The European Medical Technology Industry in figures 2021

MedTech Europe
from diagnosis to cure

Table of contents

What is Medical Technology?

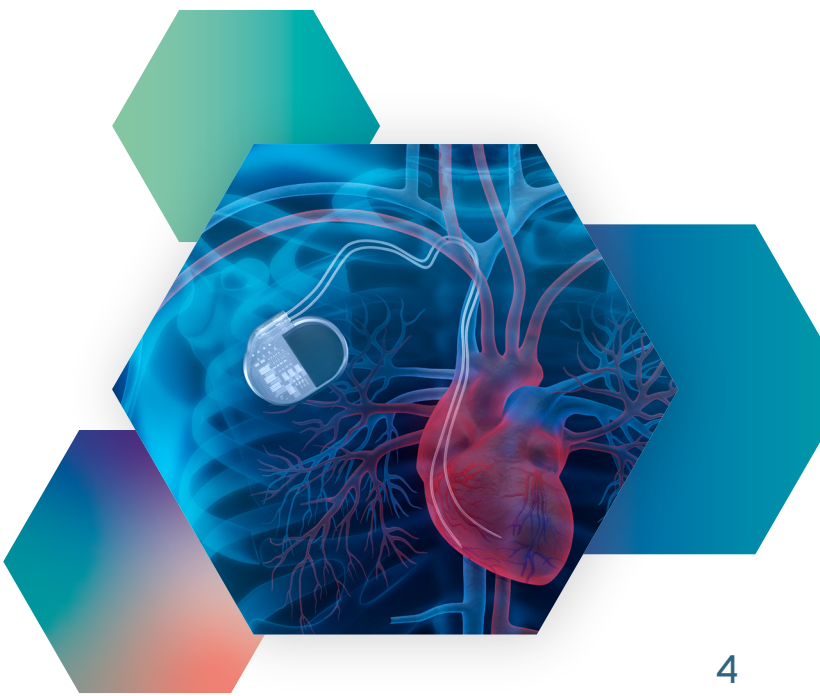
Medical technologies are products, services or solutions used to save and improve people's lives.

In their many forms, they are with you all the time, from prevention to diagnosis 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 human beings by physical means.
- ***In vitro* diagnostics** medical devices (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** refer 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 includes only medical devices and in vitro diagnostic medical devices.



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, surgical masks, or latex gloves. It could also be spectacles, wheelchairs, COVID-19 tests or 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 efficacy and sustainability of healthcare systems.

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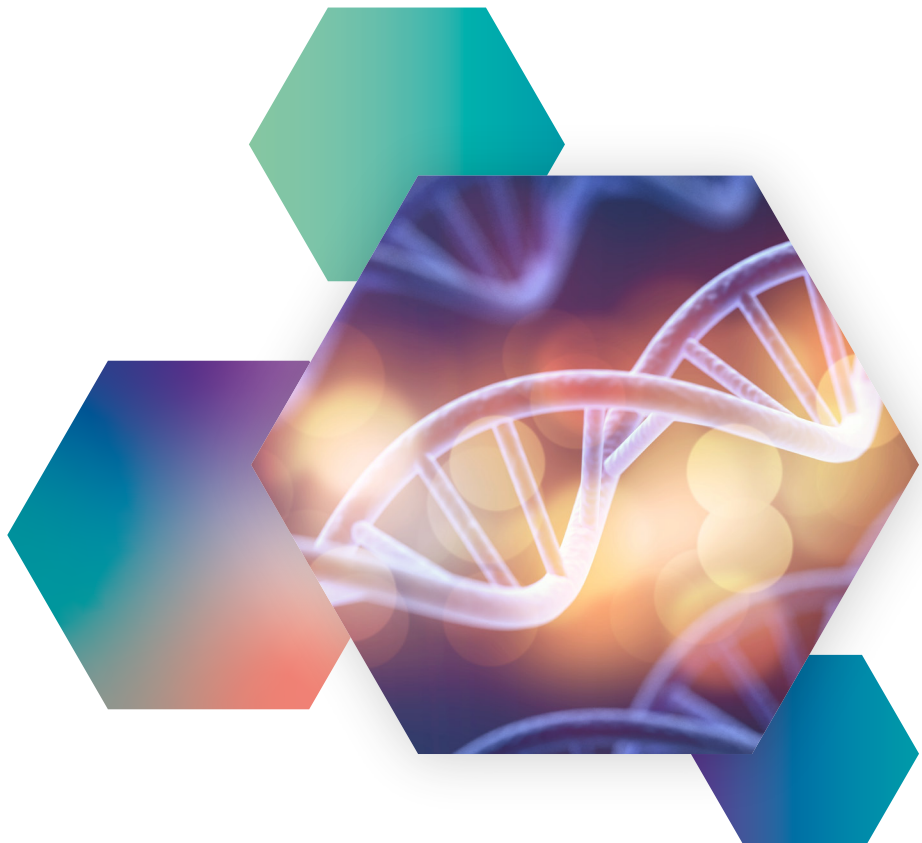


Regulations

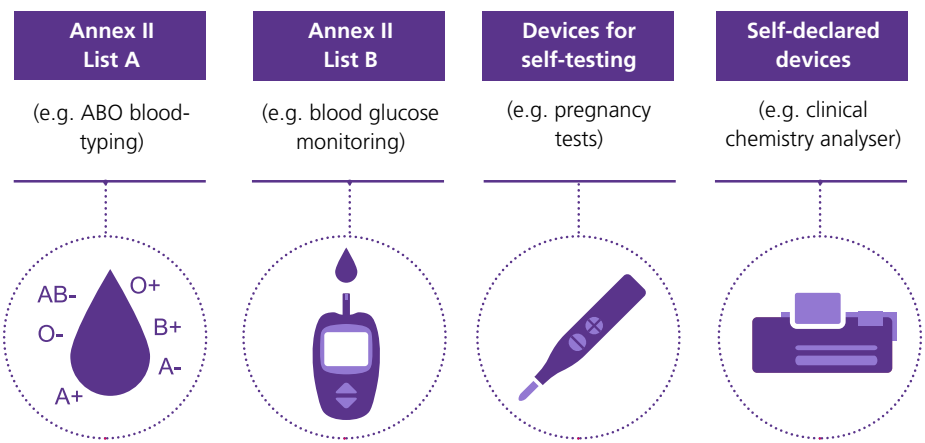
In the European Union, medical technologies are tightly regulated by laws that govern the safety and performance of devices across their lifetime, pre- and post-market. Over the next few years, the European medical technology sector will transition from being regulated under the current medical devices 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:



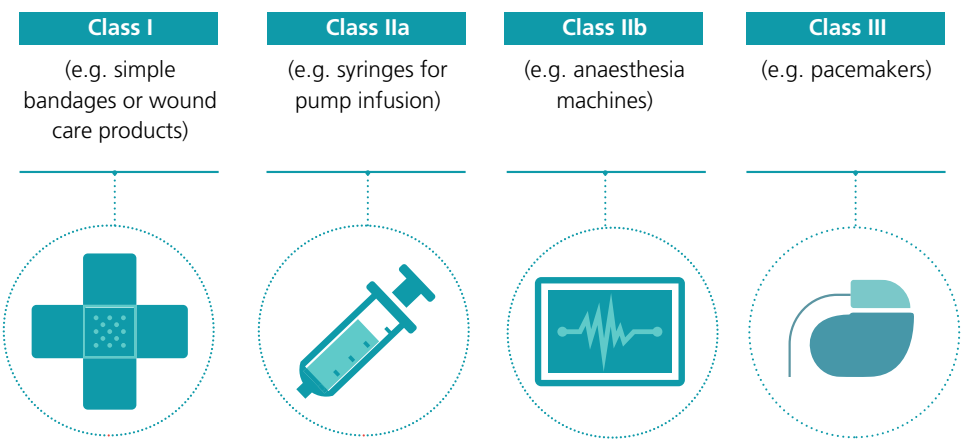
Under the **IVD Regulation**, all IVDs will be classified under a new risk-based classification system according to the risk the device poses to the health of the public and or an individual as result of an incorrect test result. All IVDs will be classified under class A, B, C or D, with class D being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

Classification of Medical Devices

Since 26 May 2021, the medical device (MD) sector is regulated by Regulation (EU) 2017/745, the so-called 'Medical Devices Regulation' (MDR), which has come into full application. The MDR replaces Directives 93/42/EC and 90/385/EEC and from 26 May 2021 on, no medical device can be certified under the old Directives anymore.

