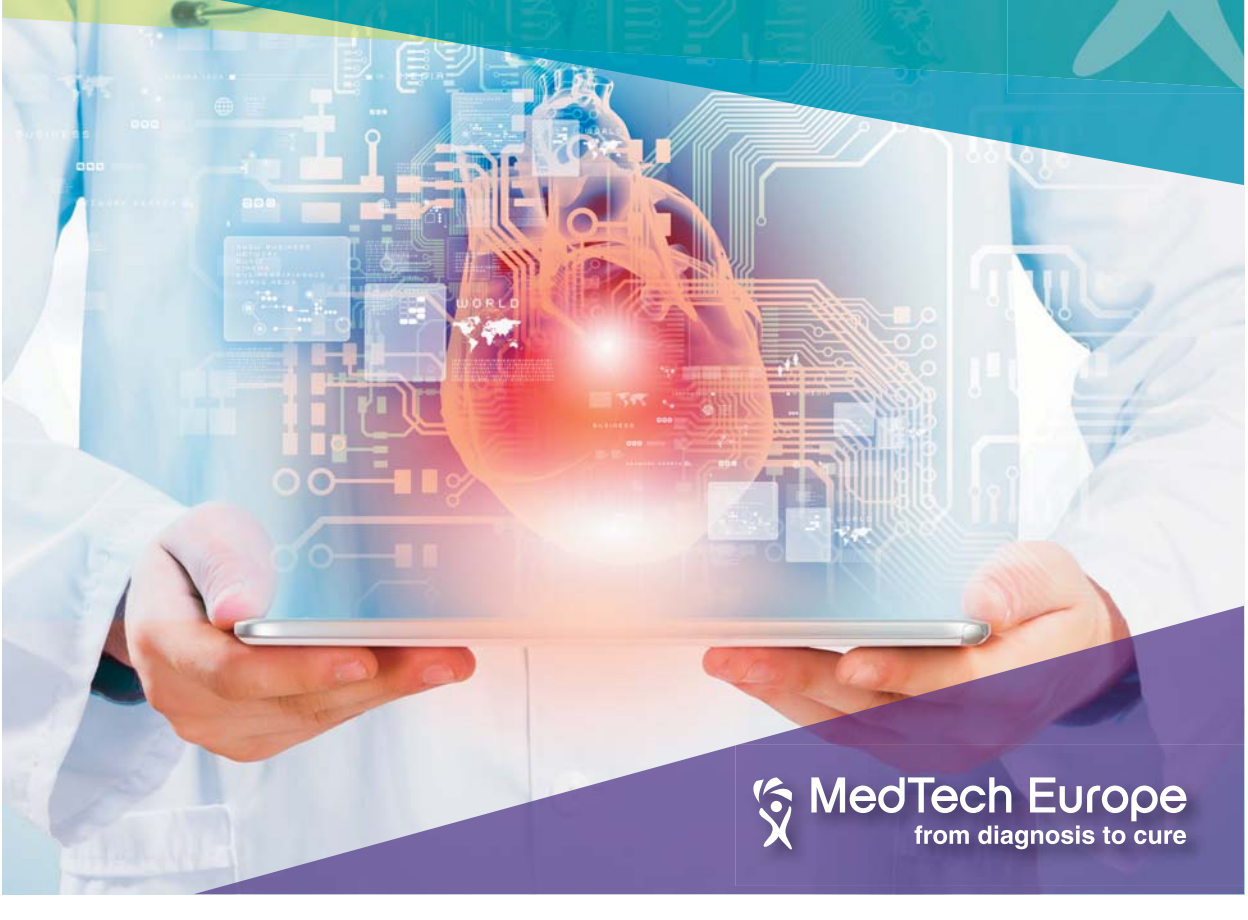
The European Medical Technology Industry

