The European Medical Technology Industry

– in figures 2019

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 empower 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

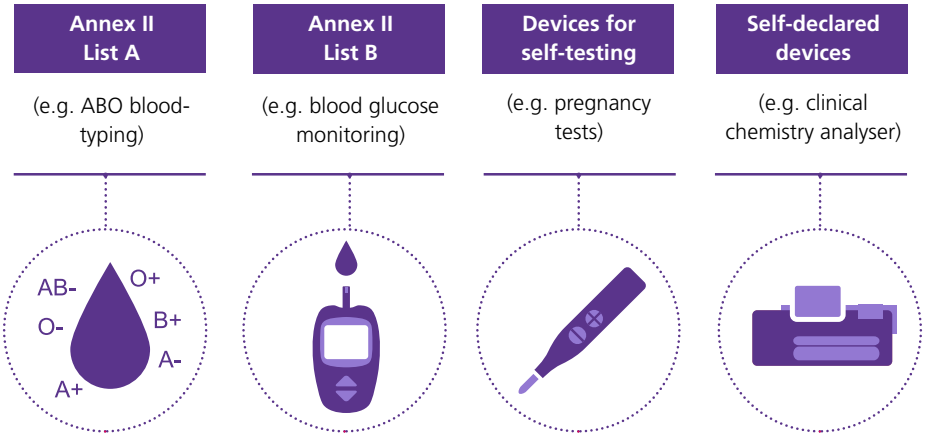
by laws that govern the safety and performance of devices across their lifetime, pre- and post-market. Over the next few years, the European medical technology sector will transition from being regulated under the current medical devices directives to two new regulations.

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:



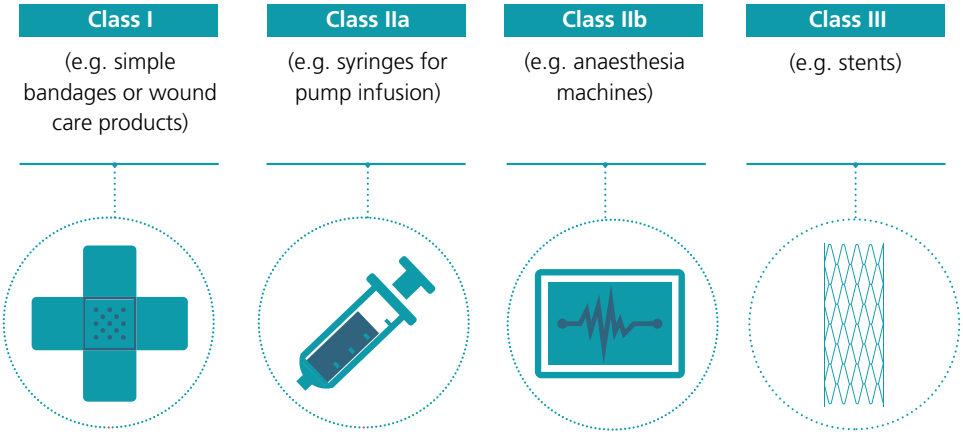
Under the IVD Regulation, all IVDs will be classified under a new risk-based classification system according to the risk the device poses to the health of the public and or an individual as result of an incorrect test result. All IVDs will be classified under class A, B, C or D, with class D being the 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 2020, 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 in the market depends on the level of impact on the human body that their use might imply. The same notified body 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 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. Products typically have a lifecycle of only 18-24 months before an improved product becomes available.

In 2017, more than 13,000 patent applications were filed with the European Patent Office (EPO) in the field of medical technology – 7.9% of the total number of applications –, still more than any other sector in Europe. 40% of these patent applications were filed from European countries (EU28, Norway and Switzerland) and 60% from other countries, out of which with the majority of applications filed from the US (37%).

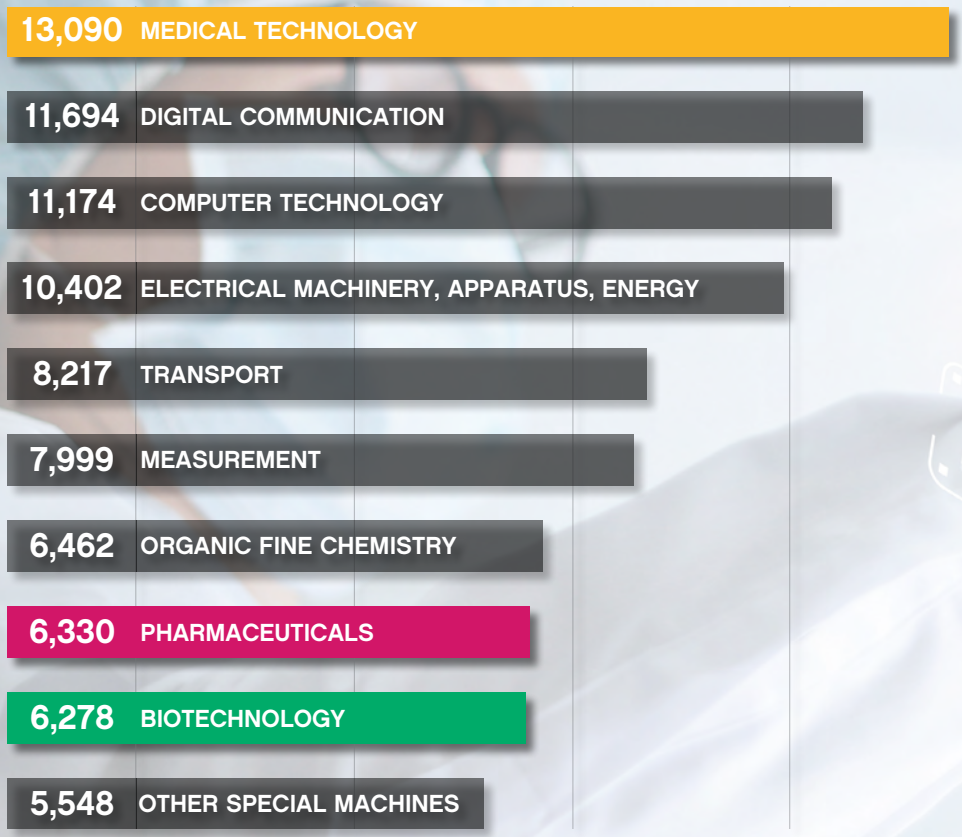
In comparison, around 6,300 applications were filed in the pharmaceutical field and also around 6,300 in the field of biotechnology. While over the last decade the number of EPO filings in the field of medical technology has doubled, pharma and biotech patent applications were relatively stagnant[1].