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 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 were 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 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

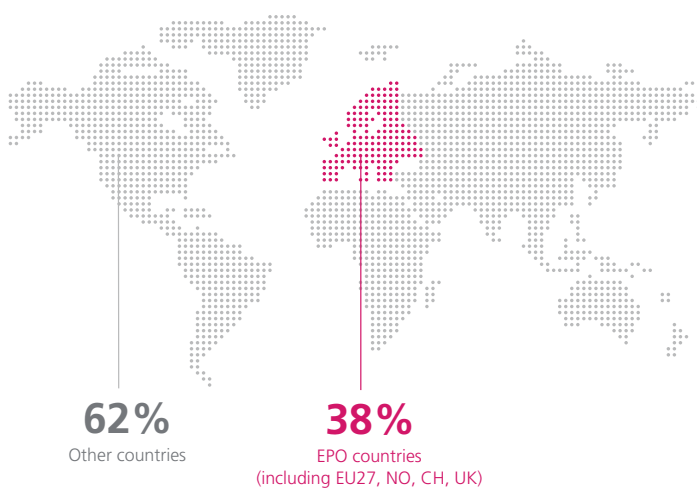

cardiovascular
system
upper injector
lower injector
CVS-100

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 spend 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 2020, more than 14,200 patent applications were filed with the European Patent Office (EPO) in the field of medical technology representing a 2.6% growth in patent applications compared to the previous year[2]. The medical technology field accounts for 8% of the total number of applications, the highest among all the sectors in Europe. 38% of these patent applications were filed from EPO countries (including EU27, UK, Norway and Switzerland) and 62% from other countries, out of which with the majority of applications filed from the US (39%).

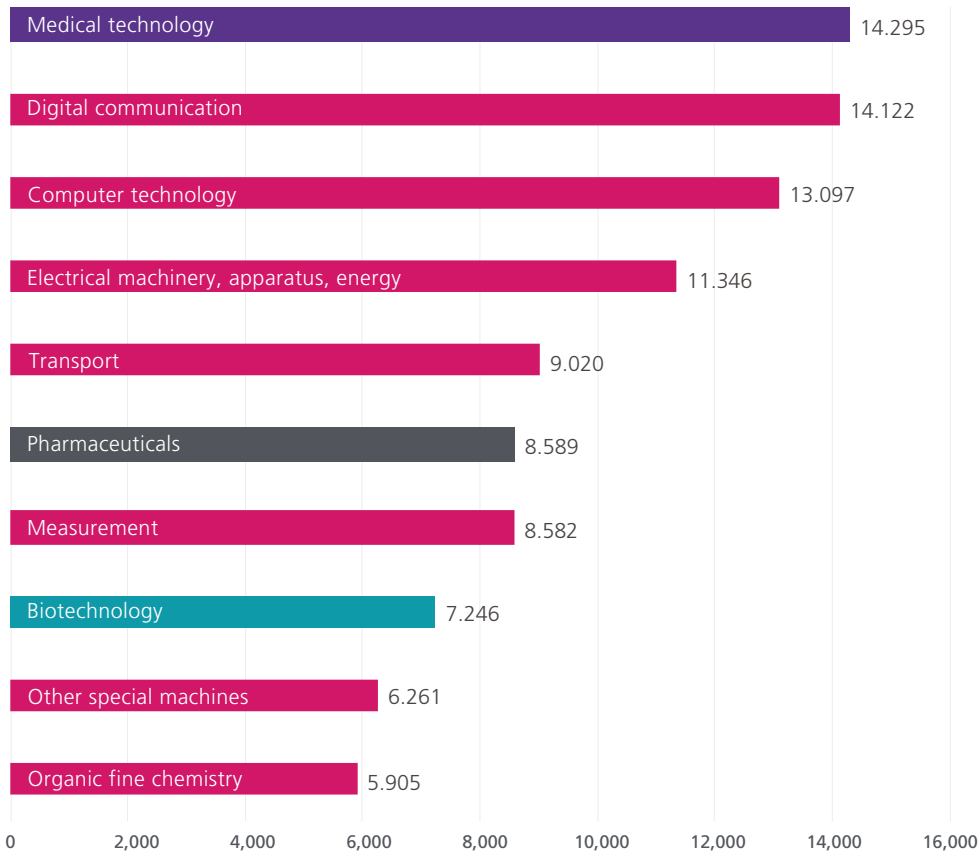
In comparison, around 8,500 applications were filed in the pharmaceutical field and around 7,200 in the field of biotechnology. While over the last decade the number of EPO filings in the field of medical technology has doubled, pharma and biotech patent applications remained relatively stagnant. Furthermore, the ratio of granted patents to patent applications has been steadily growing in the past years reaching 73% in 2020. In contrast, the same ratio is less than 50% in the pharmaceutical and biotechnology field (Graph 2).

Patent application in medical technology field filed with EPO in 2020



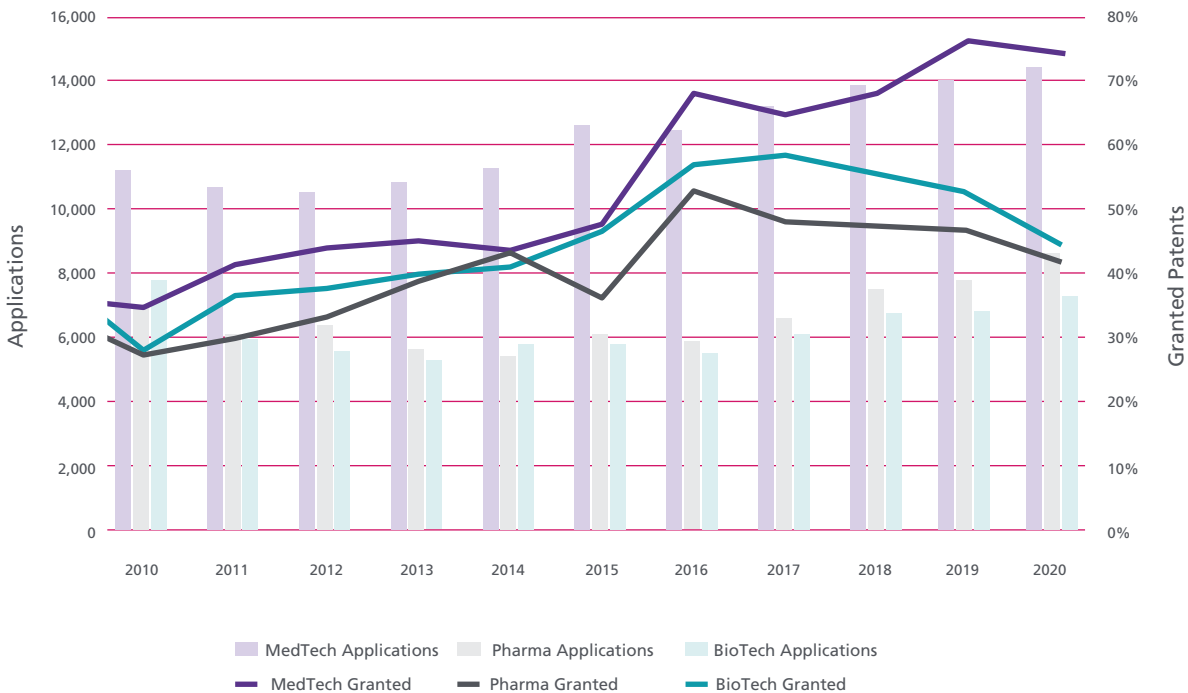
Graph 1 – Top 10 technical fields in patent applications

Number of patent applications filed with EPO, 2020 (ref. 2)



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

2020 (ref 2.)



