

The European Medical Technology Industry in Figures

2022



MedTech Europe
from diagnosis to cure

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What is Medical Technology?

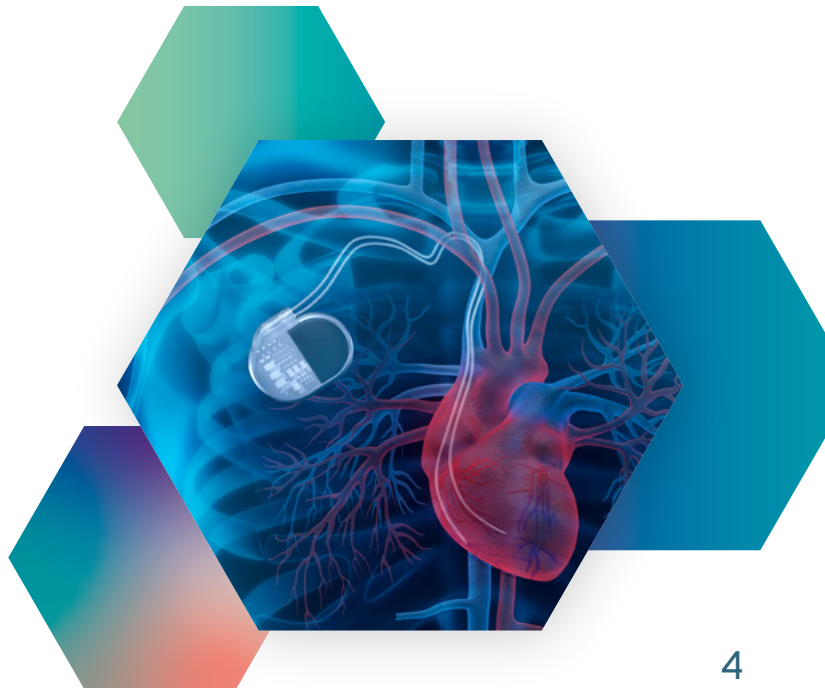


Medical technologies are products, services or solutions used to save and improve people's lives.

In their many forms, they are with you from prevention to diagnosis and 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 people.
- **In vitro diagnostics** (IVDs) are non-invasive tests used on biological samples (for example blood, urine or tissues) to determine the status of a person's health.
- **Digital health** are tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of a person's health and lifestyle.

This document addresses only medical devices and in vitro diagnostics.



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

Medical technologies can be everyday objects such as sticking plasters, syringes, surgical masks, and latex gloves, as well as spectacles, wheelchairs, COVID-19 tests and medical apps.

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, before and after they are placed on the market. The European medical technology sector is currently transitioning from being regulated under the EU medical devices and IVD directives to two new regulations.

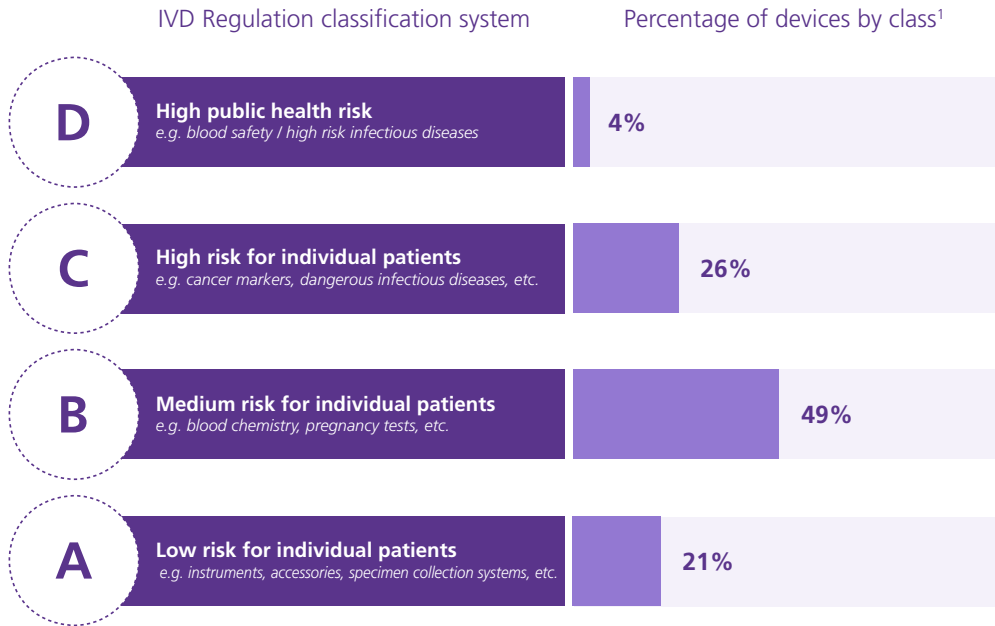


Classification of *In Vitro* Diagnostic Medical Devices

The *In Vitro* Diagnostic (IVD) sector is regulated by the Regulation 2017/746/EU.

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 generally reflects the risk of an incorrect result from the test.

Under the **IVD Regulation**, all IVDs are 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 are classified as class A, B, C or D, with class D being the highest risk class.

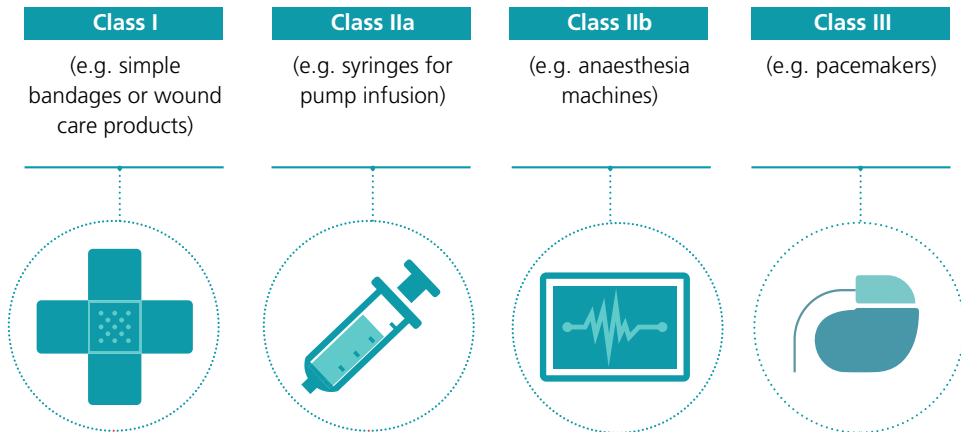


Classification of Medical Devices

Since 26 May 2021, the medical device (MD) sector has been covered by Regulation (EU) 2017/745, the so-called 'Medical Devices Regulation' (MDR), which has come into full application.

Classification of medical devices 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 is involved post-market to ensure the continued safety and performance of medical devices.

Under the **MD Regulation**, MDs are classified into 4 classes following a risk-based classification system, which links the class of the device to the potential risk posed to the public's or individual's health as a result of a fault of performance.



All MDs are classified as class I, IIA, IIB or III, with class III being the highest risk class.