PATENT APPLICATION IN
MEDICAL TECHNOLOGY FIELD
FILLED WITH EPO IN 2016

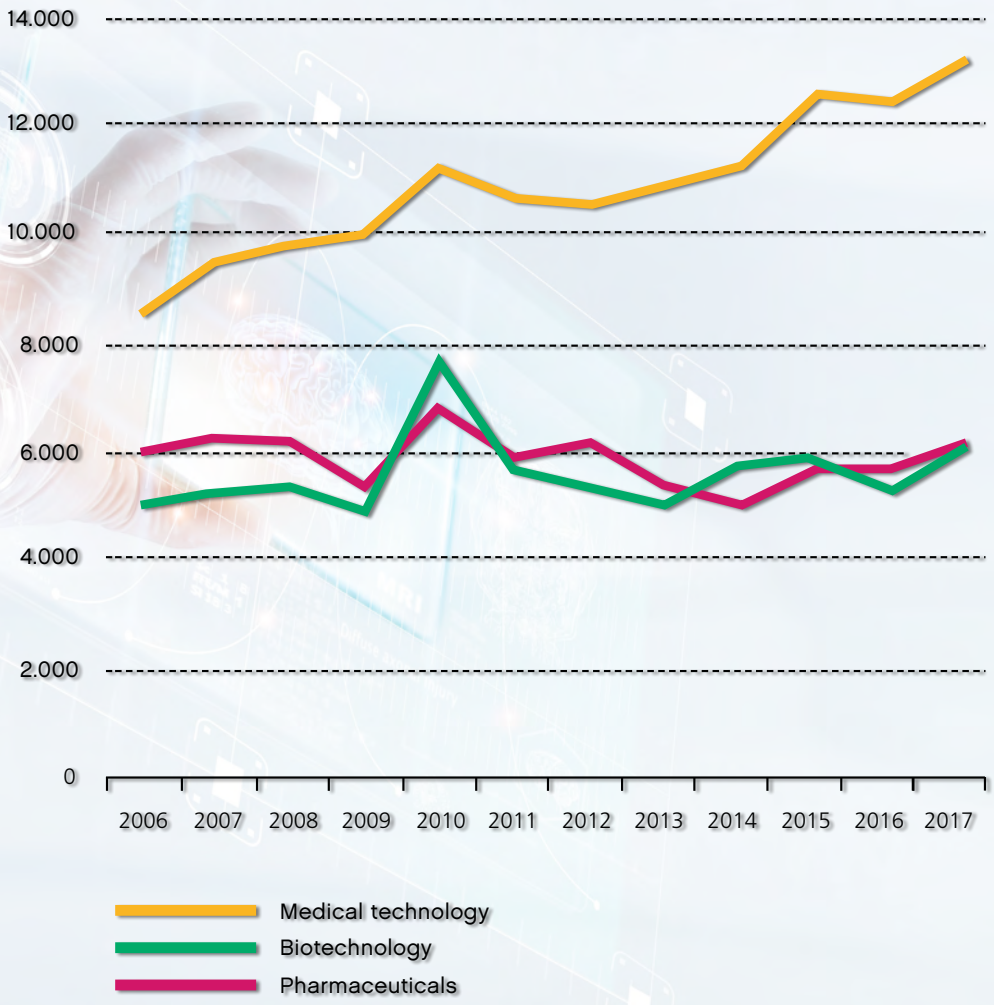
40%
EU28, Norway and Switzerland

60%
Other countries

Top 10 technical fields in patent applications. Number of patent applications filed with EPO, 2017 (ref. 1)



Evolution of European patent applications by technical field, 2017 (ref. I)