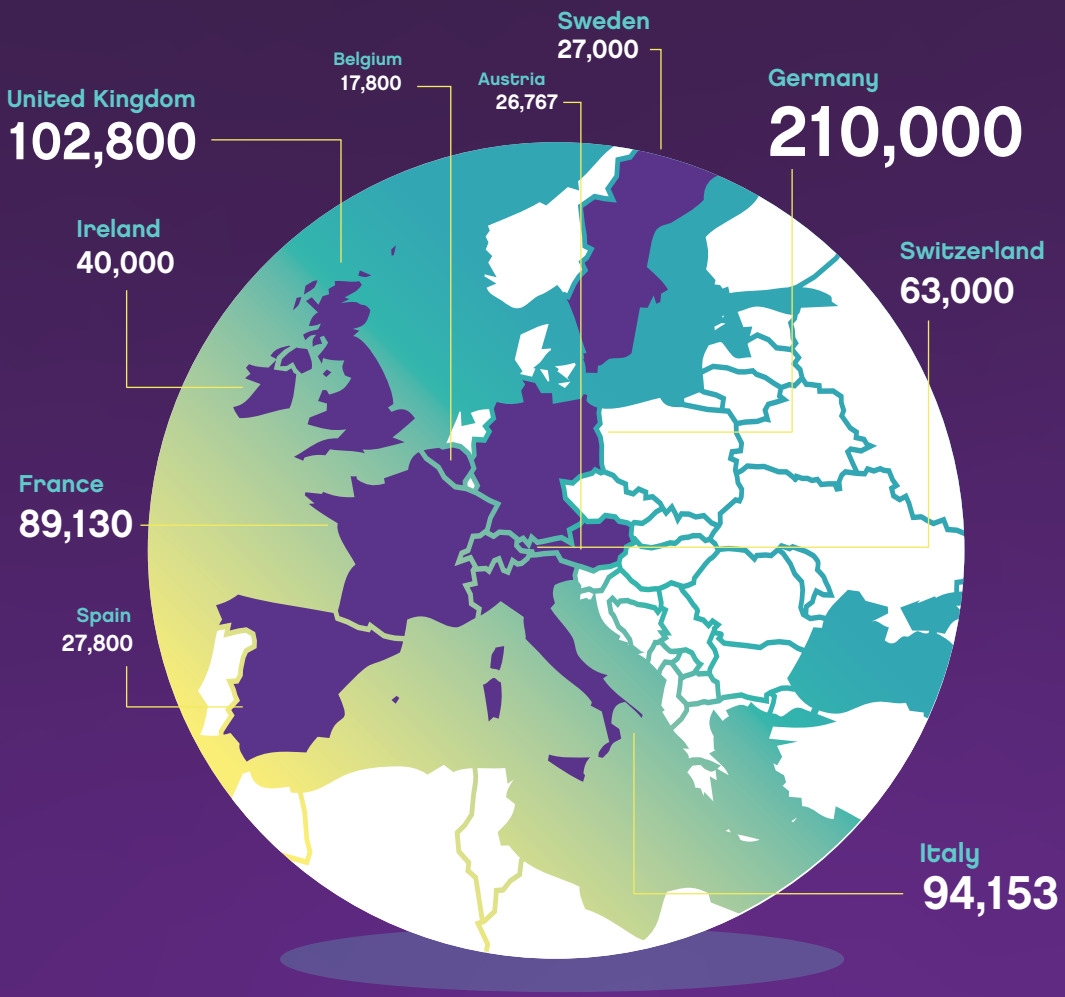
Employment

The European medical technology industry employs directly more than 760,000 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 795,000 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 €184,000 per employee. These indicators show that the medical technology industry has an important economic and societal impact in Europe.

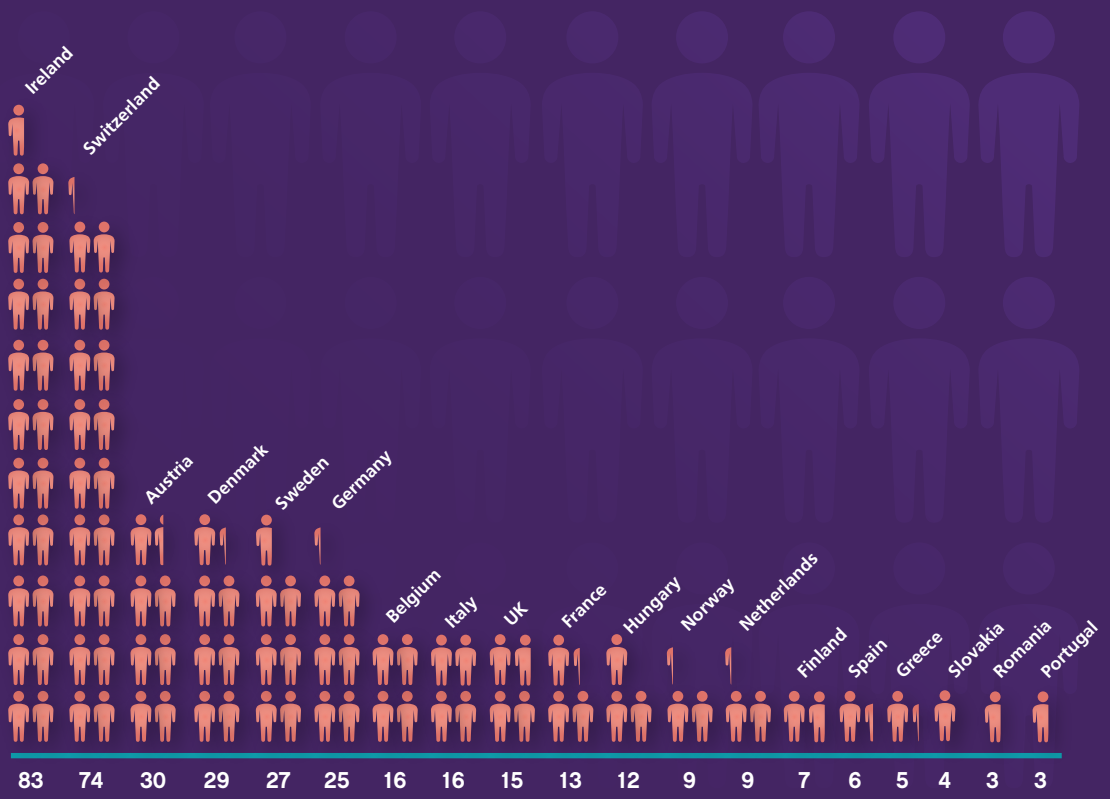
Graph 3 – Top 10 countries in Europe with highest direct employment in the medical technology industry

2020, or latest year available (ref. 3)