Innovation

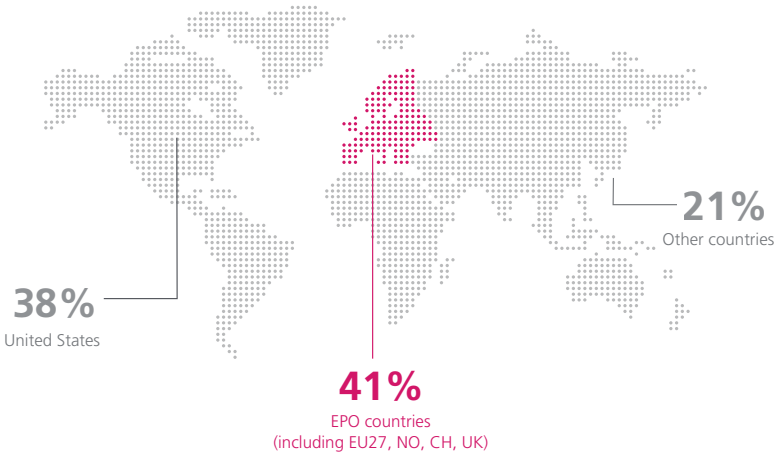


Medical technology is characterised by a constant flow of innovations, which are the results of a high level of research and development within the industry, and of close co-operation with users. The average global R&D investment rate (R&D spend as a percentage of sales) is estimated to be around 8% in the medical technology sector². Products typically have a lifecycle of only 18-24 months before an improved product becomes available.

In 2021, more than 15,300 patent applications were filed with the European Patent Office (EPO) in the field of medical technology, representing a 0.8% growth in patent applications compared to the previous year³. The medical technology field accounts for 8.1% of the total number of applications, the 2nd highest among all industrial sectors in Europe. 41% of these patent applications were filed from EPO countries (including EU27, UK, Norway and Switzerland), 38% from the US and the remaining 21% originated from other countries.

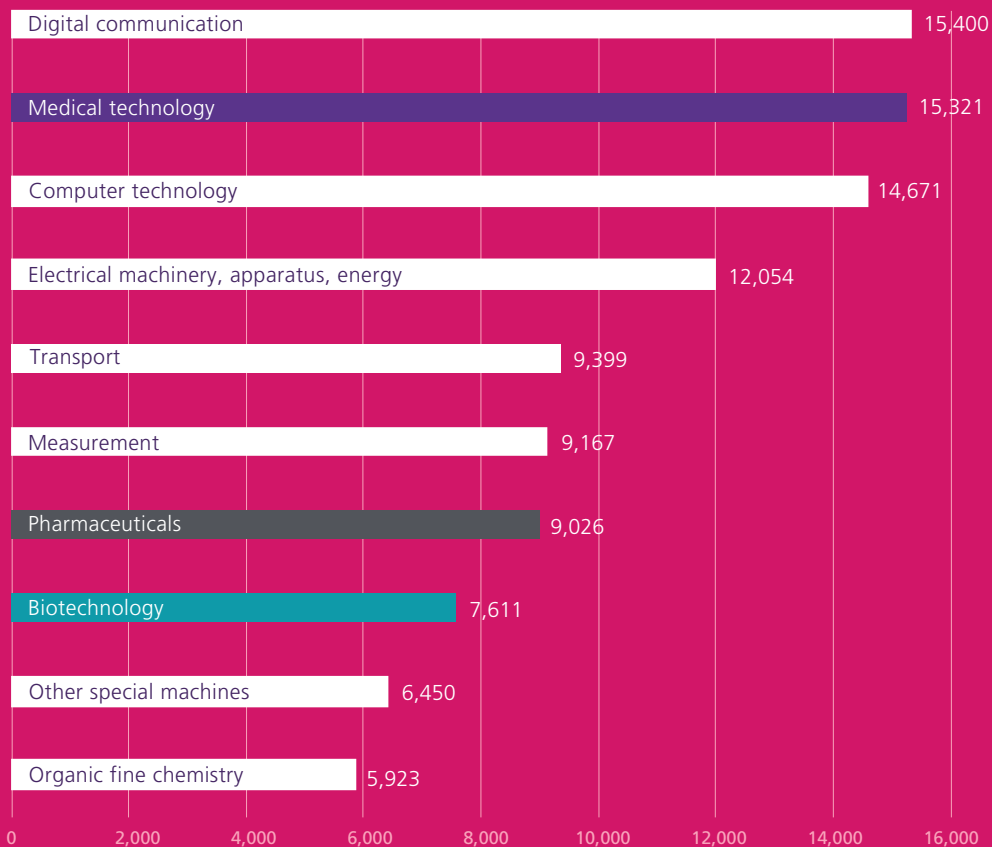
In comparison, around 9,000 applications were filed in the pharmaceutical field and around 7,600 in the field of biotechnology. While over the last two decades the number of EPO filings in the field of medical technology has almost tripled, pharma and biotech patent applications remained relatively stagnant. Furthermore, the ratio of granted patents to patent applications stands at 55% in 2021. In contrast, the same ratio is 33% in both the pharmaceutical and biotechnology field (Graph 2).

Patent applications in medical technology field filed with EPO in 2021



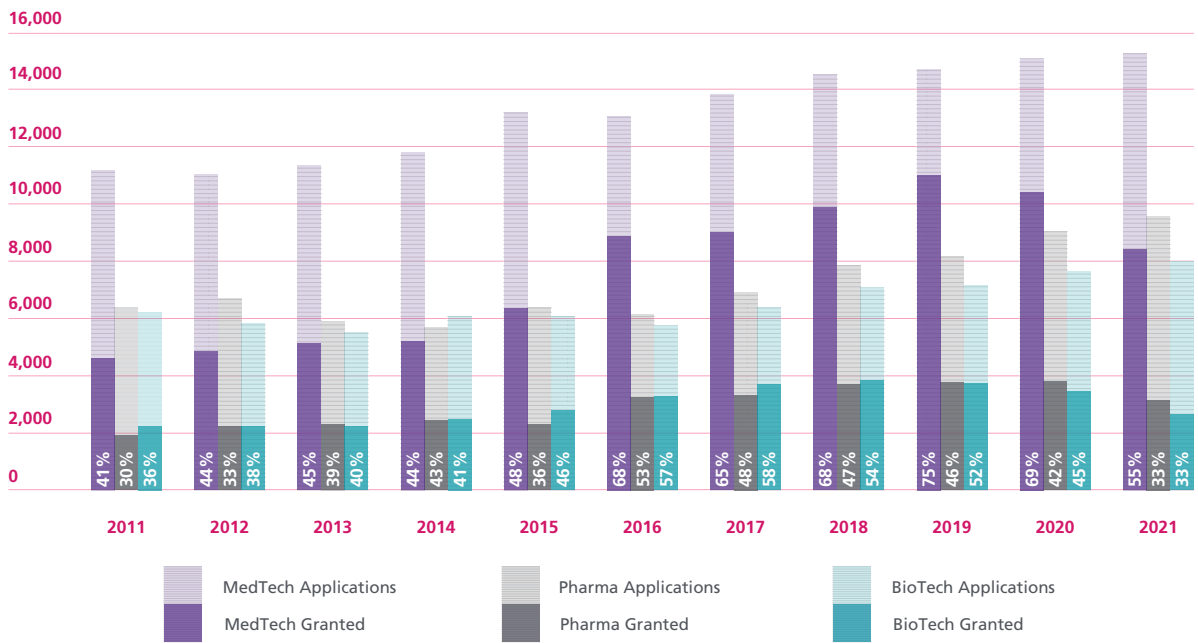
Graph 1 – Top 10 technical fields in patent applications

Number of patent applications filed with EPO, 2021 (ref. 3)



Graph 2 – Evolution of European patent applications and granted patents by technical field

2021 (ref 3.)