– in figures / 2018



MedTech Europe
from diagnosis to cure

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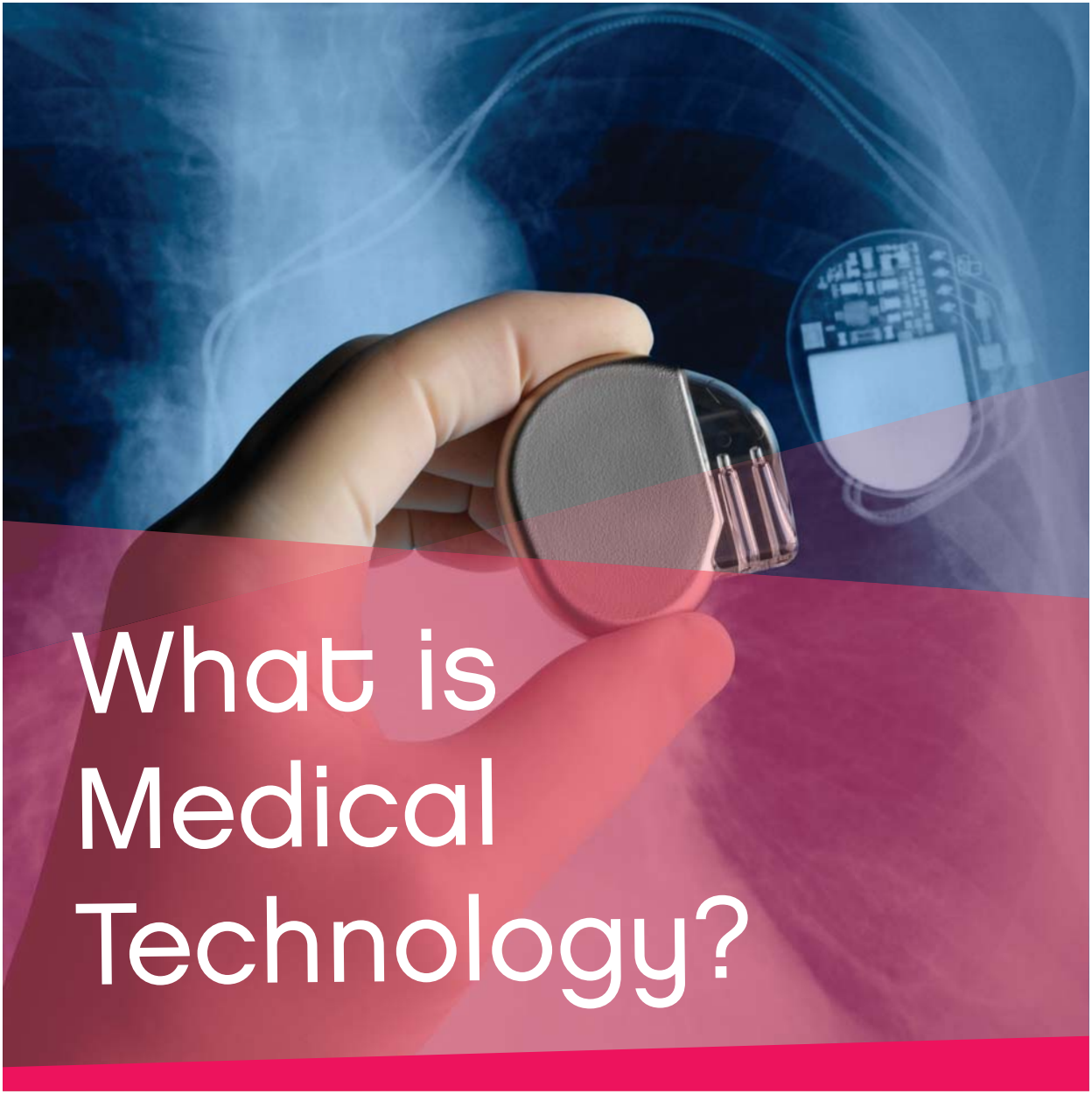


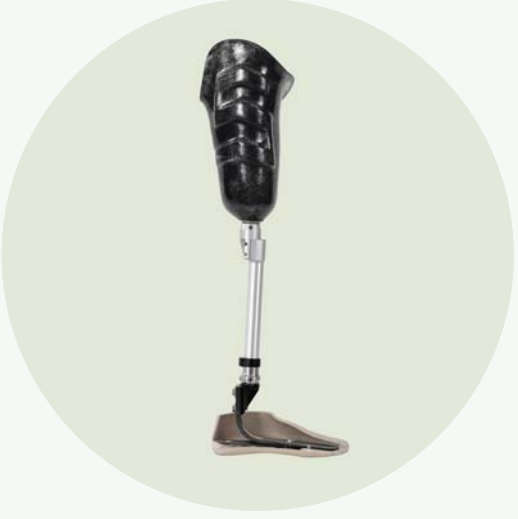
What is Medical Technology?

Medical technology is any technology used to save lives or transform the health of individuals suffering from a wide range of conditions. In its many forms, medical technology is already diagnosing, monitoring and treating virtually every disease or condition that affects us.

For the sake of this document, medical technology includes medical devices and *in vitro* diagnostic medical devices. Medical devices are products intended to perform a therapeutic or diagnostic action on human beings by physical means. In vitro diagnostic medical devices are products which provide medically useful diagnostic information by examination of a specimen derived from the human body.

There are more than 500,000 medical technologies currently available and they all share a common purpose: improving, extending and transforming people's lives. Medical technology can be familiar, everyday products such as blood glucose meters, sticking plasters, syringes or latex gloves. Alternatively, it can also be pregnancy tests, spectacles, wheelchairs and hearing aids. Meanwhile, at the high-tech end of the scale, medical technology includes molecular diagnostics, total body scanners, ultrasounds, life-supporting machines, implantable devices such as heart valves and pacemakers, neurostimulators and replacement joints for knees and hips.

The common thread through all applications of medical technology is the beneficial impact on health, quality of life and in society as a whole. Medical technologies contribute to living longer and better, and empower citizens to contribute to society for longer. In so doing, they improve the quality of care and the efficacy, efficiency and sustainability of healthcare systems.