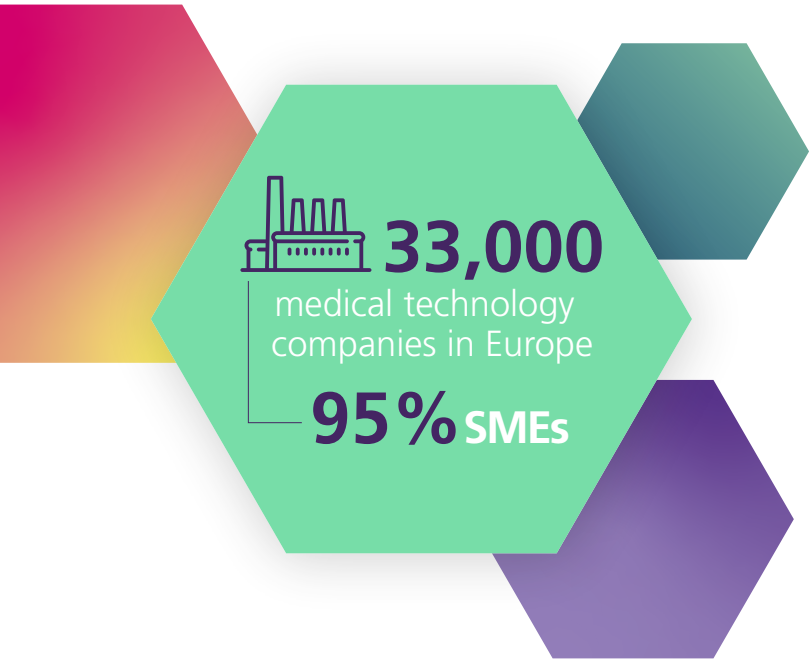


Graph 4 – Number of people directly employed in the medical technology industry per 10,000 inhabitants

2020 or latest year available (ref. 3)



Companies



There are more than 33,000 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].

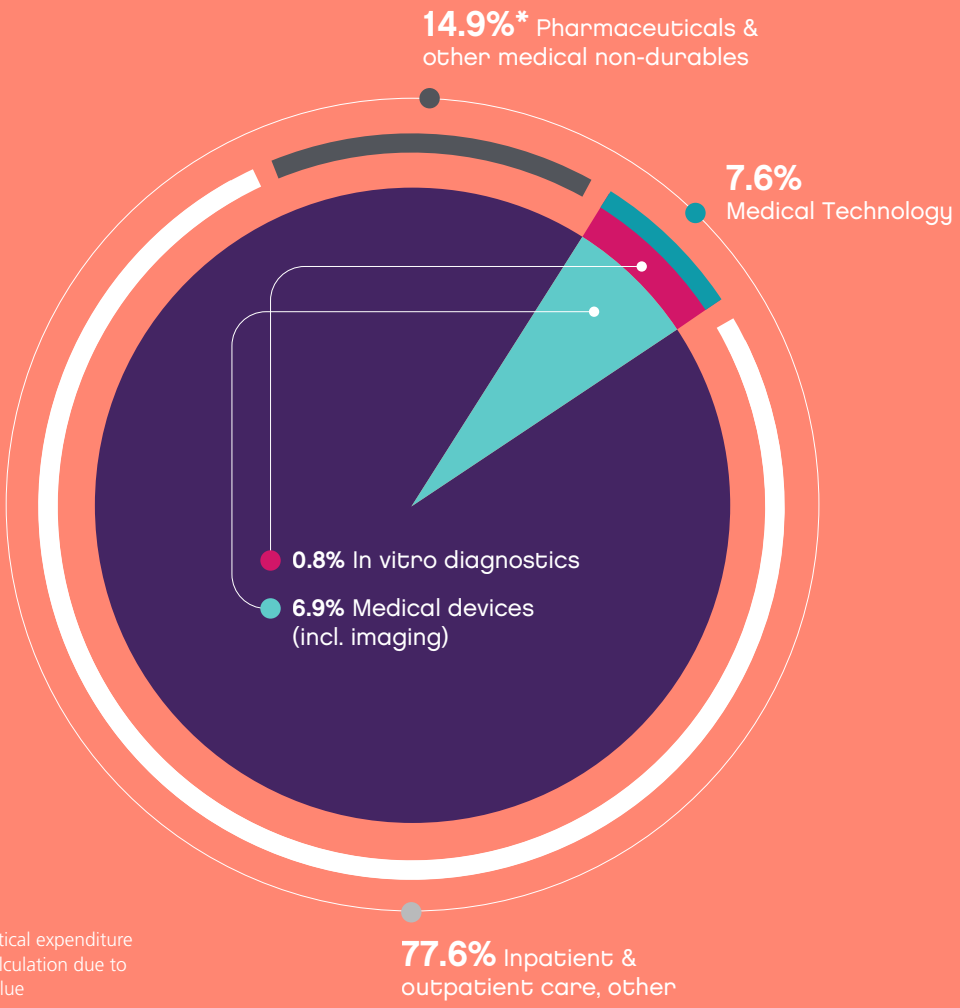
Expenditure on Medical Technology

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 €265 (weighted average).*

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

Graph 5 – Breakdown of total healthcare expenditure in Europe

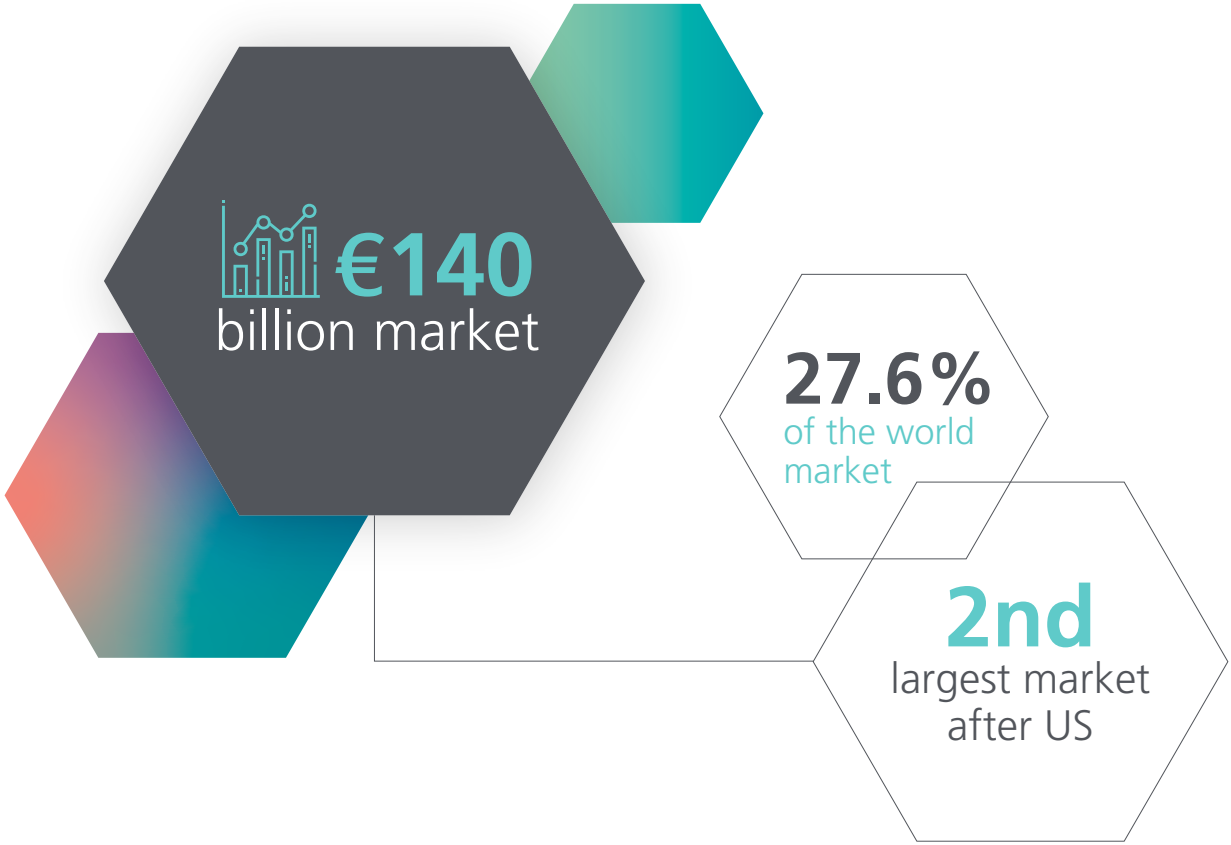
2020 (ref. 4–8)