Employment



The European medical technology industry employs directly more than 800,000 people⁴. 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 840,000 people⁵.

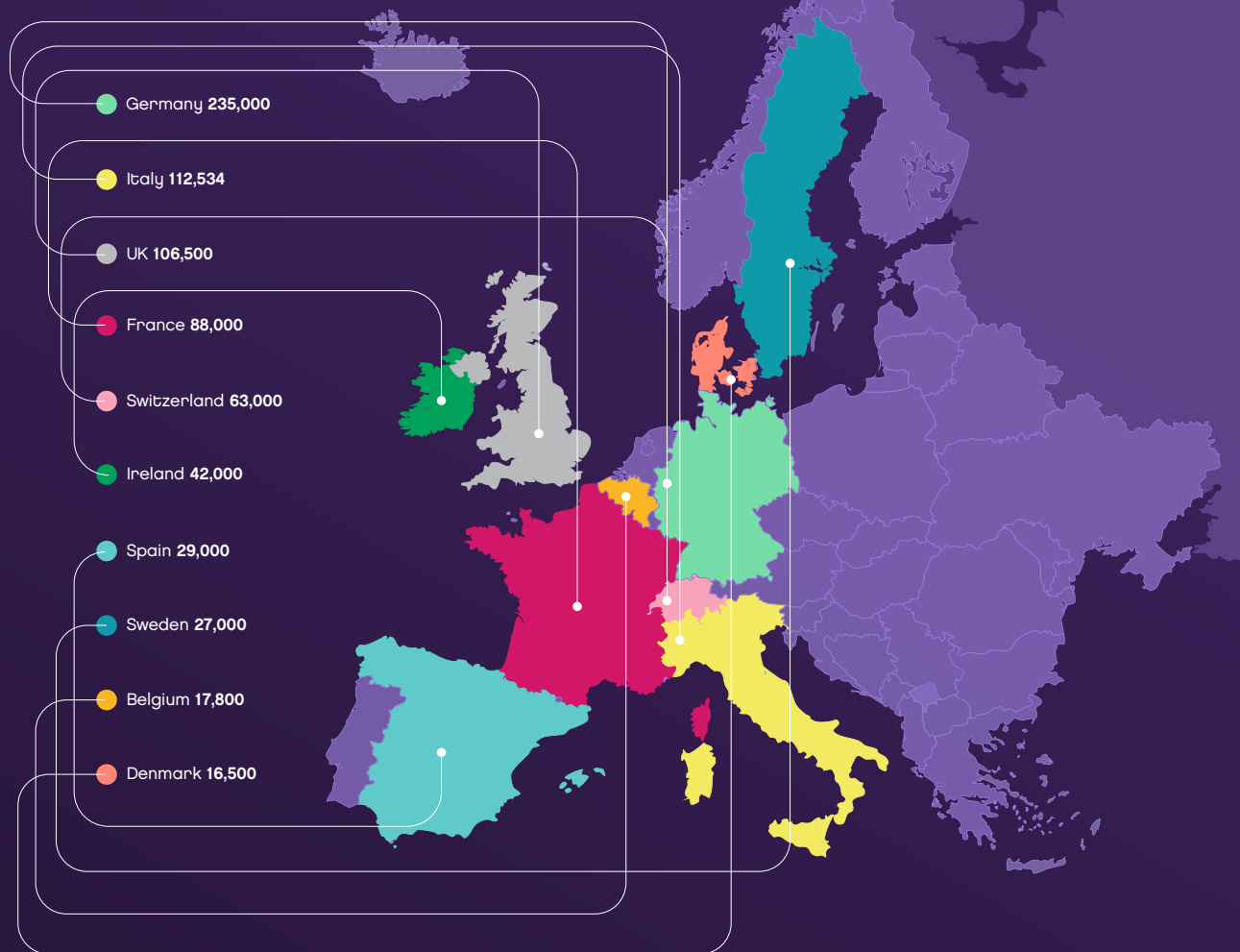
The jobs created by the medical technology industry account for around 0.3% of total employment in Europe.⁶ These jobs are also highly productive, as the value added per employee is estimated to reach around €184,000 per employee. These indicators show that the medical technology industry has an important economic and societal impact in Europe.



800,000+
employees⁴

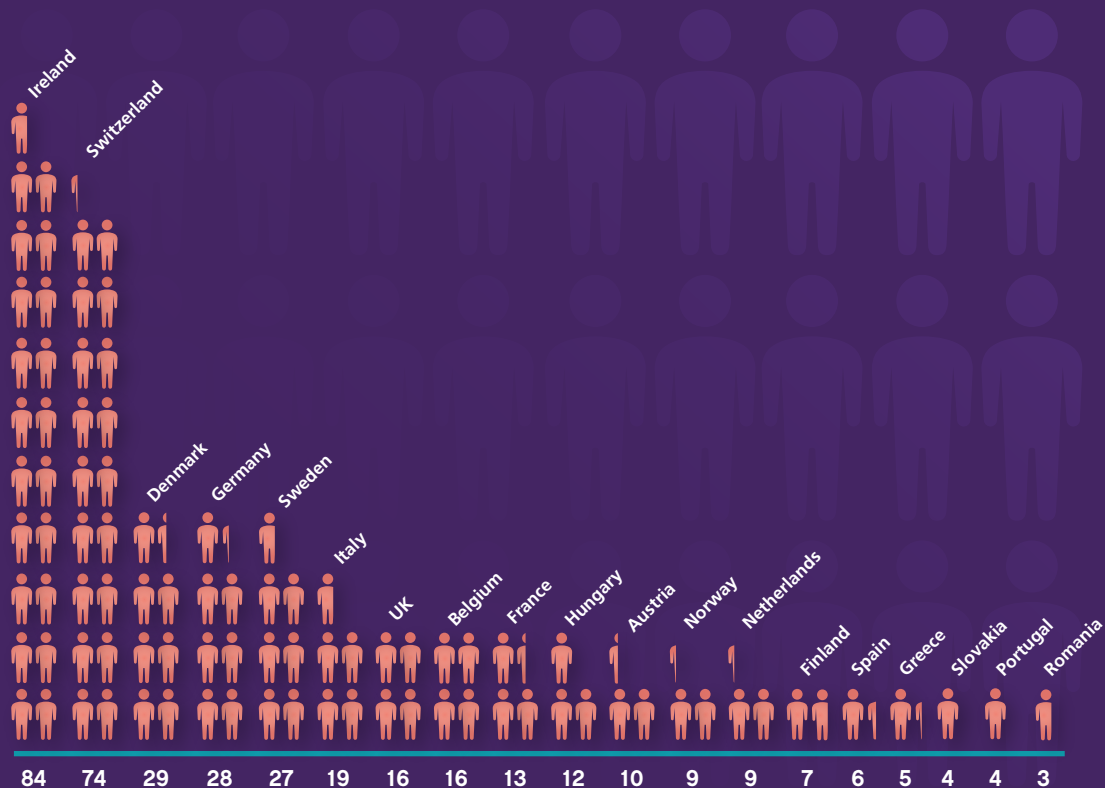
Graph 3 – Top 10 countries in Europe with highest direct employment in the medical technology industry