Regulation and classification of medical technologies

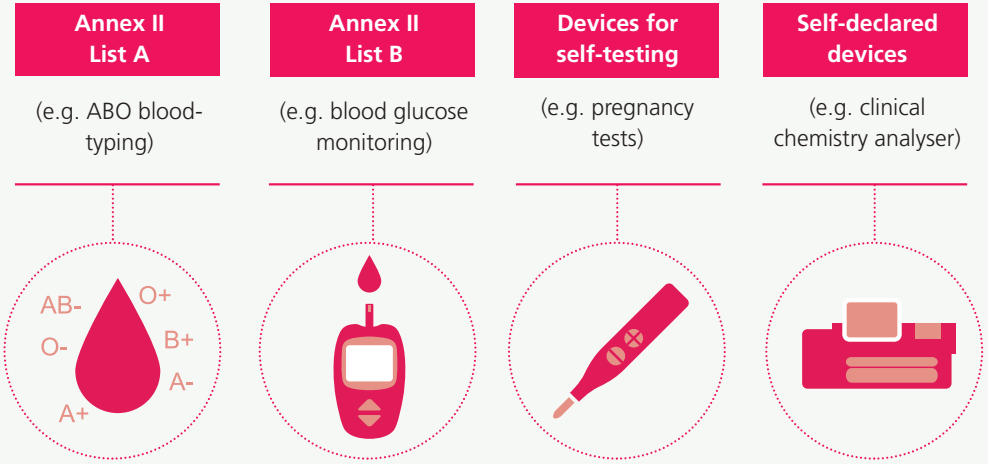
In the European Union, medical technologies are tightly regulated by laws that govern the safety and performance of devices across their lifetime, pre- and post-market. Over the next few years, the European medical technology sector will transition from being regulated under the current medical devices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

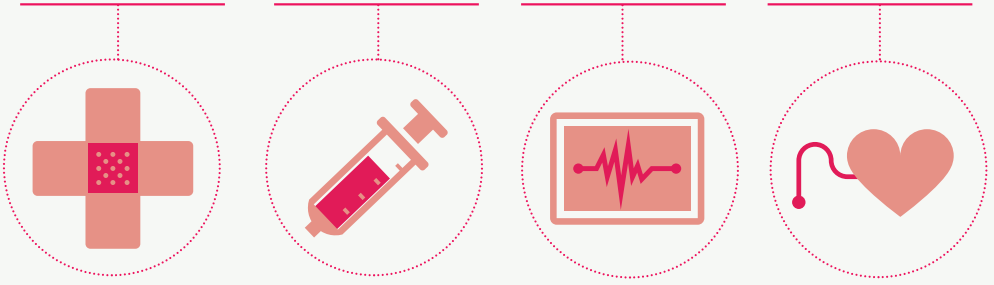
Classification of medical devices

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:

Class I	Class IIa	Class IIb	Class III
(e.g. simple bandages or wound care products)	(e.g. syringes without the needle)	(e.g. anaesthesia machines)	(e.g. pacemakers)



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.


10:12
Synchronization
10:12
100%
Health Book
72
bpm
Heart Rate
Sleep
Emergency

Innovation

Medical technology is characterised by a constant flow of innovation, which is the result 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 2016, more than 12,200 patent applications were filed with the European Patent Office (EPO) in the field of medical technology – 7.7% of the total number of applications –, still more than any other sector in Europe. 41% of these patent applications were filed from European countries (EU28, Norway and Switzerland) and 59% from other countries, out of which with the majority of applications filed from the US (38%).