*2019 Pharmaceutical expenditure is used for the calculation due to a lack of 2020 value


CYTOSINE
GUANINE
ADENINE
THYMINE

MedTech Market in Europe

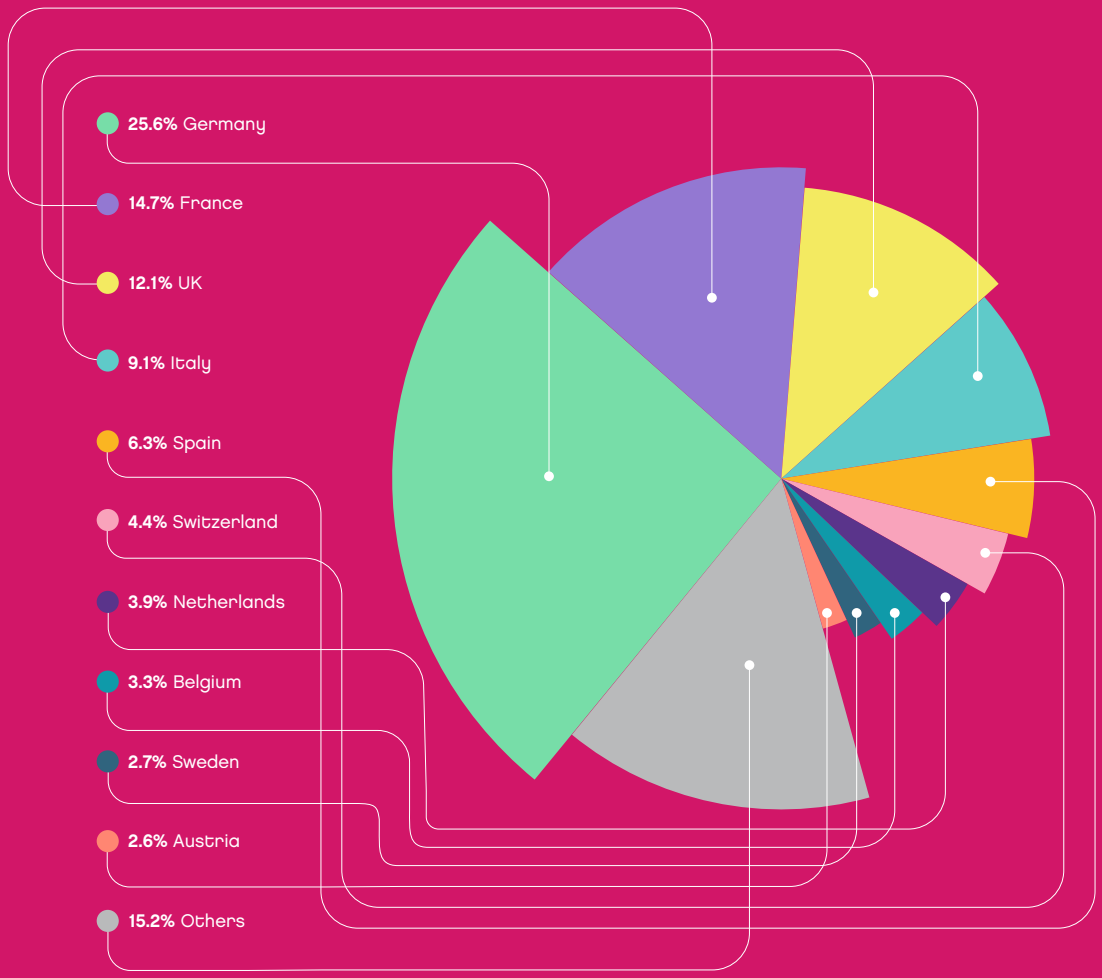


The European medical technology market is estimated at roughly €140 billion in 2020.[7,8] The biggest medical device markets in Europe are Germany, France, the United Kingdom, Italy and Spain. The same group of countries forms the top 5 IVD markets in Europe. (Graphs 6 and 7)

Based upon manufacturer prices the European medical device market is estimated to make up 27.6% of the world market. It is the second largest medical device market after the US (41.6%).[8]

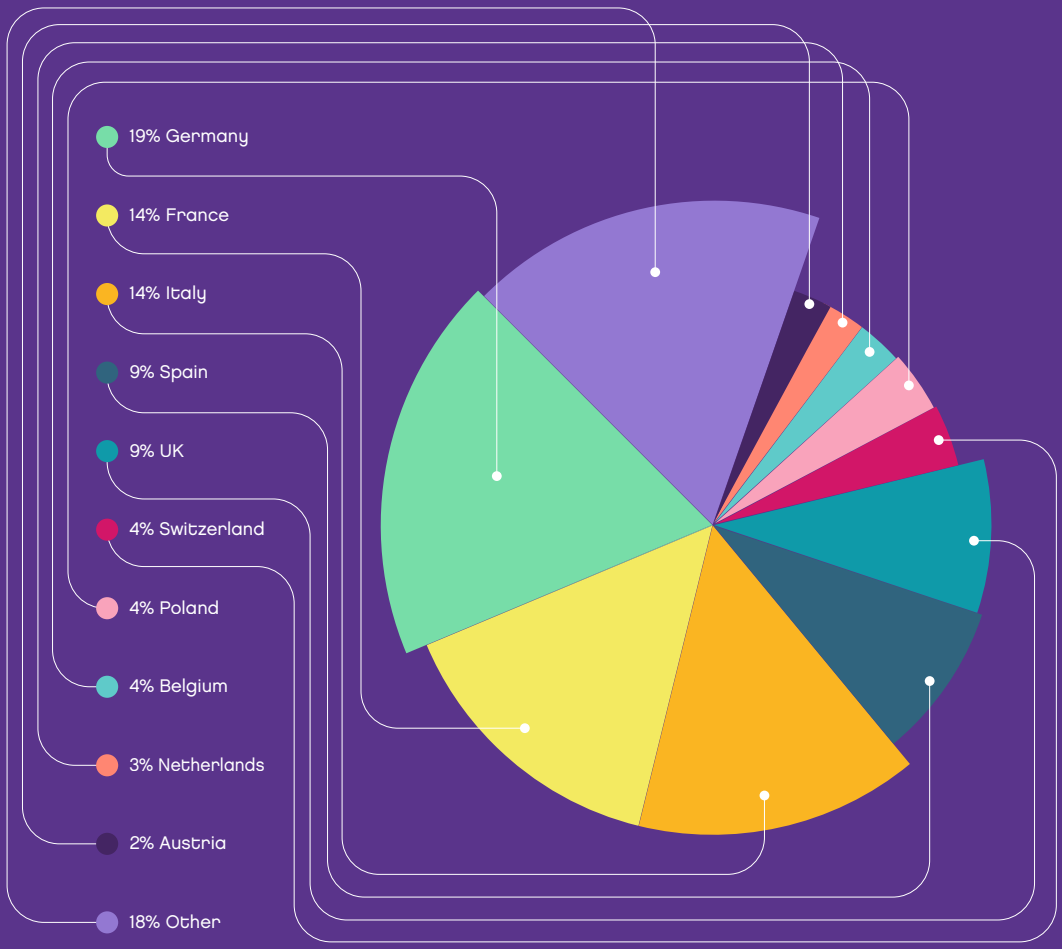
Graph 6 – European medical device market by country

