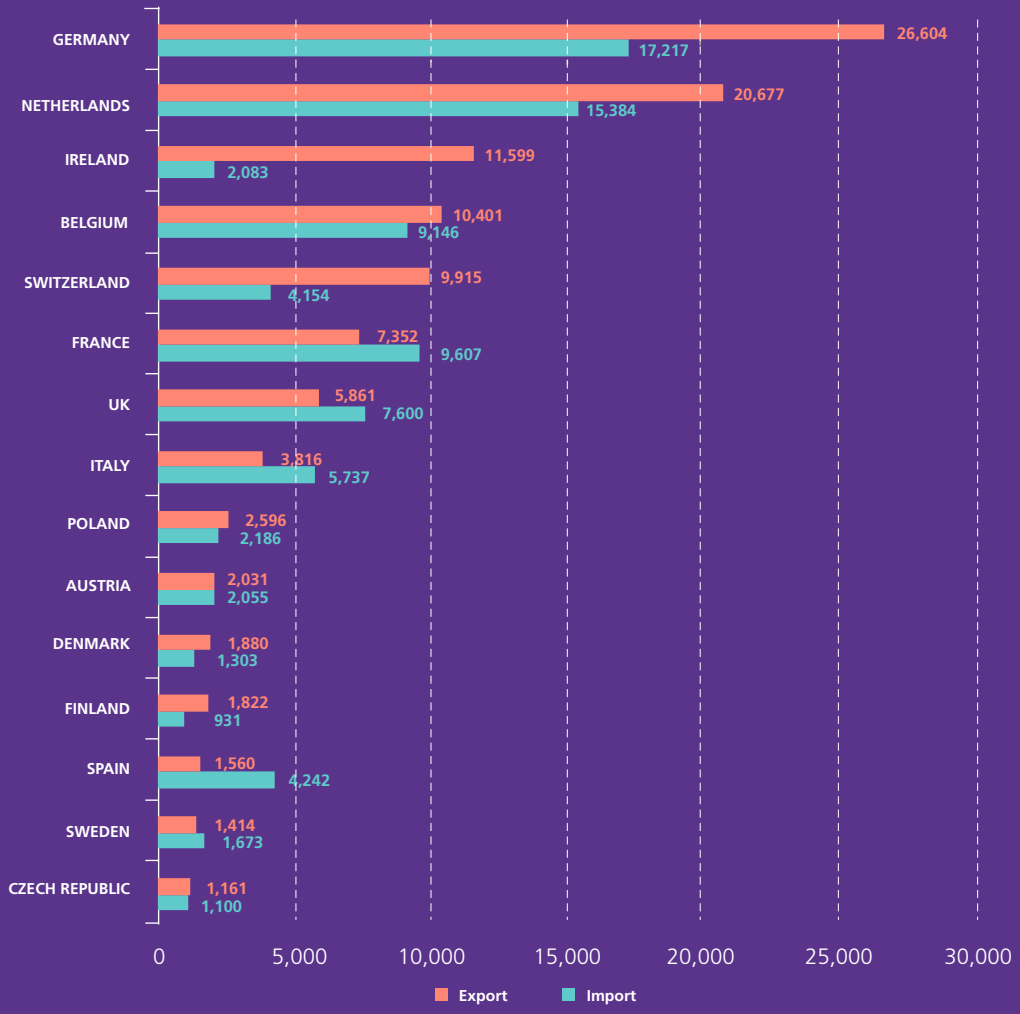
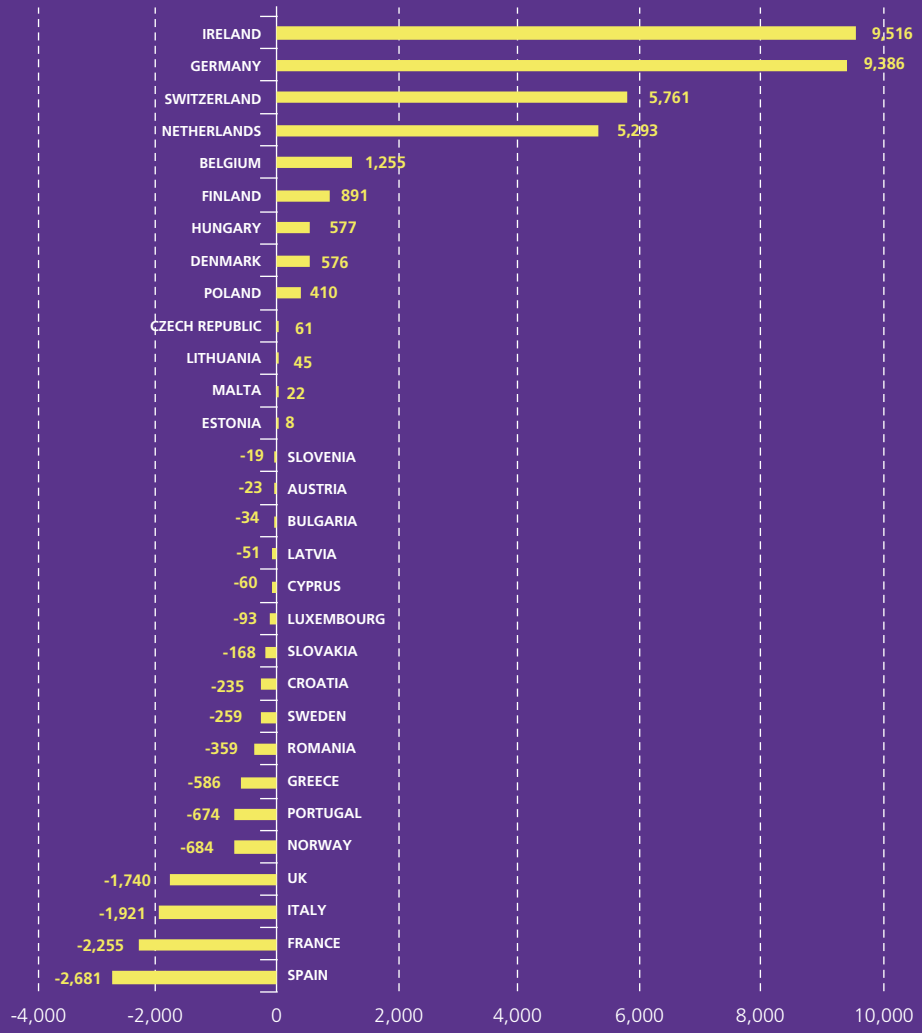