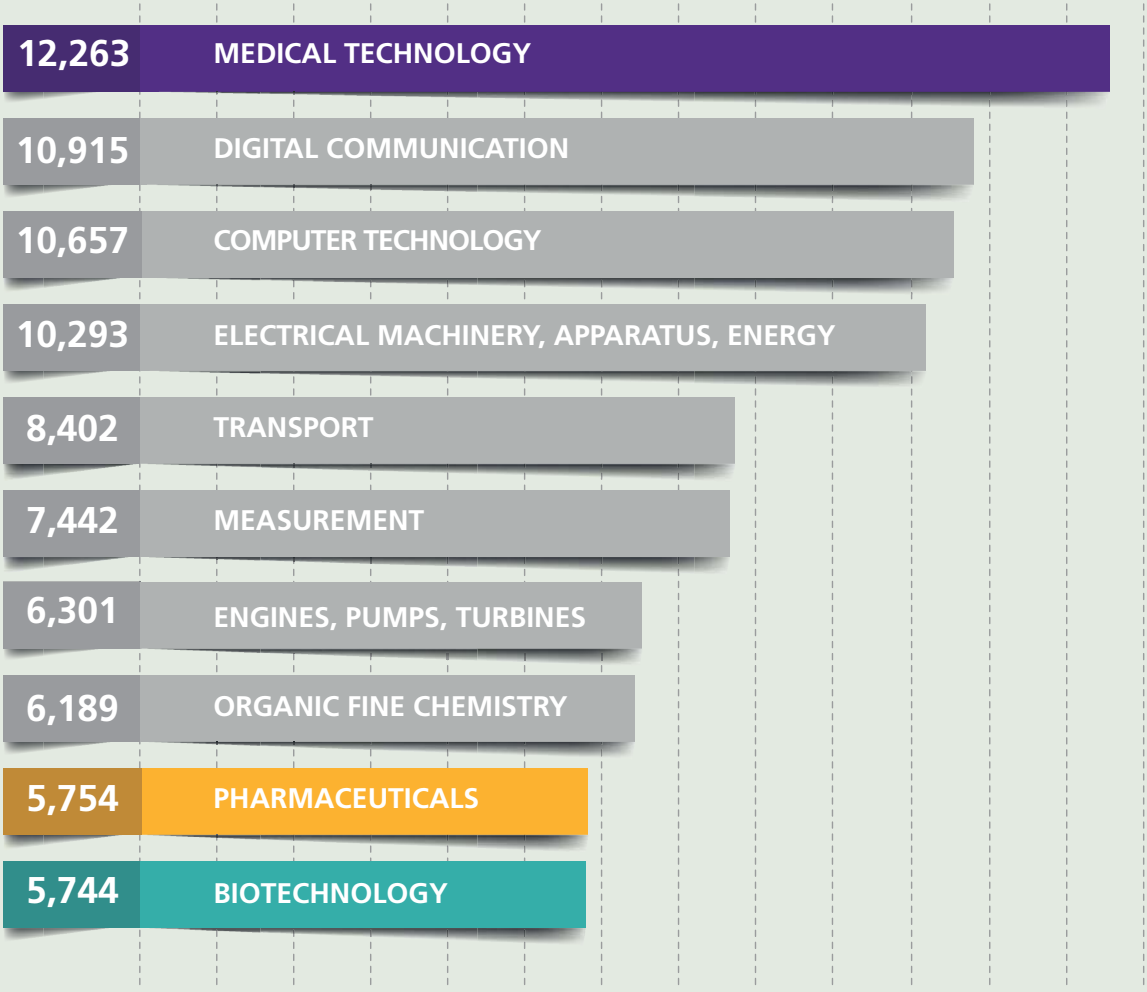
In comparison, around 5,700 applications were filed in the pharmaceutical field and around 5,700 also in the field of biotechnology. While over the last decade the number of EPO filings in the field of medical technology has doubled, pharma and biotech patent applications were relatively stagnant[1].