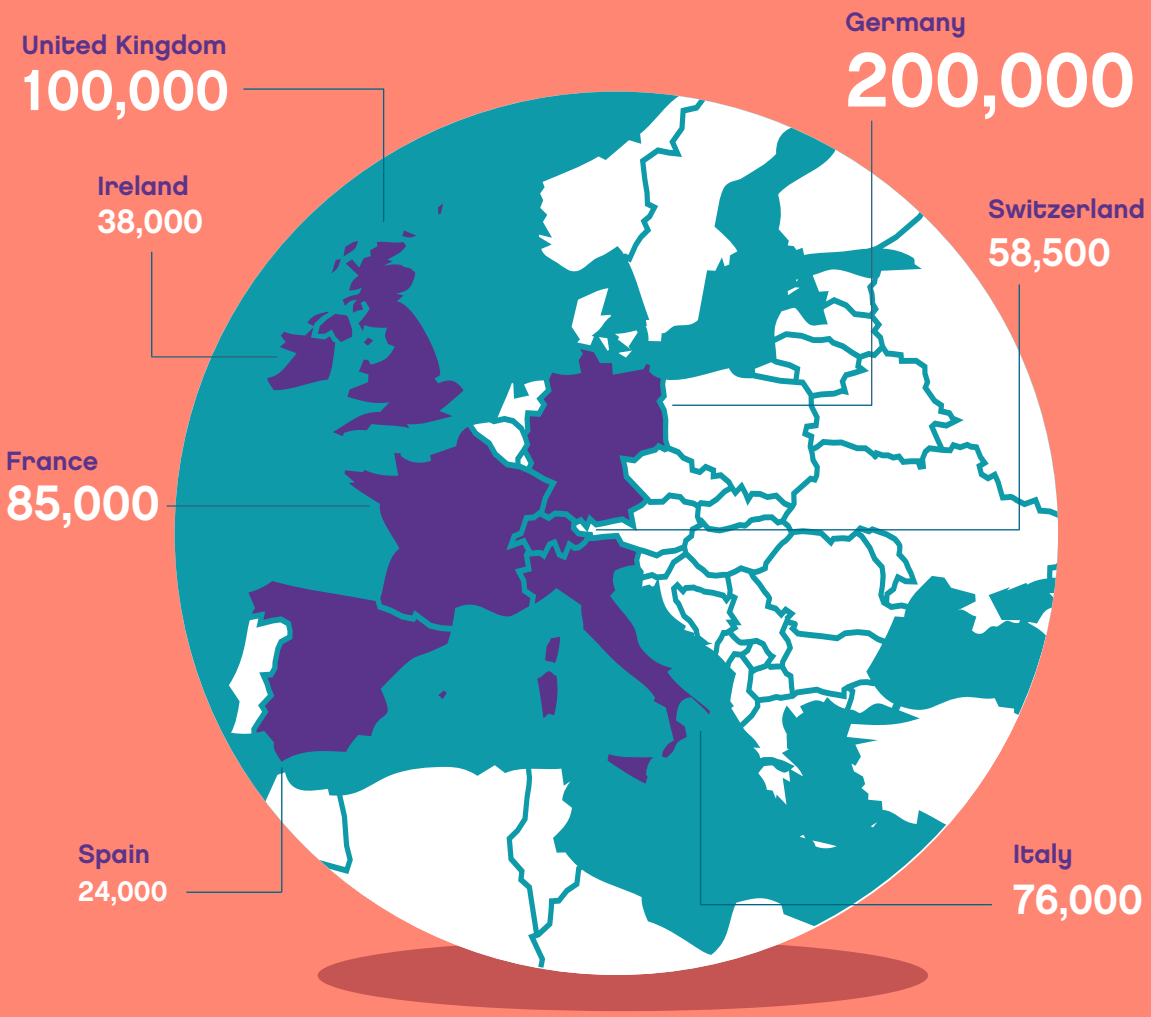
Employment

The European medical technology industry employs directly more than 675,000 people. Germany has the highest absolute number of people employed in the medical technology sector, while the number of medtech employees per capita is highest in Ireland and Switzerland. This high level of employment shows that the medical technology industry is an important player in the European economy.

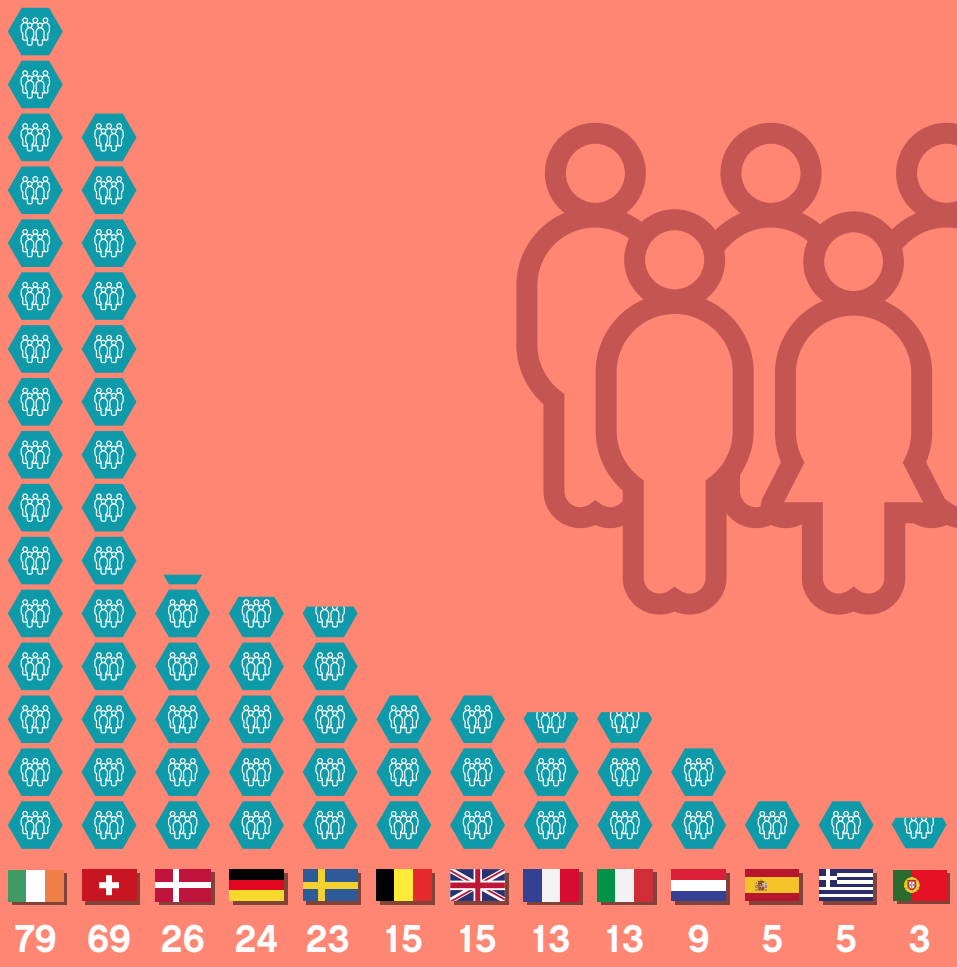
In comparison, the European pharmaceutical industry employs more than 750,000 people[2].

Europe refers to EU 28, Norway and Switzerland unless specified otherwise.

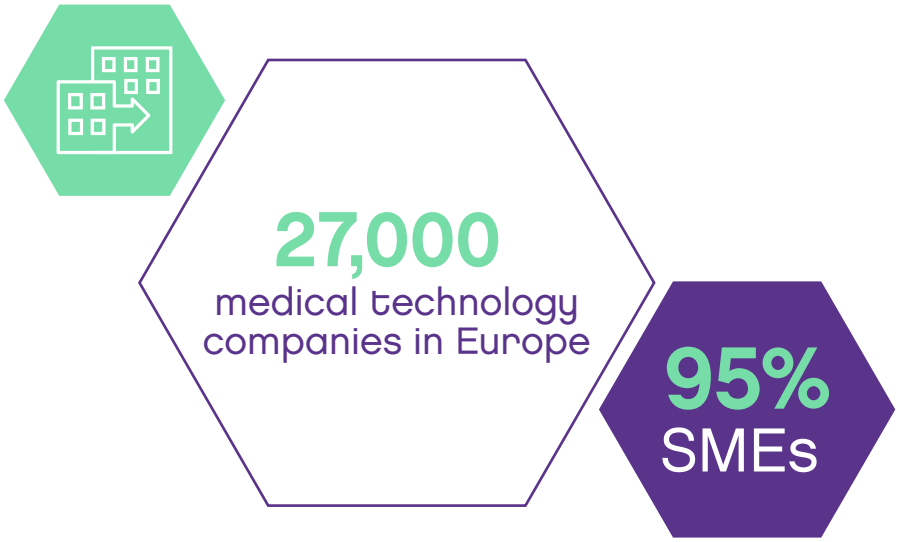
Top 7 countries with highest direct employment in the medical technology industry, 2017 (ref. 3)



Number of people directly employed in the medical technology industry per 10,000 inhabitants, 2017 (ref. 3)



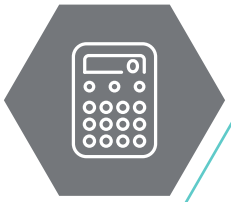
Companies



There are almost 27,000 medical technology companies in Europe. Most of them are based in Germany, followed by the UK, Italy, Switzerland, Spain and France. 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].