2021 or latest year available (ref. 4)



Graph 4 – Number of people directly employed in the medical technology industry per 10,000 inhabitants

2021 or latest year available (ref. 4)



Companies





34,000

medical technology
companies in Europe

95% SMEs

There are more than 34,000 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)⁴.

Expenditure on Medical Technology





€284

expenditure on medical
technology per capita
in Europe

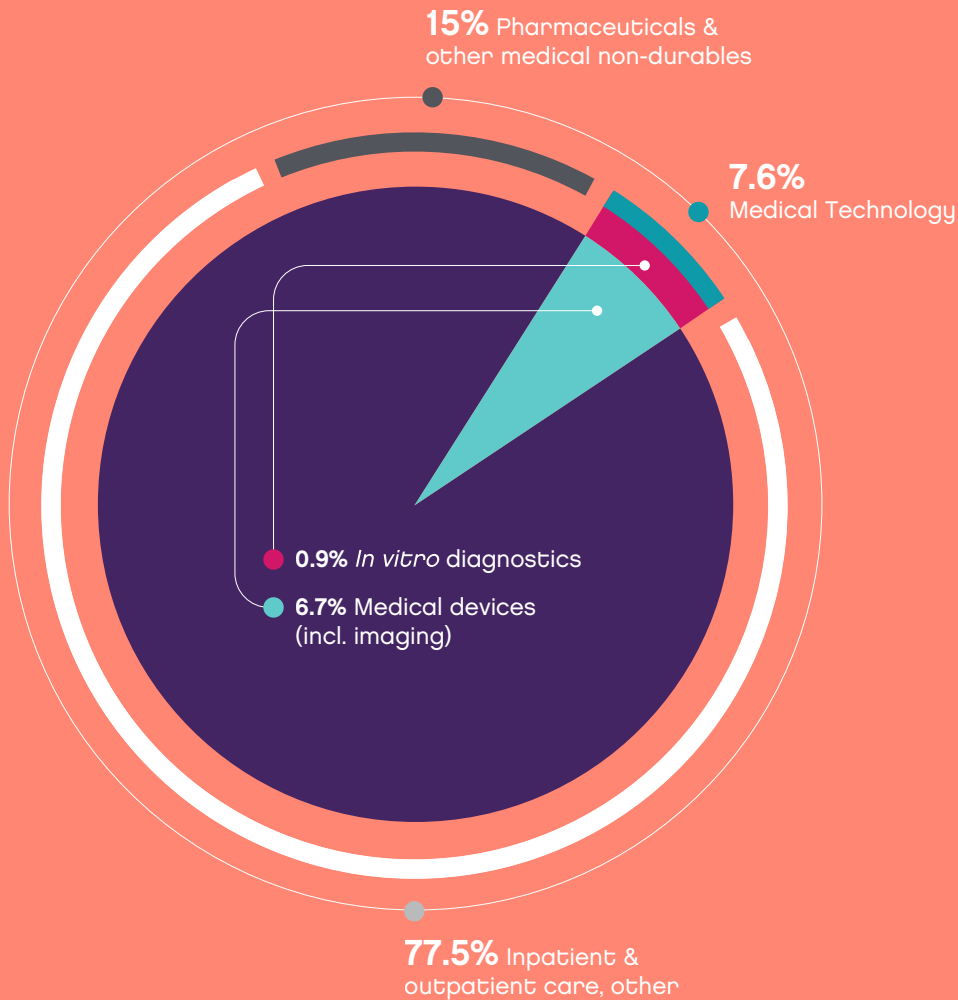
7.6% of total
healthcare expenditure
is spent on medical
technologies

In Europe, an average of approximately 11% of gross domestic product (GDP) is spent on healthcare. Of this figure, around 7.6% 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 €284.*

* MedTech Europe calculation based on sources 5-9.

Graph 5 – Breakdown of total healthcare expenditure in Europe

2021 (ref. 5–9)