PATENT APPLICATION IN MEDICAL TECHNOLOGY FIELD FILLED WITH EPO IN 2016

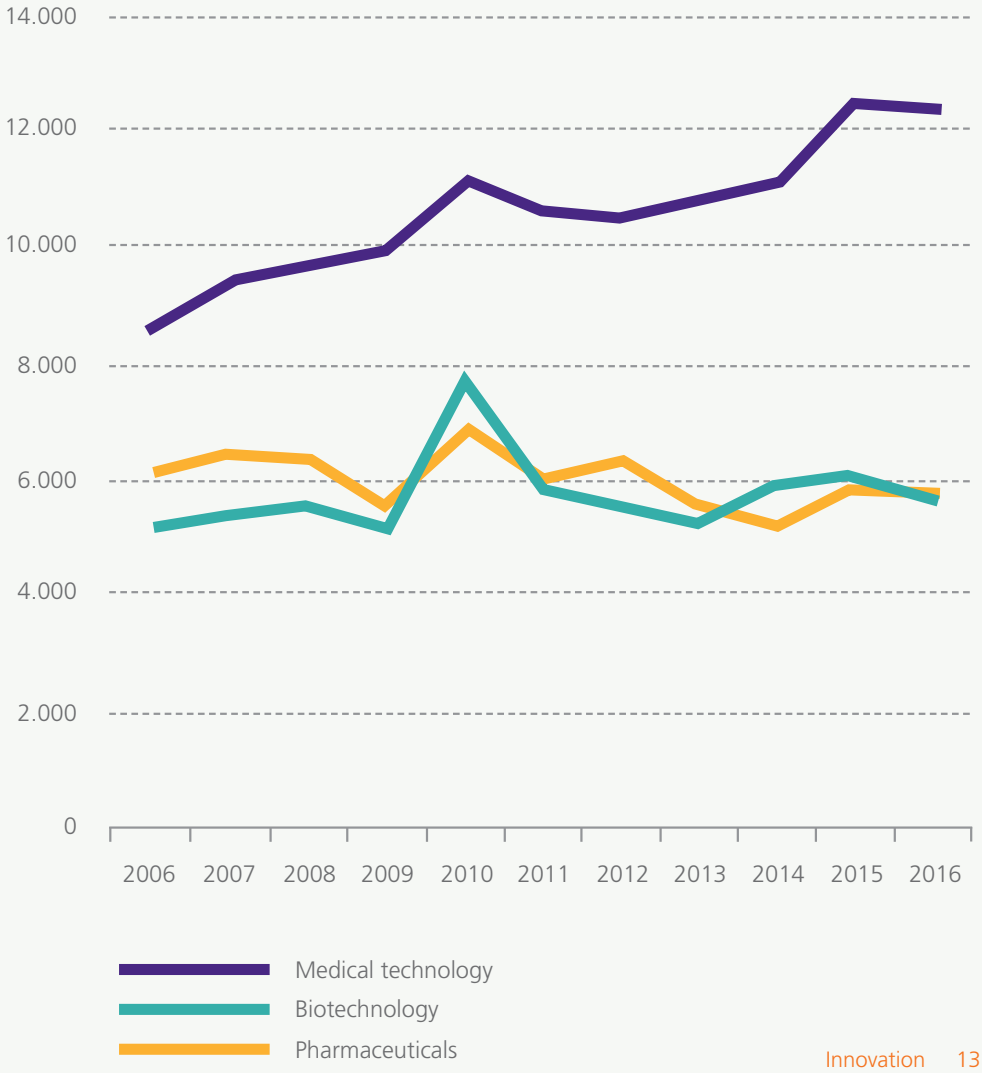
41%
EU28, Norway and Switzerland

59%
Other countries

TOP 10 TECHNICAL FIELDS IN PATENT APPLICATIONS.
NUMBER OF PATENT APPLICATIONS FILED WITH EPO, 2016 (REF. 1)



EVOLUTION OF EUROPEAN PATENT APPLICATIONS BY TECHNICAL FIELD (REF. 1)



Employment

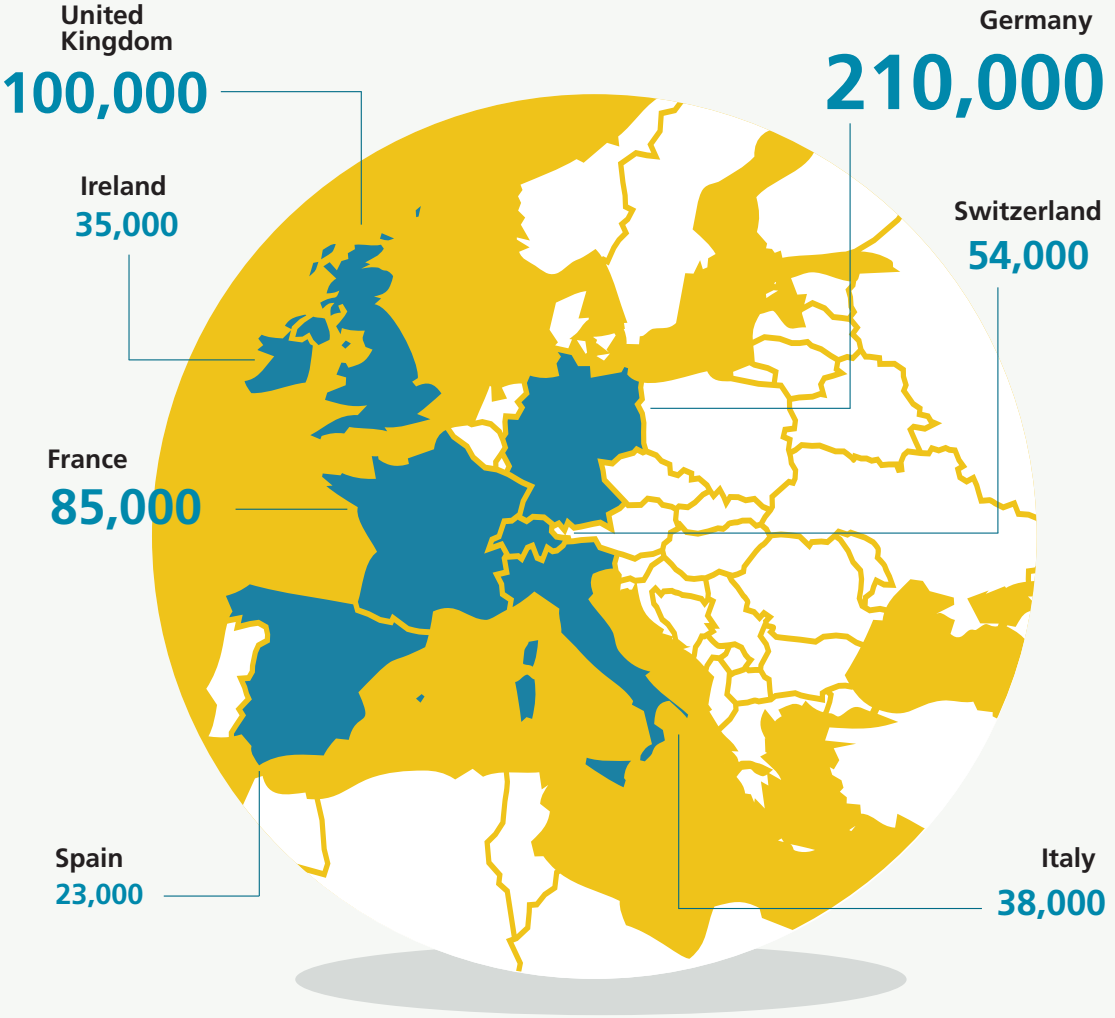
>675,000 employees[3]

The European medical technology industry employs directly more than 675,000 people. Germany had 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.