2020 (ref. 8)



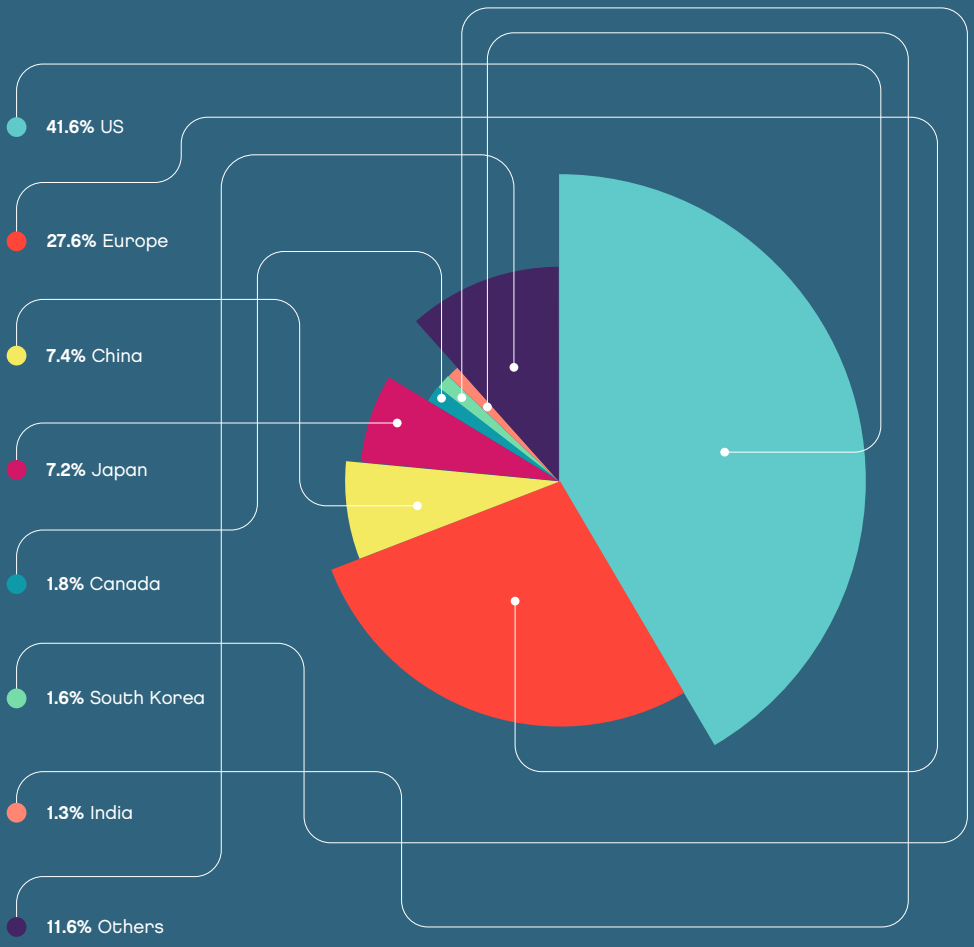
Graph 7 – European IVD market by country

2019 (ref. 7)



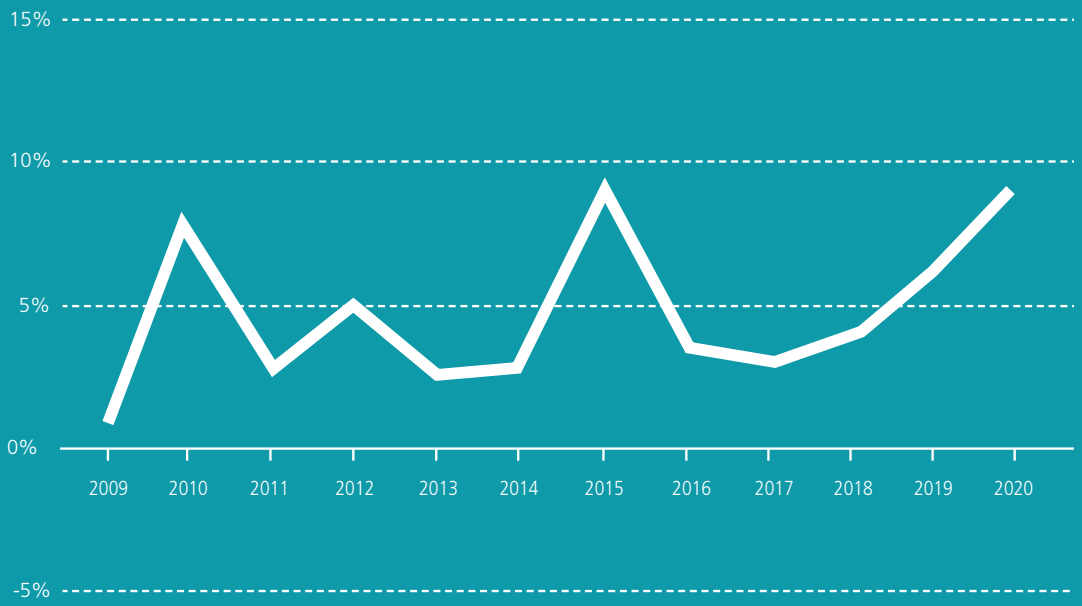
Graph 8 – Europe in the world medical device market

2020 (ref. 8)



Graph 9 – European medical device market growth rates

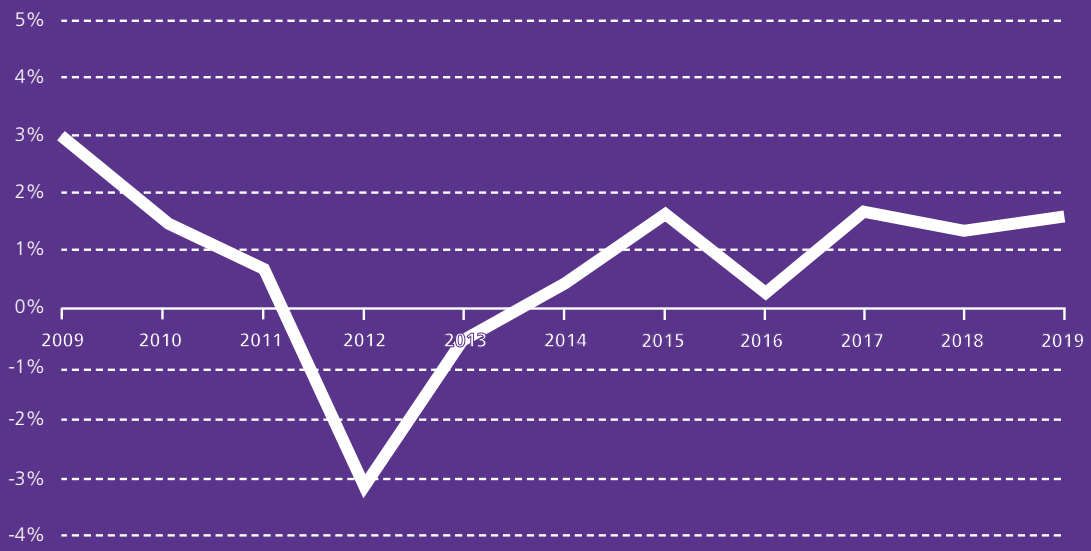
2009-2020 (ref. 8)