Figure 16 – Medical devices trade balance by country

Including intra-community trade, million euros, 2018 (ref. 9)



About MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure.

We represent diagnostics and medical devices manufacturers operating in Europe.

MedTech Europe's mission is to make innovative medical technology available to more people while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations. It also promotes medical technology's value for Europe focusing on innovation and stakeholder relations, using economic research and data, communications, industry events and training sessions.

MedTech Europe's Facts & Figures publication is an annually updated report with robust industry data compiled from multiple sources. The publication is used as the quintessential source of data by international stakeholders seeking an up-to-date view of industry innovation and employment, SME activity, expenditure on medical technology, trade and market size in Europe.

Scope of this report

- In this report Europe refers to EU27, Norway, Switzerland and the United Kingdom, unless specified otherwise.
- The Innovation chapter defines medical technology following the methodology of the World Intellectual Property Organization (based on the WIPO IPC-Technology concordance as revised in August 2014).
  Patents are attributed by the country of residence of the applicant. EPO countries refer to the 38 member states of the European Patent Organisation.
- The Employment and Companies chapters are based on data from the 2019 survey carried out among MedTech Europe's National Associations. Figures refer to 2018 or the latest year available.
  An enterprise is considered to be a SME if it employs fewer than 250 persons and has an annual turnover not exceeding €50 million (small and micro-sized companies employ fewer than 50 persons and have a turnover of less than €10 million).
- The Expenditures on Medical Technology chapter is based on MedTech Europe calculations using healthcare statistics from the following sources: EFPIA, Eurostat, Fitch Solutions, WHO.
- The MedTech Market in Europe chapter is based on manufacturers' sales (revenue) not including margins, such as value added in the wholesaling and retailing, transportation costs, some taxes included in the final price, etc.
- The Trade in Europe chapter data refers to the medical technology products in the following categories, excluding in vitro diagnostics: orthopaedics & prosthetics, patient aids, dental products, diagnostics imaging, consumables, other medical devices (incl. wheelchairs, ophthalmic instruments, hospital furniture, medical & surgical sterilisers, ultra-violet or infra-red ray apparatus, blood pressure monitors, endoscopy apparatus, dialysis apparatus, transfusion apparatus, anaesthetic apparatus & instruments).

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Members of HealthTech Ireland provide safe, effective and innovative health technologies that save and enhance lives, benefiting people and society.

HealthTech Ireland
ASSOCIATION

HealthTech Ireland
Kandoy House, 2 Fairview Strand, Dublin 3

Tel: + 353 (0)1 484 7828
Fax: + 353 (0)1 484 7826
E-mail: admin@healthtechireland.ie
www. healthtechireland.ie

HealthTech Ireland is an independent trade association for manufacturers, developers and distributors of health technology products and solutions to the health system in Ireland.