**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 company- employs fewer than 50 persons and has a turnover of less than €10 million).*

Expenditures on Medical Technology



€213

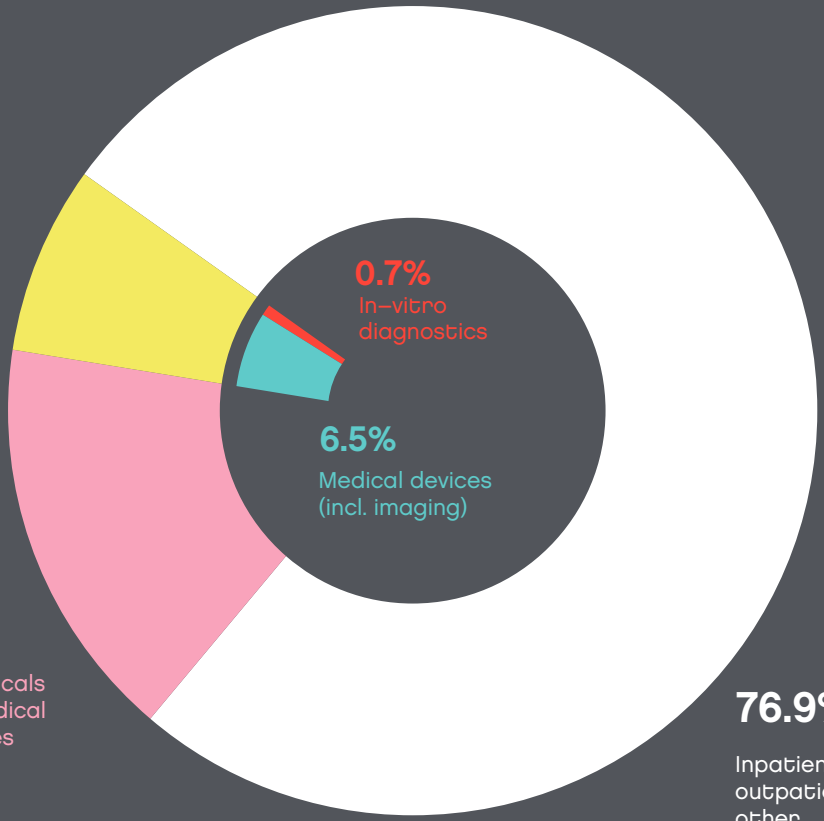
Expenditure on medical technology per capita in Europe

In Europe, an average of approximately 10% of gross domestic product (GDP) is spent on healthcare. Out of the total healthcare expenditure, around 7.2% 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 10% of the total healthcare expenditure[4]. Expenditure on medical technology per capita in Europe is at around €213 (weighted average).

10%

of GDP spent on healthcare

Breakdown of total healthcare expenditure in Europe, 2017 (ref. 5)



MedTech Market in Europe

€115
billion market

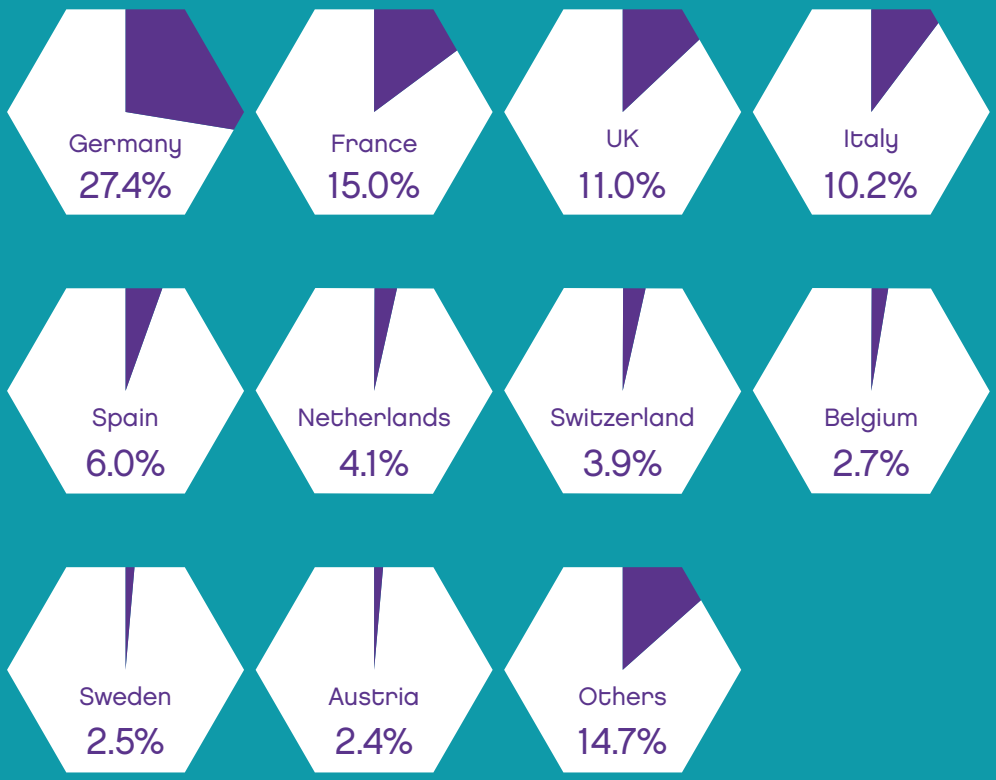
The European medical technology market is estimated at roughly €115 billion in 2017.

Based upon manufacturer prices, the European medical technology market is estimated to make up 27% of the world market. It is the second largest medical technology market after the US (+/- 43%)[6].