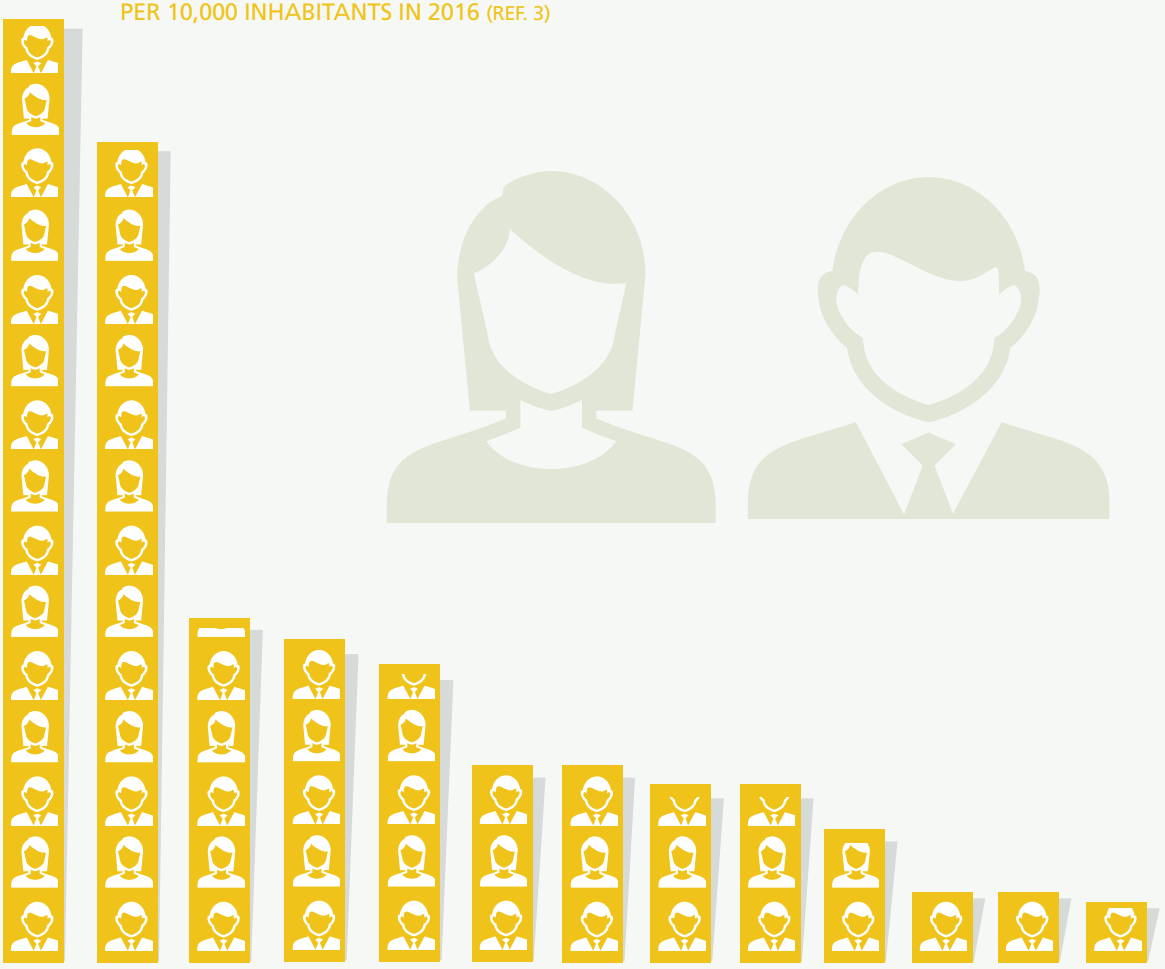
In comparison, the European pharmaceutical industry employs more than 740,000 people[2].

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

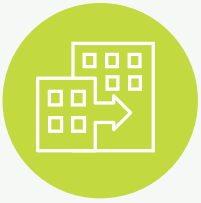
TOP 7 COUNTRIES WITH HIGHEST EMPLOYMENT IN THE MEDICAL TECHNOLOGY INDUSTRY (REF. 3)



NUMBER OF PEOPLE DIRECTLY EMPLOYED IN THE MEDICAL TECHNOLOGY INDUSTRY PER 10,000 INHABITANTS IN 2016 (REF. 3)



Companies



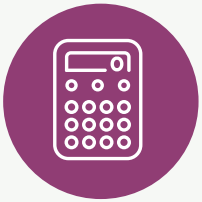
27,000
medical technology companies in Europe

95%
SMEs

There are approximately 27,000 medical technology companies in Europe. Most of them are based in Germany, followed by the UK, Italy, Switzerland, France and Spain. Small and medium-sized companies (SMEs*) make up almost 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).