The European medical device market has been growing on average by 2% per year over the past 10 years. Demand fell in 2009 due to the economic crisis, resulting in a growth rate of only 1% (lowest in 12 years). The market regained its pace in 2010, and since then the annual growth rate has varied between 2.6% (2013) and 9.3% (2015), being 8.5% in 2020.[8]

Graph 10 – European IVD market growth rates

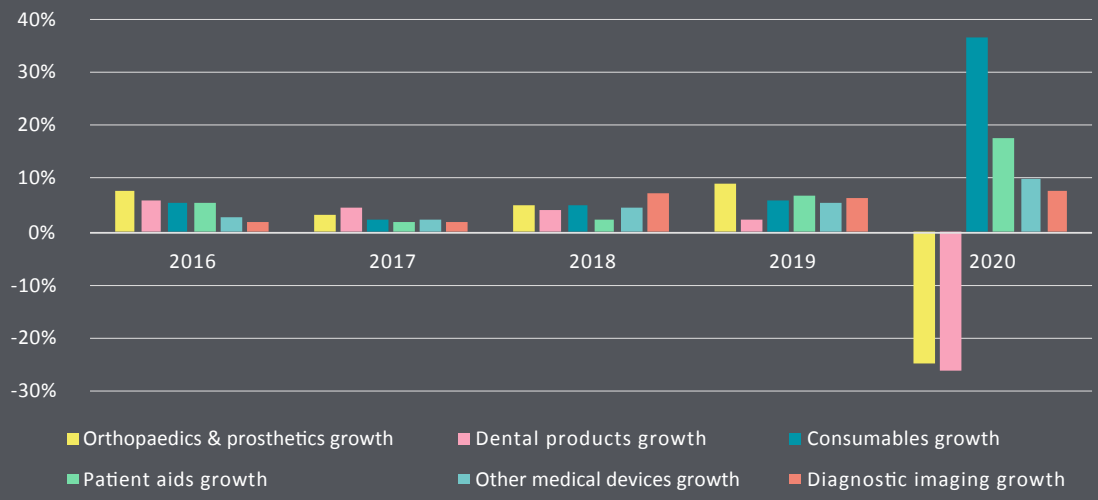
2009-2019 (ref. 7)



The European IVD market growth has been slowing down until 2013 with annual growth rates at around 2-4%. The average growth rate since 2013 has been 0.9% while the 2019 annual growth rate for the European IVD market was 1.5%.

Graph 11 - European medical technology growth rates by sectors

2016-2020 (ref. 8)



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

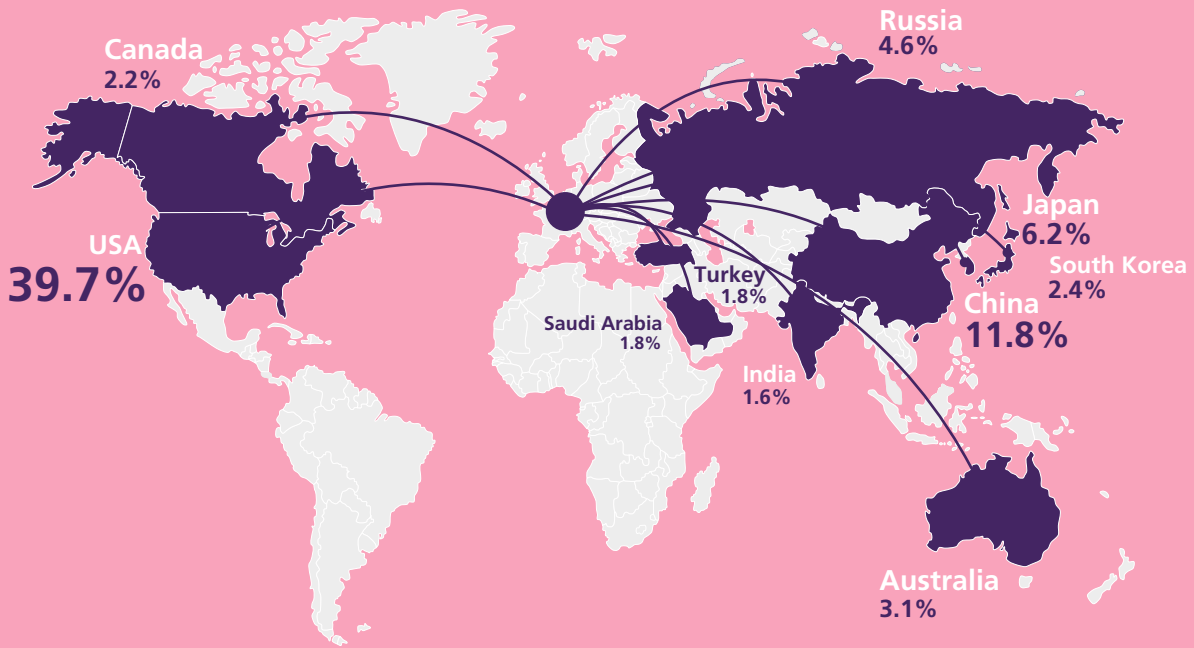
On the other end of the spectrum, sales of IVD (e.g. PCR tests), consumables (e.g. nasal cannulae, syringes, surgical gloves) and patient aids (artificial respiration apparatus such as ventilators) products skyrocketed as these medical technologies provided the special care severe COVID-19 patients require.

Trade in Europe

Europe has a positive medical devices trade balance of €8.7 billion (2020). Compared to the previous years, the main European medical device trade partners remain the same: the US, China, Japan and Mexico.[9]

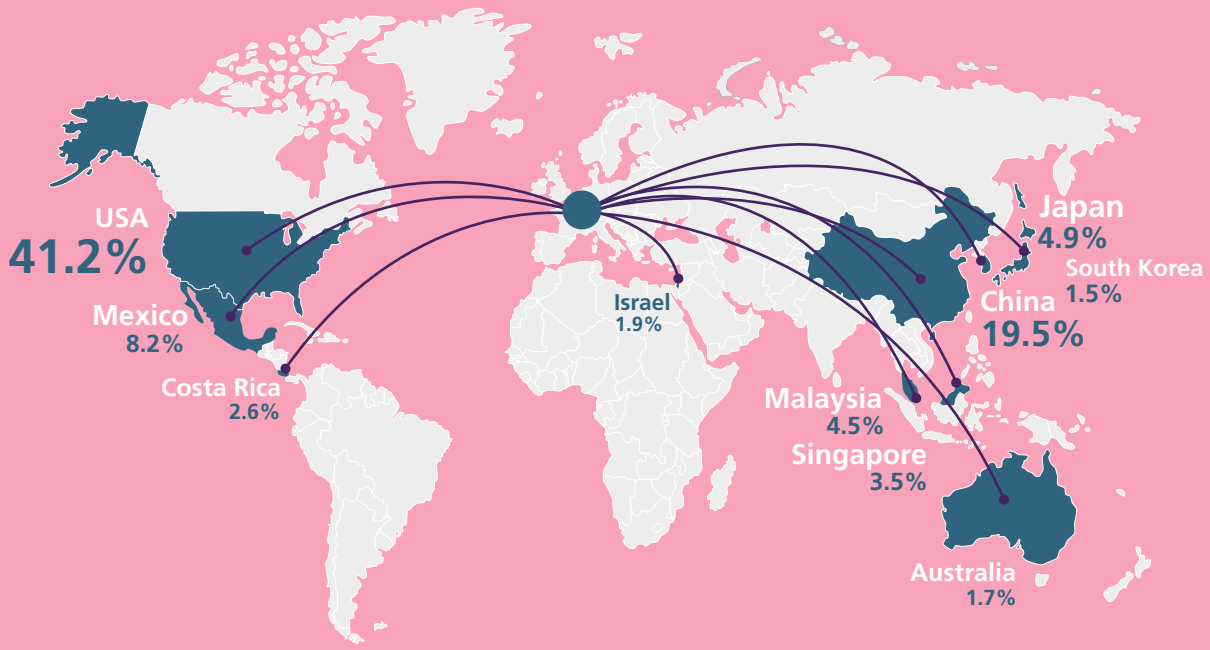
Graph 12 - Top European medical technology export destinations