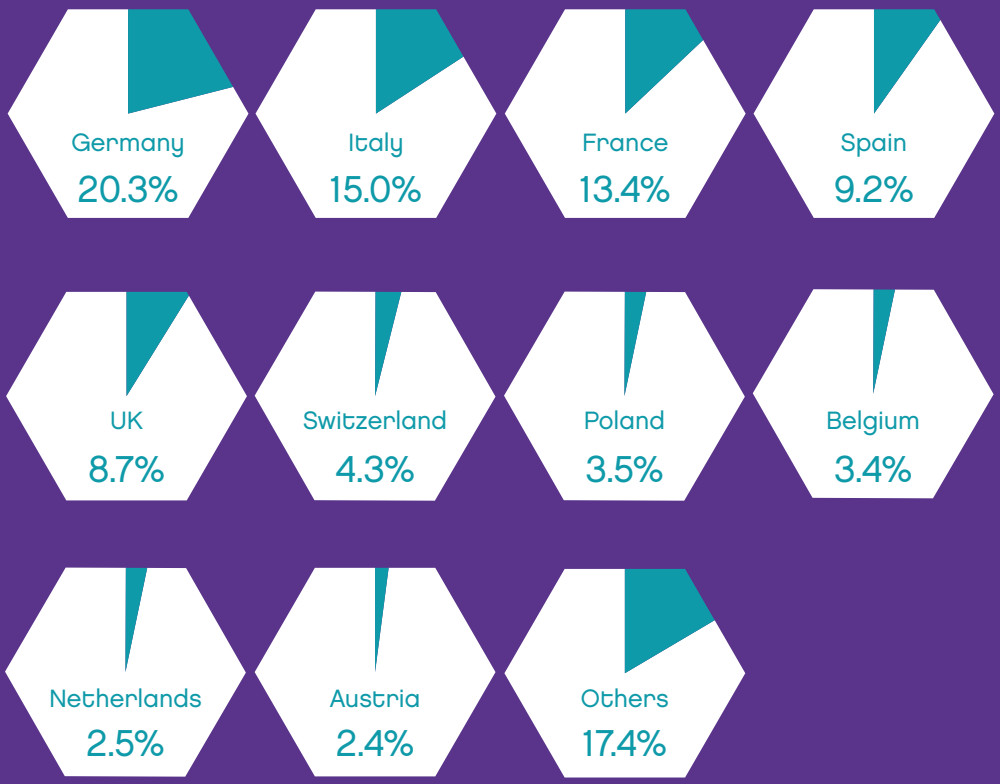
27%
of the world market

2nd
largest market after US

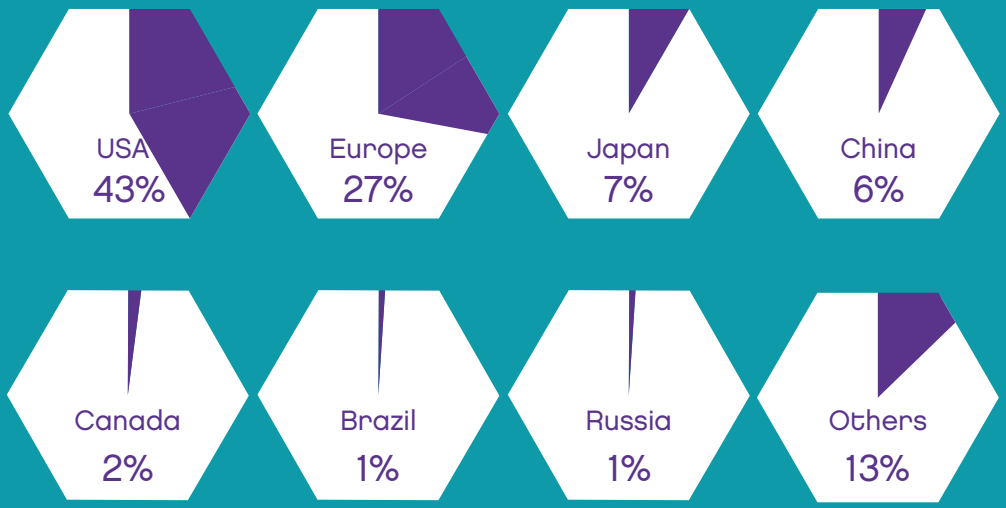
European medical device market by country, based upon manufacturer prices, 2017 (ref. 6)



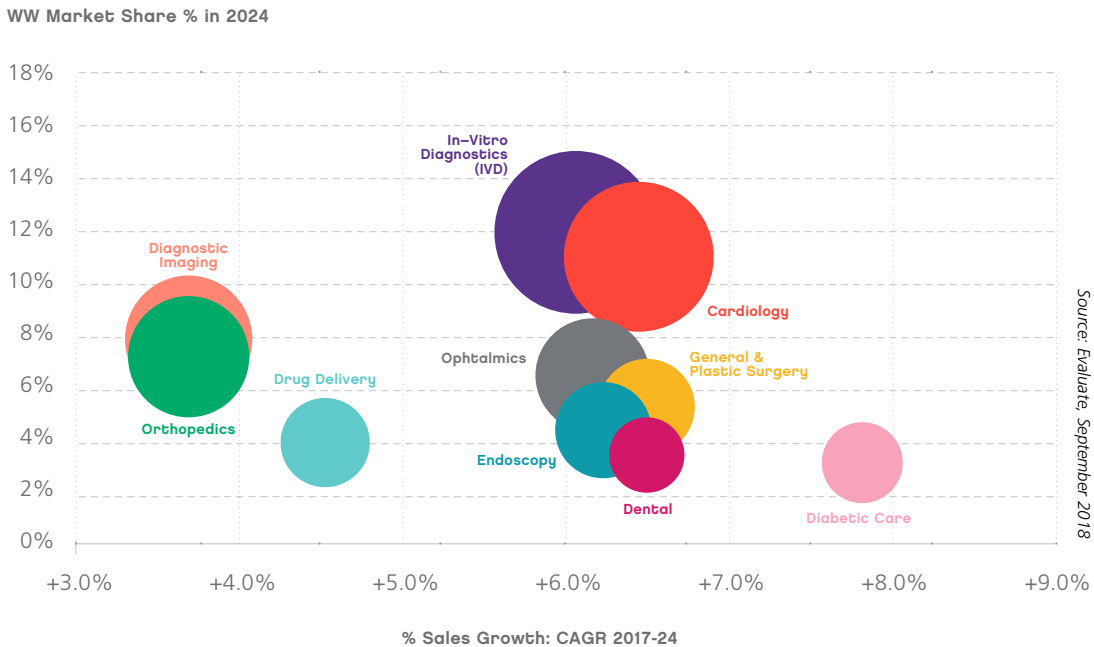
European IVD market by country, 2017 (ref. 7)