Expenditure on Medical Technology

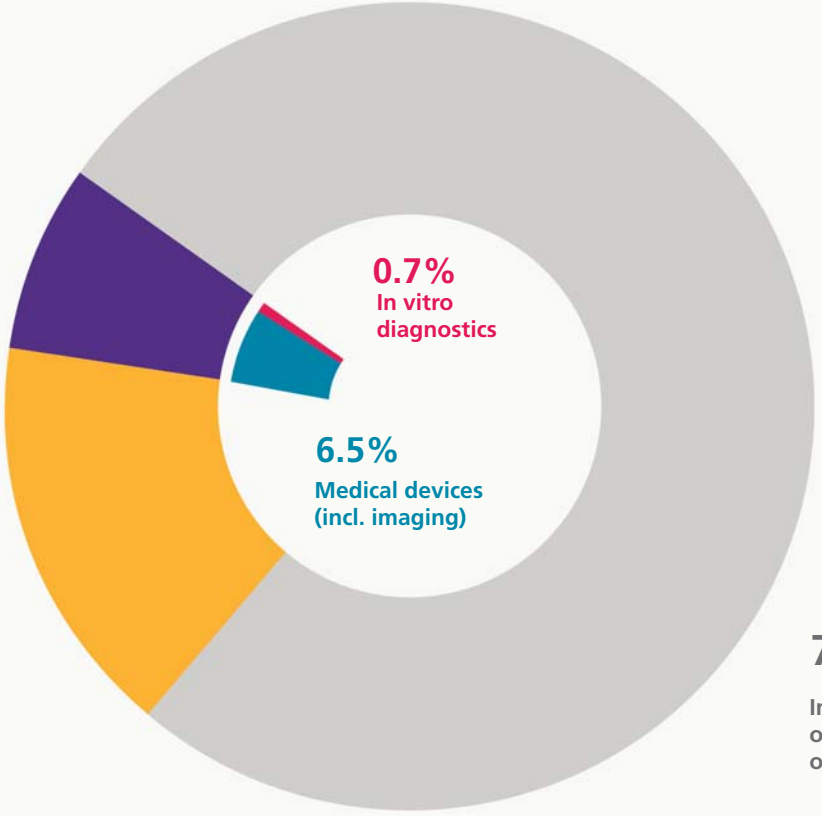


€203

Expenditure on medical technology per capita in Europe

In Europe, an average of 10% of gross domestic product (GDP) is spent on healthcare. Of this figure, 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 €203 (weighted average).

BREAKDOWN OF TOTAL HEALTHCARE EXPENDITURE IN EUROPE (REF. 5)