MedTech Market in Europe



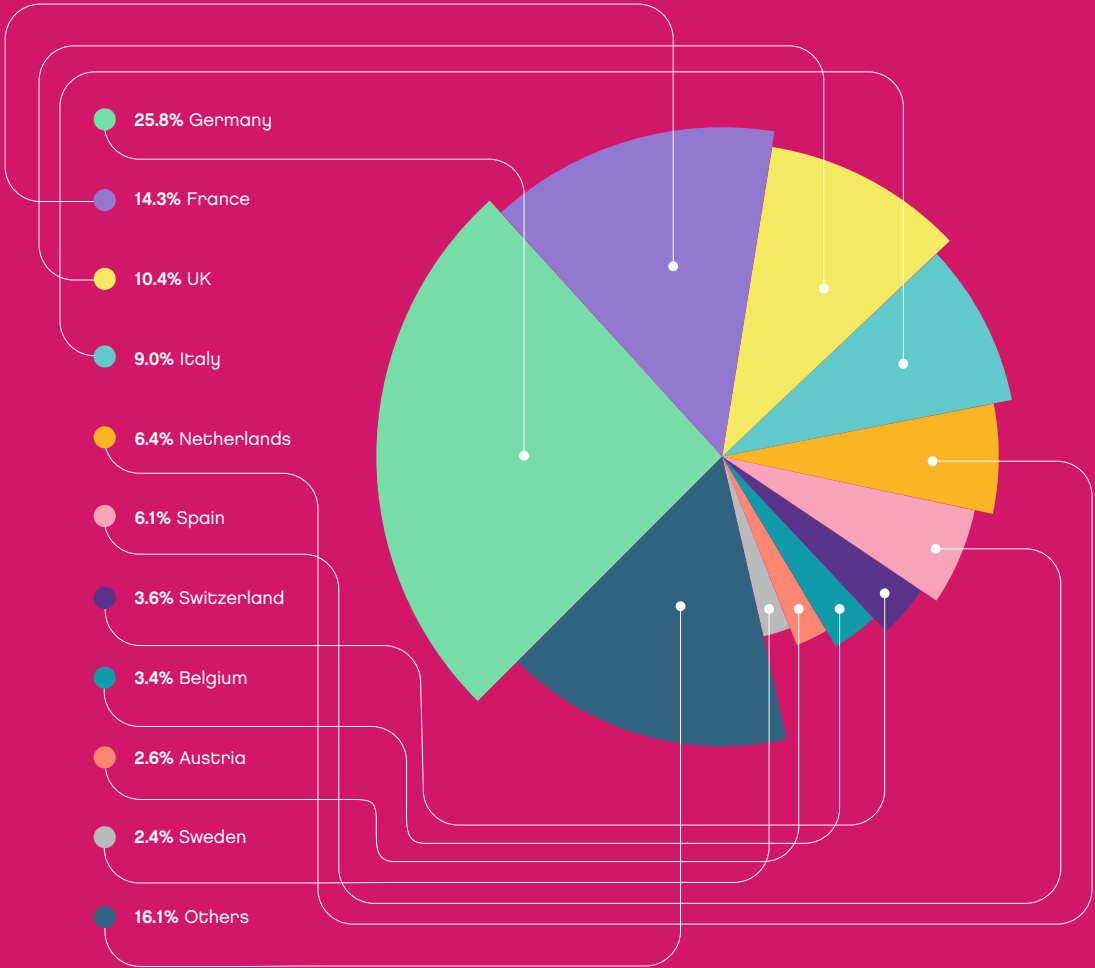


The European medical technology market is estimated at roughly €150 billion in 2021.^{8,9} The top five biggest markets are Germany, France, the United Kingdom, Italy, and Spain.

Based upon manufacturer prices, the European medical device market is estimated to make up 27.3% of the world market. It is the second largest medical device market after the US (43.5%).⁹

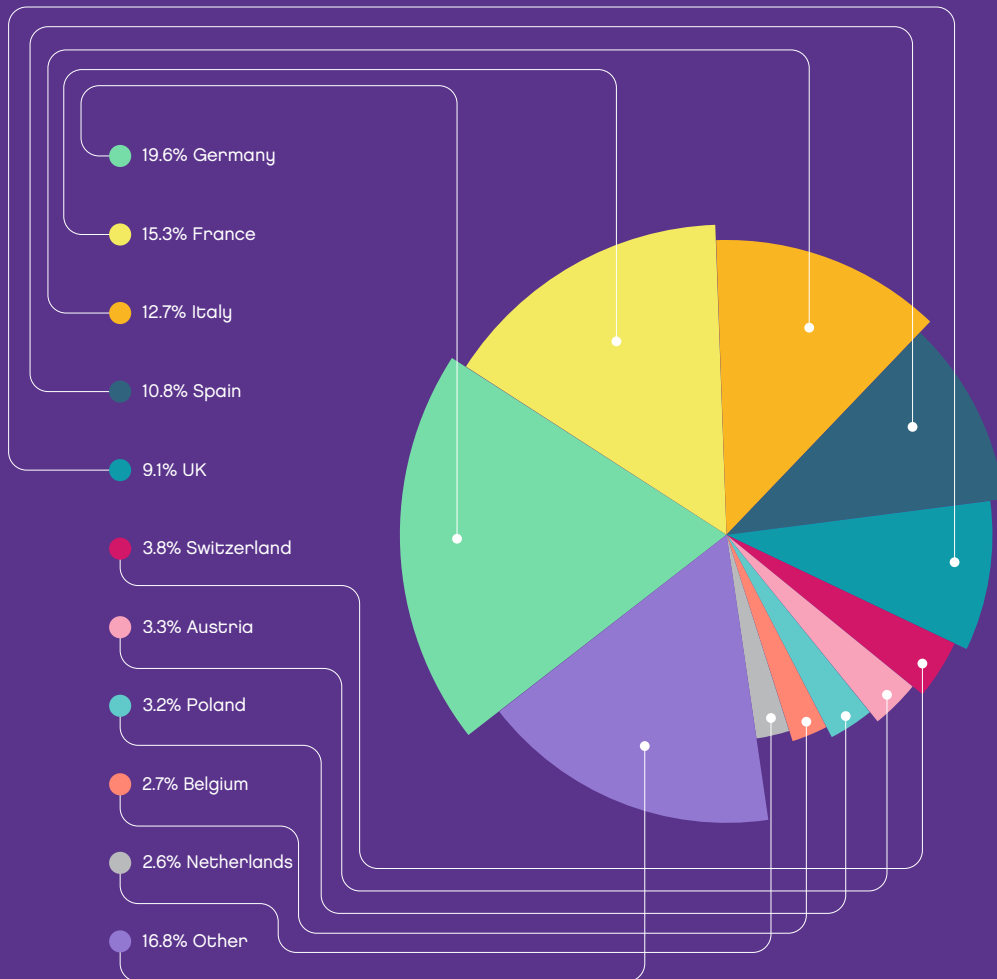
Graph 6 – European medical device market by country

2021 (ref. 9)



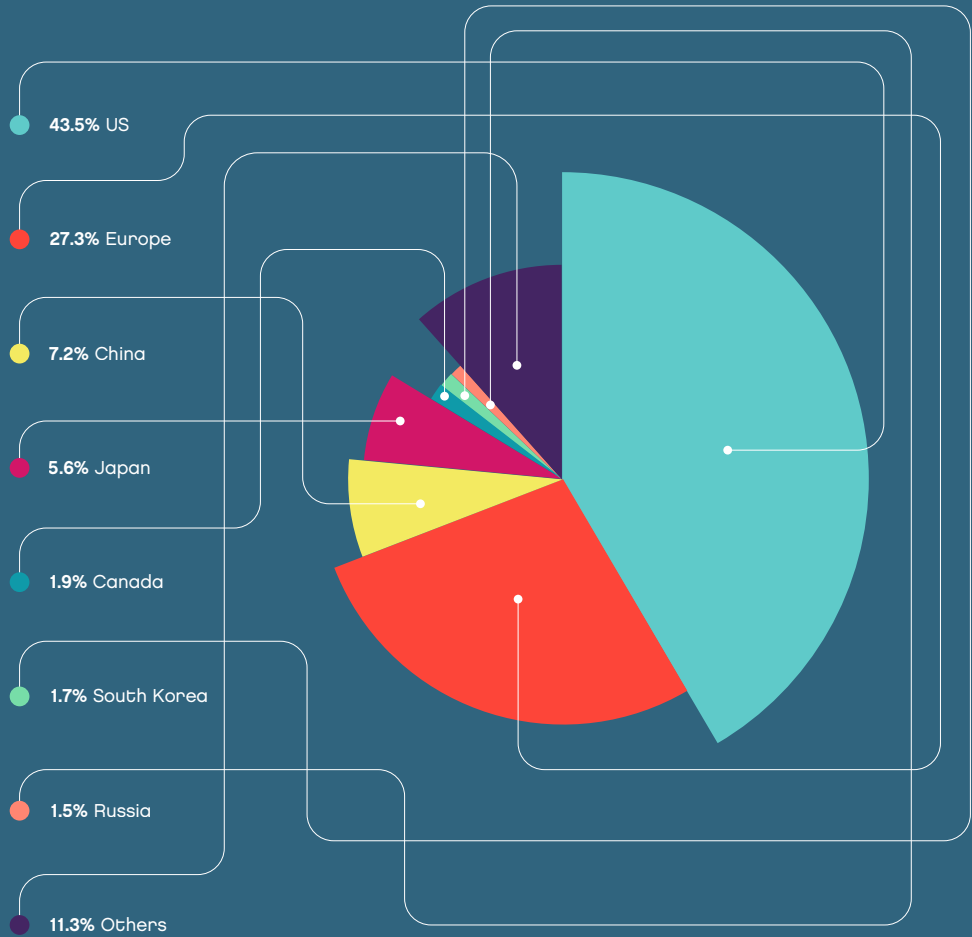
Graph 7 – European IVD market by country