World medical device market by region based upon manufacturer prices, 2017 (ref. 6)

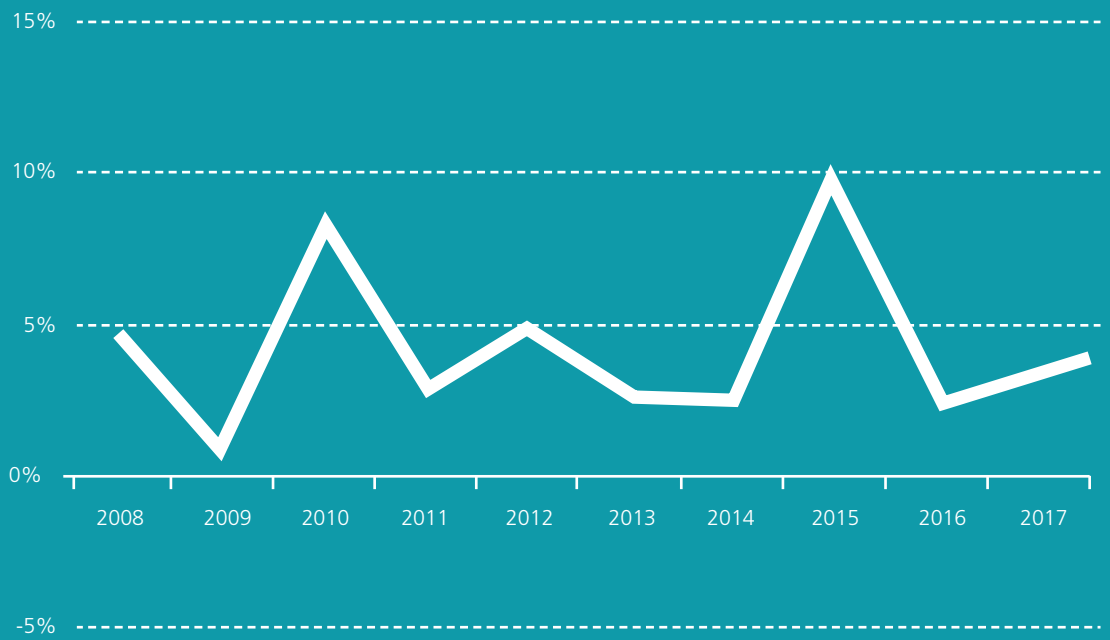


World medical technology market by area and sales growth, 2017-2024 (ref. 8)



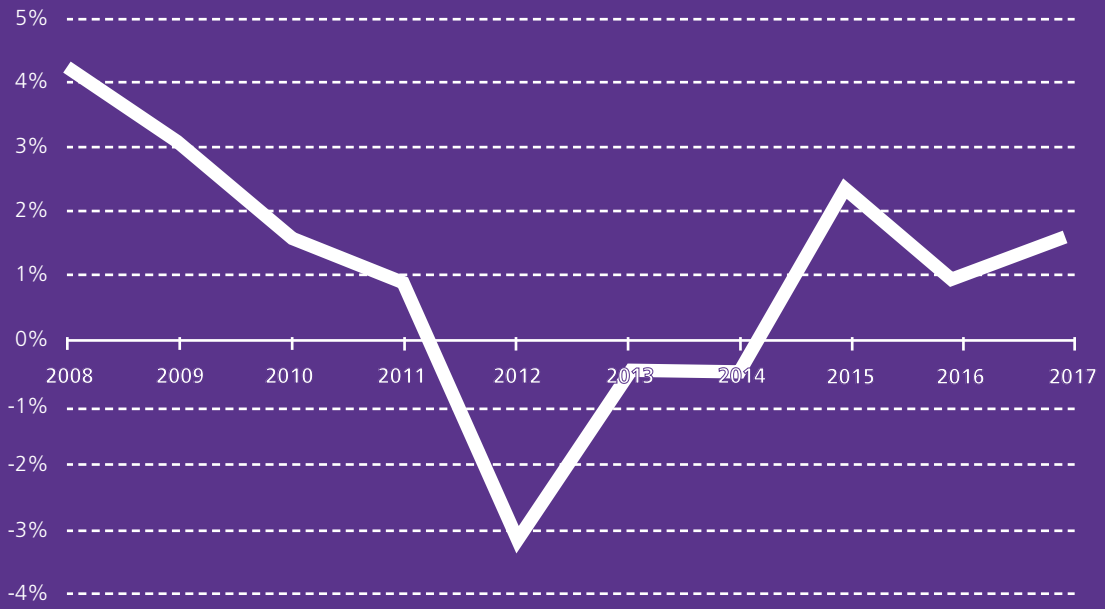
Medical technology offers solutions for many disease areas. On a worldwide perspective, in–vitro diagnostics are the largest sector, followed by cardiology and diagnostic imaging.

European medical device market growth rates, based upon manufacturer prices, 2008-2017 (ref. 6)



The European medical device market has been growing on average by 4.3% 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, but growth rates fell back in 2011. In general, there is ever since a 2-5% growth per annum.

European IVD market growth rates, 2008-2017 (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 2017 was around 1%.