2020 (ref. 9)



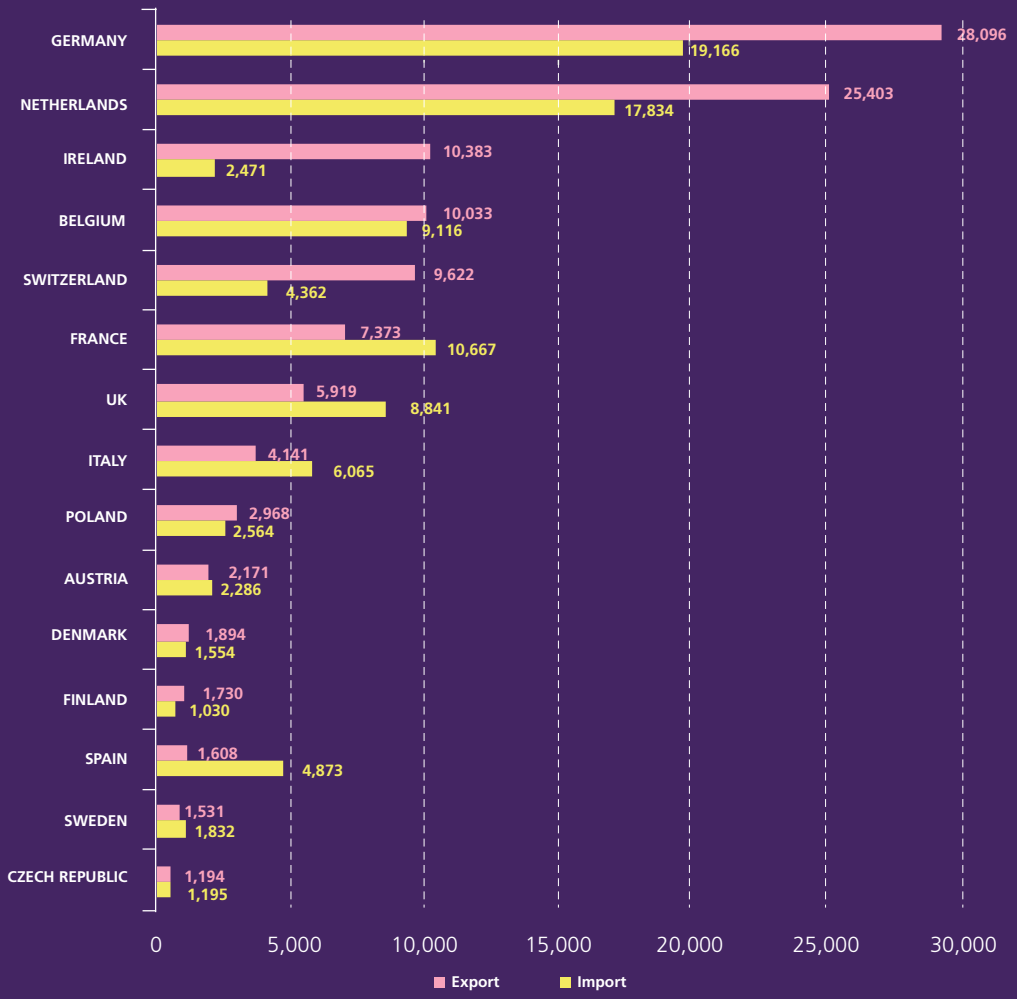
Graph 13 – Top import suppliers to the European medical devices market

2020 (ref. 9)



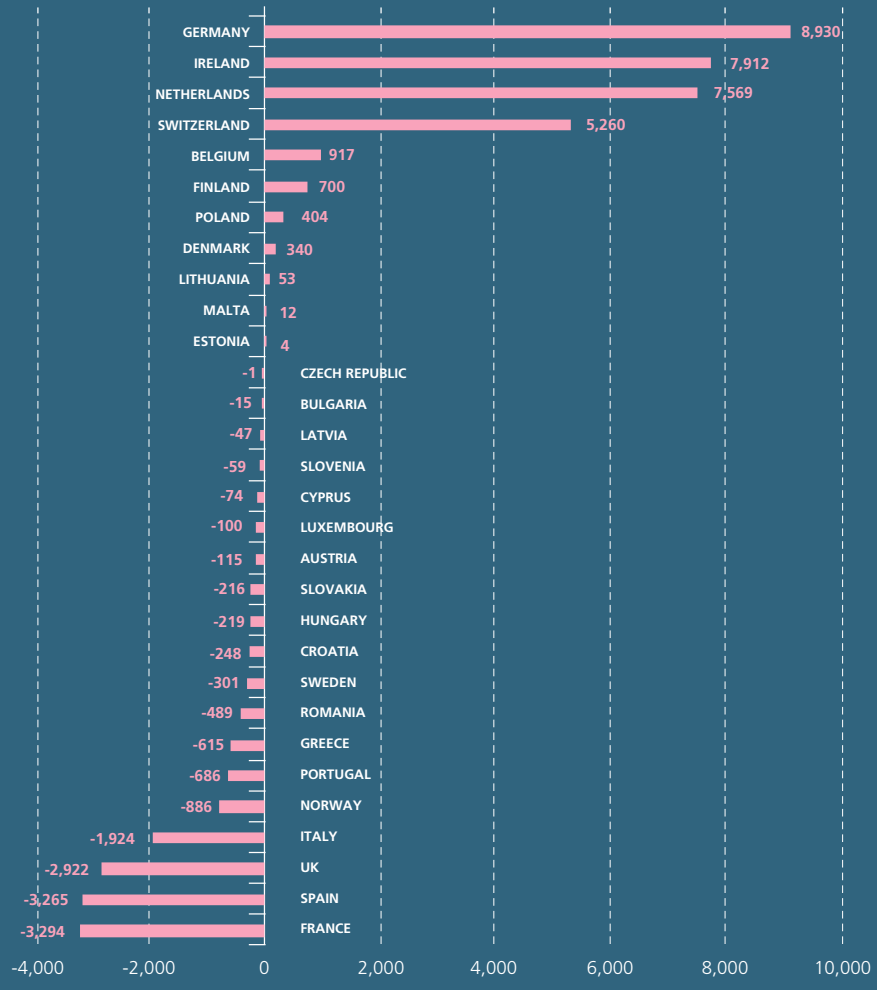
Graph 14 – Export and import of medical devices by country

Including intra-community trade, million euros, 2020 (ref. 9)



Graph 15 – Medical devices trade balance by country

Including intra-community trade, million euros, 2020 (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 2020 survey carried out among MedTech Europe's National Associations. 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 Evaluate MedTech, 2018, World Preview 2018, Outlook to 2024.

2 European Patent Office (EPO), 2021, Patent Index 2020.

3 MedTech Europe, 2020, National Associations Survey.

4 EFPIA, 2020, The Pharmaceutical Industry in figures.

5 Eurostat, 2021, Employment and Population Statistics.

6 WHO, 2019, Global Health Expenditure Database.

7 MedTech Europe, 2020, European IVD Market Statistics Report 2020. 2020 IVD market size data is preliminary and is based on MedTech Europe Statistics Programmes

8 Fitch Solutions, 2021, Worldwide Medical Devices Market Factbook 2020.

9 International Trade Centre, 2021, International Trade Statistics – MedTech Europe calculations.

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