2020 (ref. 8)



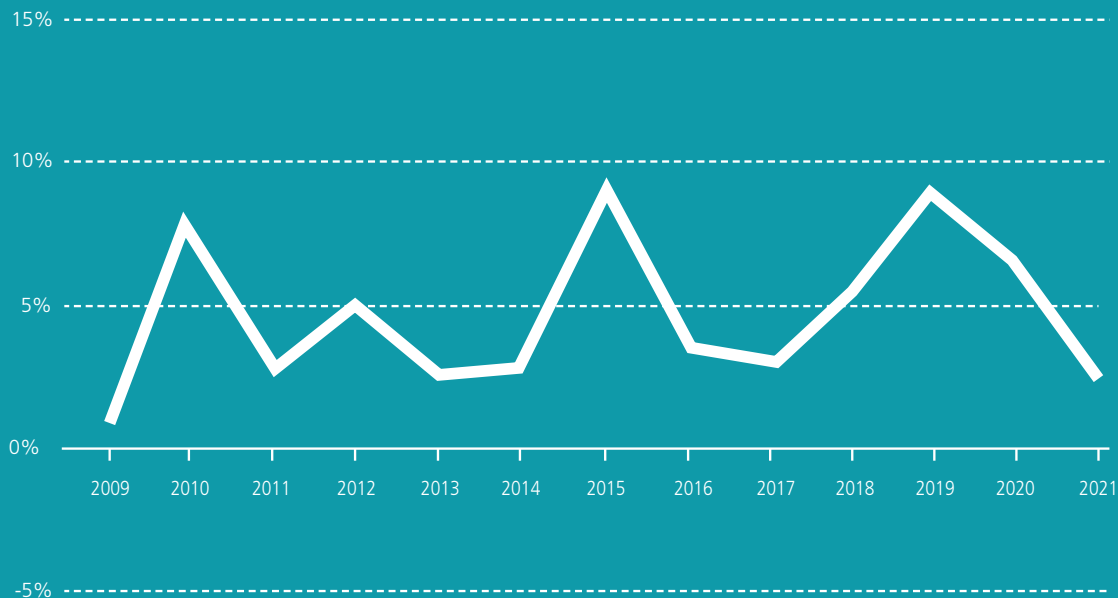
Graph 8 – Europe in the world medical device market

2021 (ref. 9)



Graph 9 – European medical device market growth rates

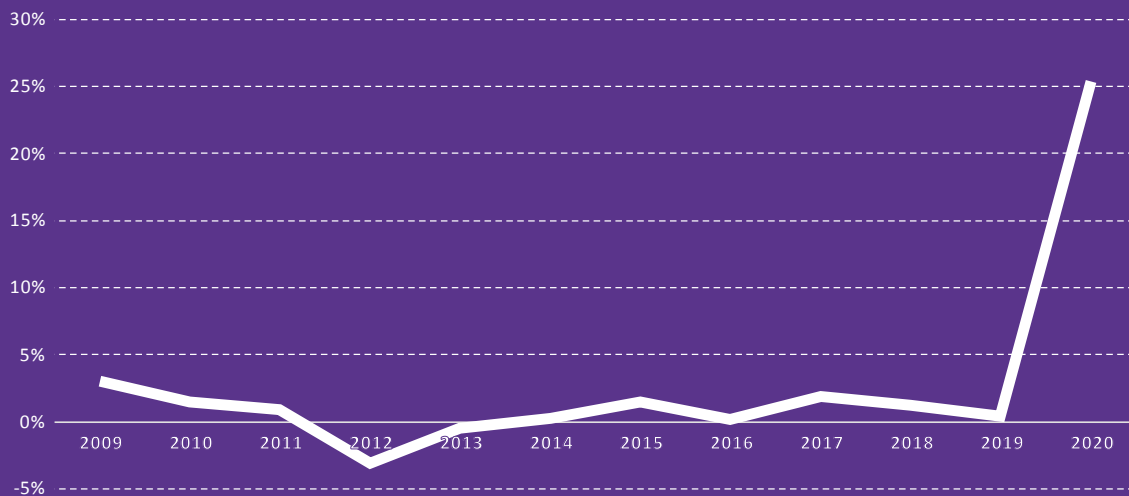
2009-2021 (ref. 9)



The European medical device market has been growing on average by 4.8% per year over the past 10 years. Demand fell in 2009 due to the economic crisis, resulting in a growth rate of only 1% (the lowest in 13 years). The market regained its momentum in 2010, and since then the annual growth rate has varied between 2.4% (2017) and 9.3% (2015), standing at 2.9% in 2021.⁹

Graph 10 – European IVD market growth rates

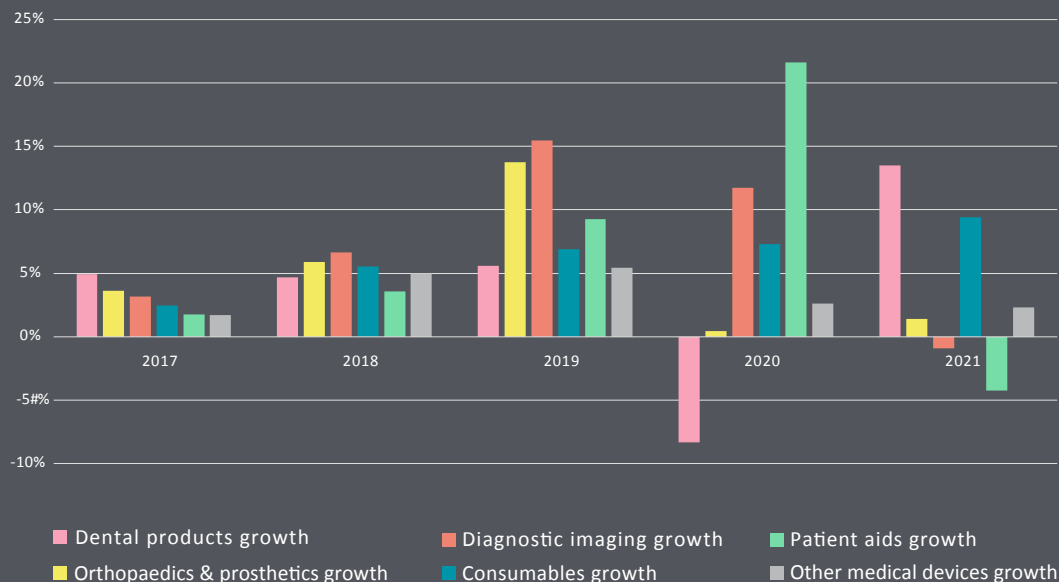
2010-2020 (ref. 8)



Growth in the European IVD market was in decline for several years until 2013. Since then, the annual growth rate for the European IVD market has been 2.7% on average, hitting the record 25% in 2020.