Trade in
Europe

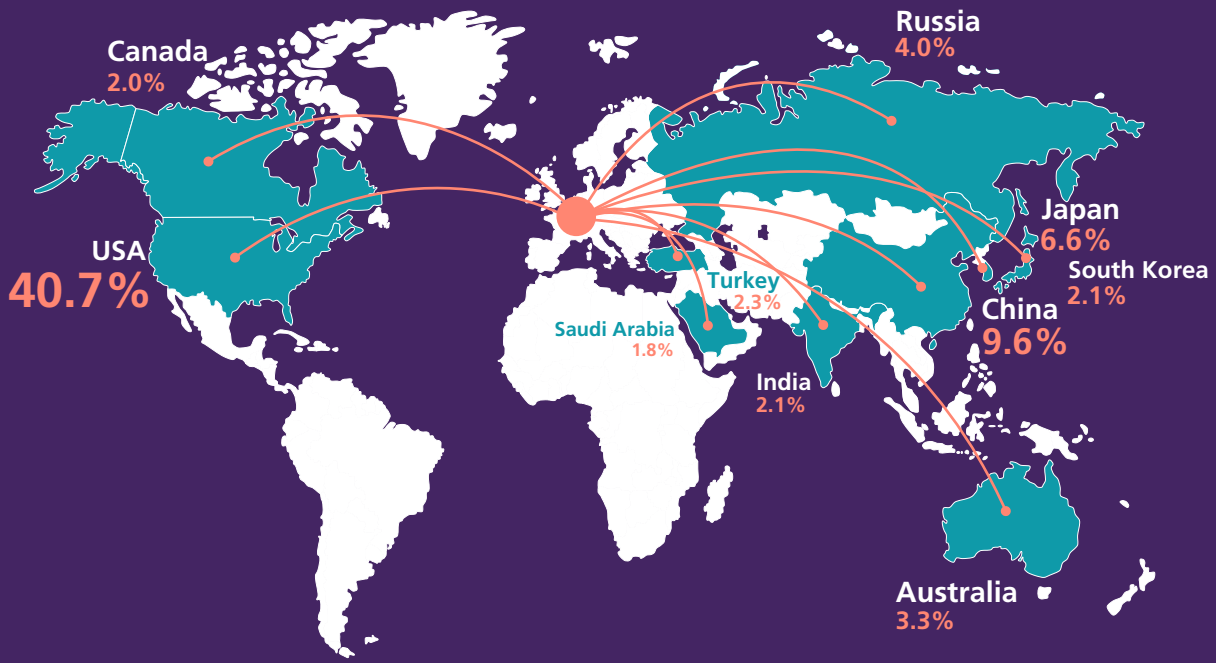
€19.7 billion

Estimation of Europe's trade surplus in 2017

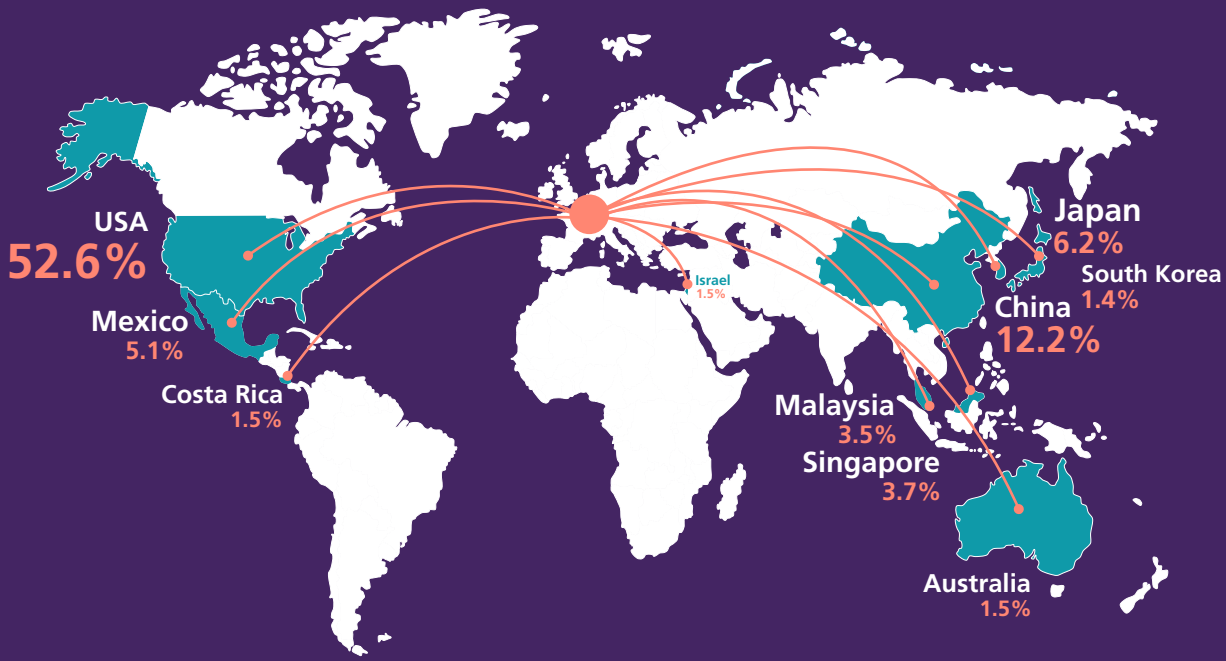
Europe has a positive medical devices trade* balance of €19.7 billion (2017). In comparison, US medical devices trade surplus is at €2 billion. Compared to the previous years, the main European medtech trade partners remain the same: the US, China and Japan[6].