Graph 11 - European medical technology growth rates by sectors

2017-2021 (ref. 9)



COVID-19 affected the medical technology industry in several ways. Postponement of elective surgeries across EU countries in 2020 led to deferred patient care within the Orthopaedics and Dental fields.

On the other end of the spectrum, sales of IVDs (e.g. PCR tests), patient aids (artificial respiration apparatus such as ventilators) and consumables (e.g. nasal cannulae, syringes, surgical gloves) increased significantly in 2020 as these medical technologies were essential to the special care that severe COVID-19 patients require.

Trade in Europe





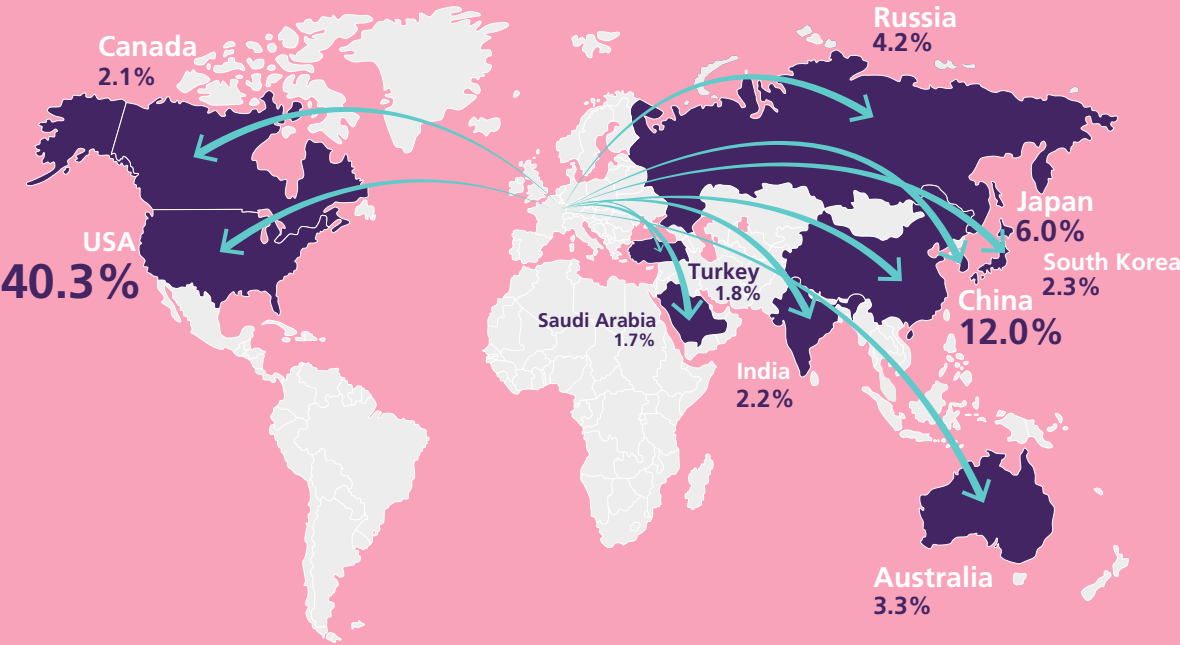
€6 billion

Estimation of Europe's
trade surplus in 2021

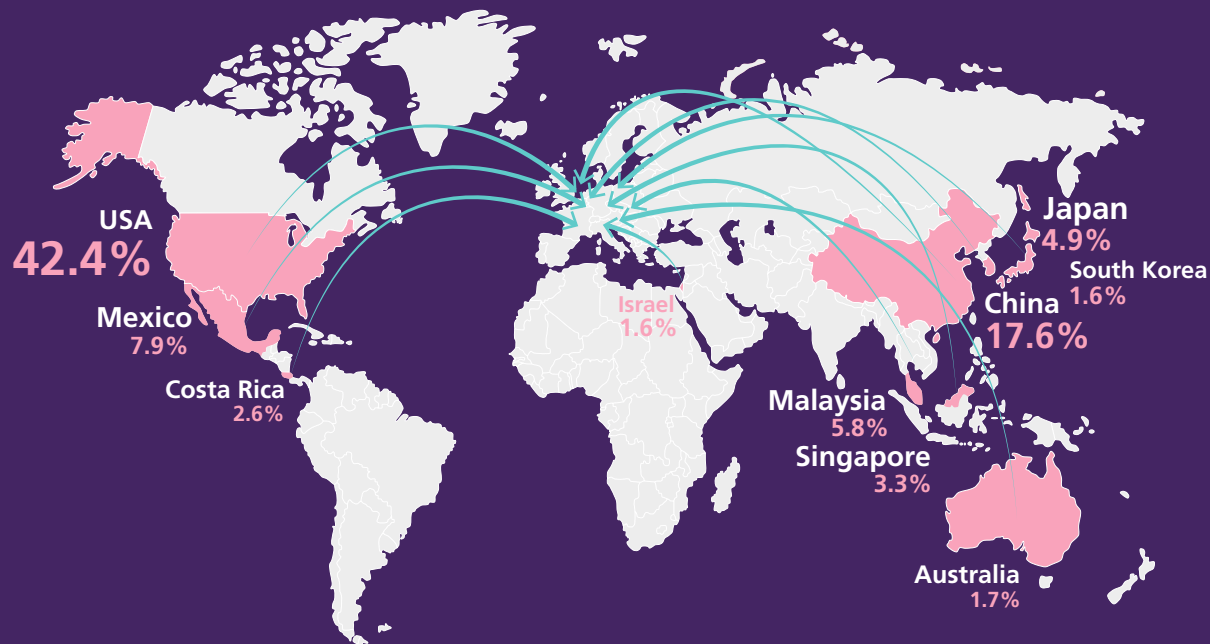
Europe has a positive medical devices trade balance of €6 billion (2021). The main European medical device trade partners remain the same as in previous years: the US, China, Japan and Mexico.¹⁰

Graph 12 - Top European medical technology export destinations

2021 (ref. 10)