**Trade section does not include in–vitro diagnostics in the figures for medical technology.*

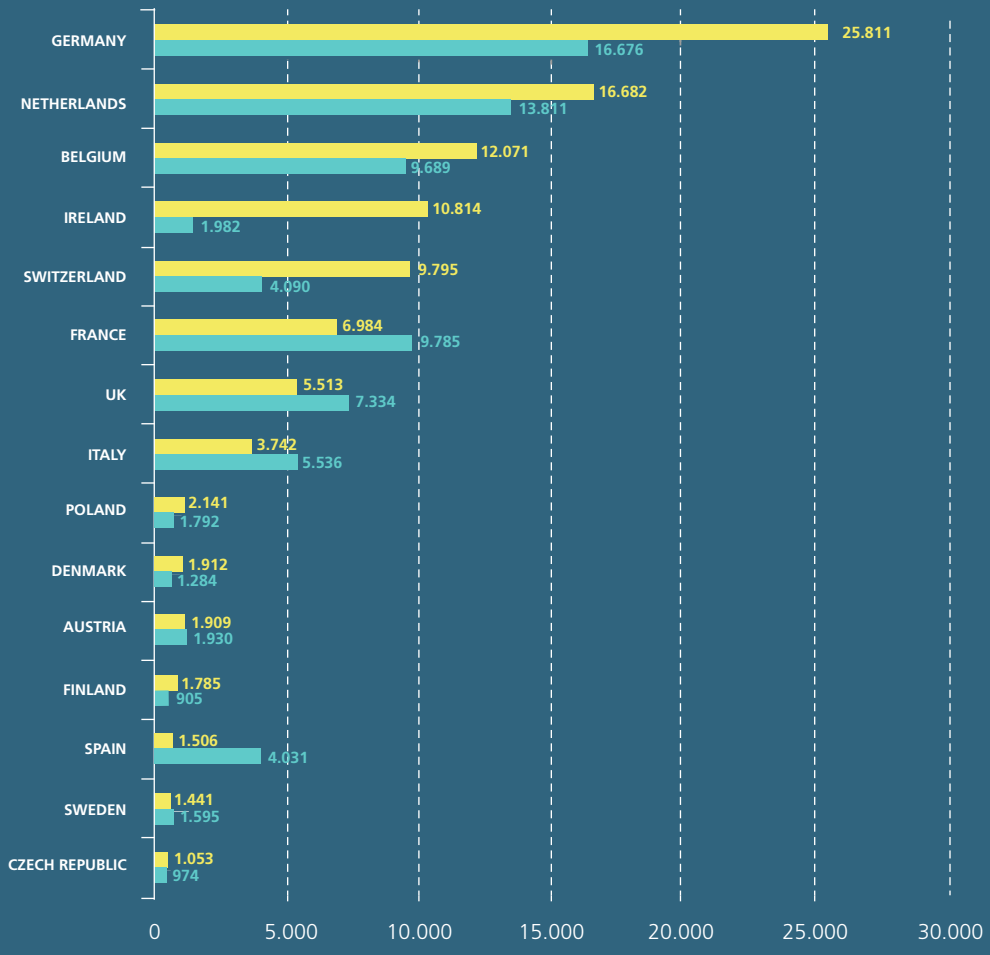
Top European medical devices export destinations, 2017 (ref. 6)



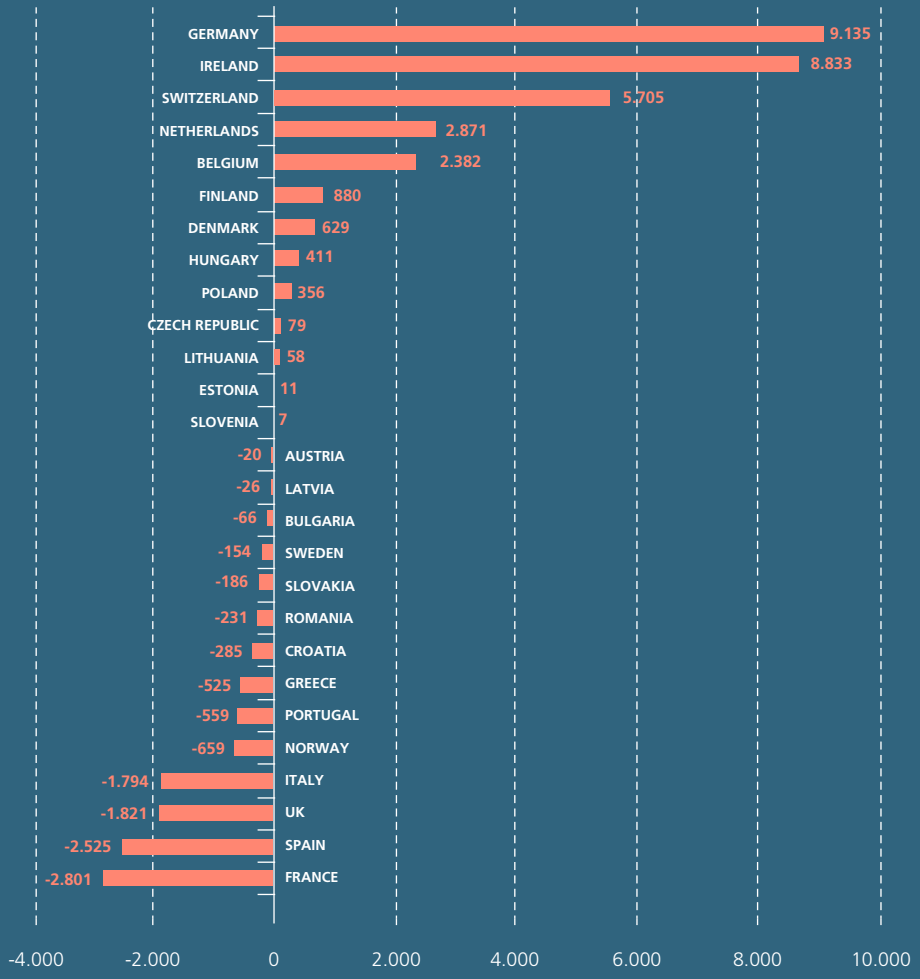
Top suppliers to European medical devices market (imports), 2017 (ref. 6)



Export & imports of medical devices by country (including intra-community trade, million euros), 2017 (ref. 6)



Medical device trade balance by country (including intra-community trade million euros), 2017 (ref. 6)



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.

References

1 European Patent Office, MedTech Europe calculations. Medical technology as defined by World Intellectual Property Organization (based on the WIPO IPC-Technology concordance as revised in August 2014). European countries refer to EU + Norway, Switzerland. Patents are attributed by the country of residence of the applicant.

2 EFPIA – The Pharmaceutical Industry in Figures. Key Data 2018. Europe refers to EU + Norway, Switzerland.

3 MedTech Europe calculation based on the data obtained from National Associations of 12 countries for the latest year available. Europe refers to EU + Norway, Switzerland.

4 WHO Global Health expenditure Database, Eurostat, BMI Research, MedTech Europe calculations based on the data obtained from National Associations of 15 countries for the latest year available.

5 BMI Research, WHO, Eurostat, EFPIA, EDMA, MedTech Europe calculations. Europe refers to EU + Norway, Switzerland.

6 BMI Research, MedTech Europe calculations. Manufacturer prices. Medical technology excluding in–vitro diagnostics.

7 MedTech Europe - European IVD Market Statistics Report 2017.

8 Worldwide Medtech Sales by EvaluateMedTech® Device Area: Top 15 Categories & Total Market (2017 - 2024) - http://info.evaluategroup.com/WPMT2018-CS.html

www.medtecheurope.org