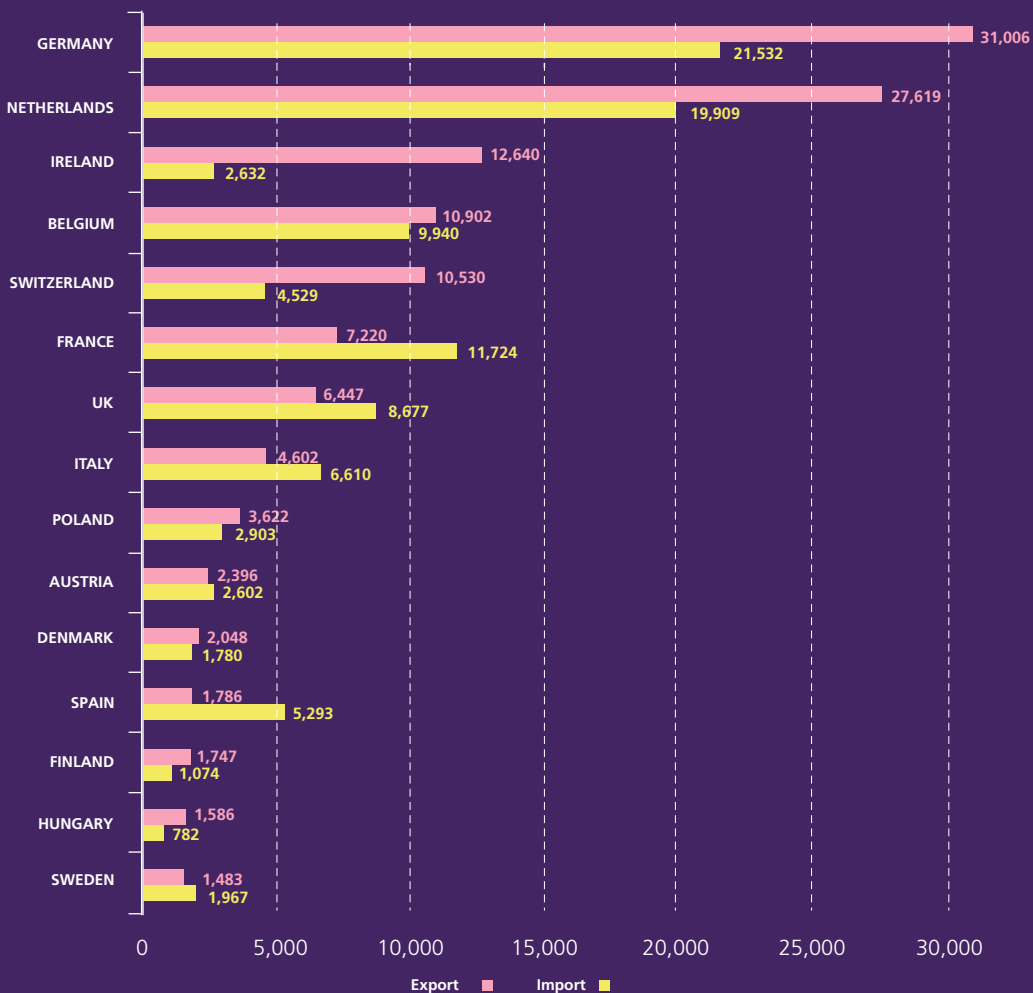


Graph 13 – Top import suppliers to the European medical devices market
2021 (ref. 10)



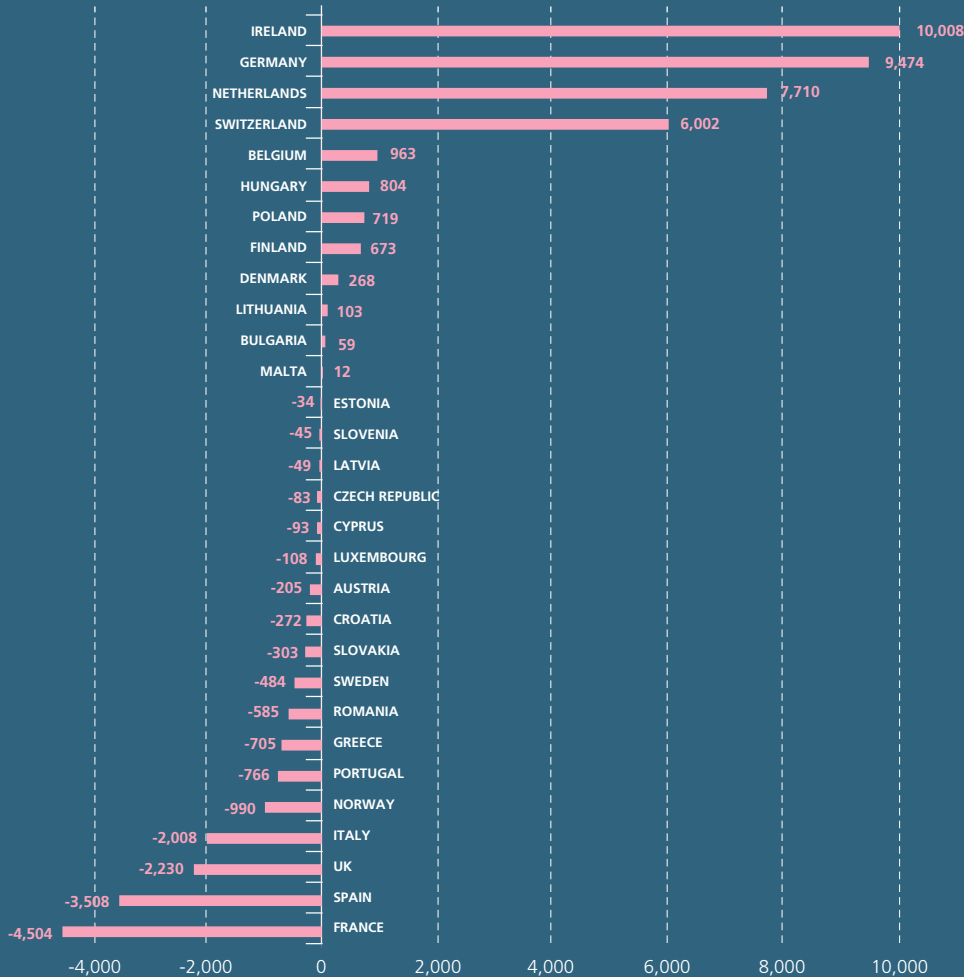
Graph 14 – Export and import of medical devices by country

Including intra-community trade, million euros, 2021 (ref. 10)



Graph 15 – Medical devices trade balance by country

Including intra-community trade, million euros, 2021 (ref. 10)



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. It is an essential source of data for international stakeholders seeking an up-to-date view of industry innovation and employment, SME activity, expenditure on medical technology, trade flows 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 annual surveys MedTech Europe carries out among its member National Associations. The most recent survey was finalized in March 2022. Figures refer to 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 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).

References

- 1 MedTech Europe Survey Report analysing the availability of *In vitro* Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies.
- 2 Evaluate MedTech, 2018, World Preview 2018, Outlook to 2024.
- 3 European Patent Office (EPO), 2022, Patent Index 2021.
- 4 MedTech Europe, 2021, National Associations Survey.
- 5 EFPIA, 2022, The Pharmaceutical Industry in figures..
- 6 Eurostat, 2022, Employment and Population Statistics.
- 7 WHO, 2019, Global Health Expenditure Database.
- 8 MedTech Europe, 2021, European IVD Market Statistics Report 2021. 2021 IVD market size data is preliminary and is based on MedTech Europe Statistics Programmes
- 9 Fitch Solutions, 2022, Worldwide Medical Devices Market Factbook 2021.
- 10 International Trade Centre, 2022, International Trade Statistics – MedTech Europe calculations.

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