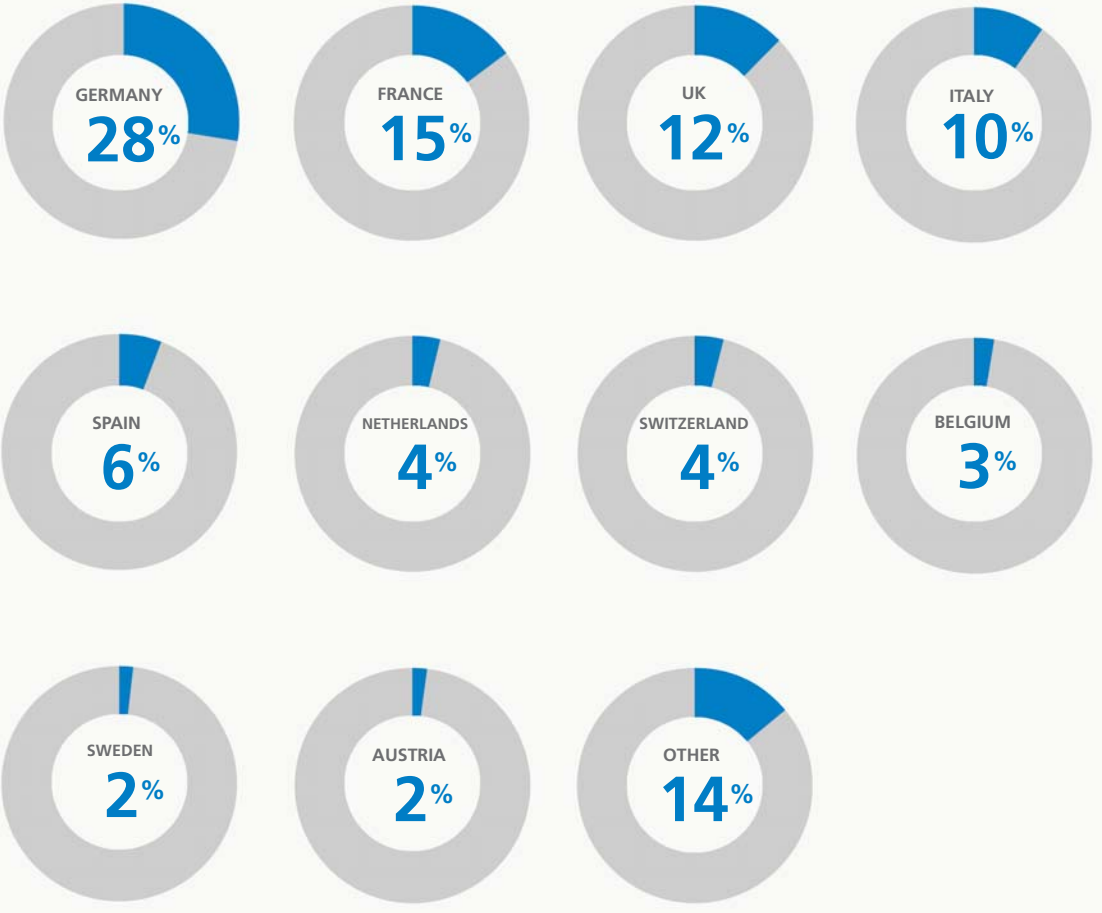
MedTech Market in Europe

€110
billion market

The European medical technology market in 2016 is estimated at roughly €110 billion[6].

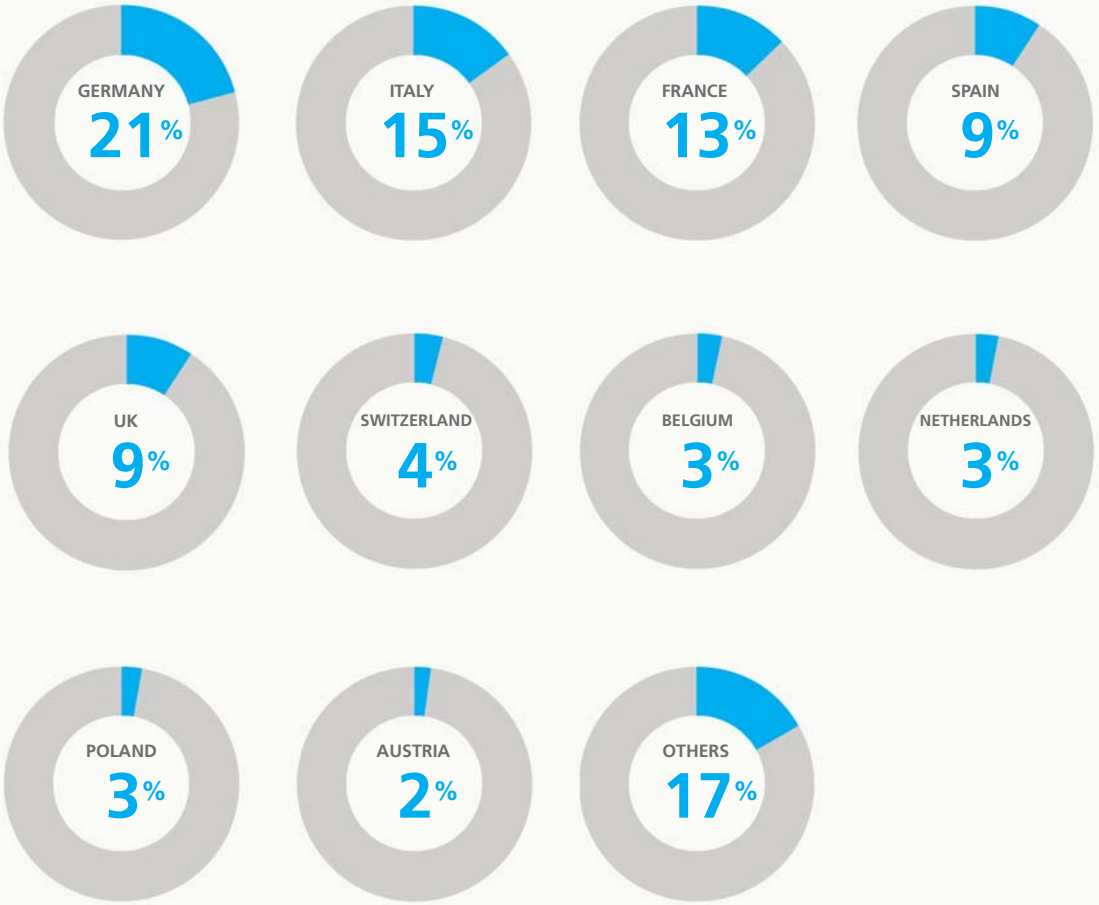
Based upon manufacturer prices the European medical technology market is estimated to make up 29% of the world market. It is the second largest medical technology market after the US (approximately 43%).

EUROPEAN MEDICAL DEVICE MARKET BY COUNTRY, BASED UPON MANUFACTURER PRICES, 2016 (REF. 6)

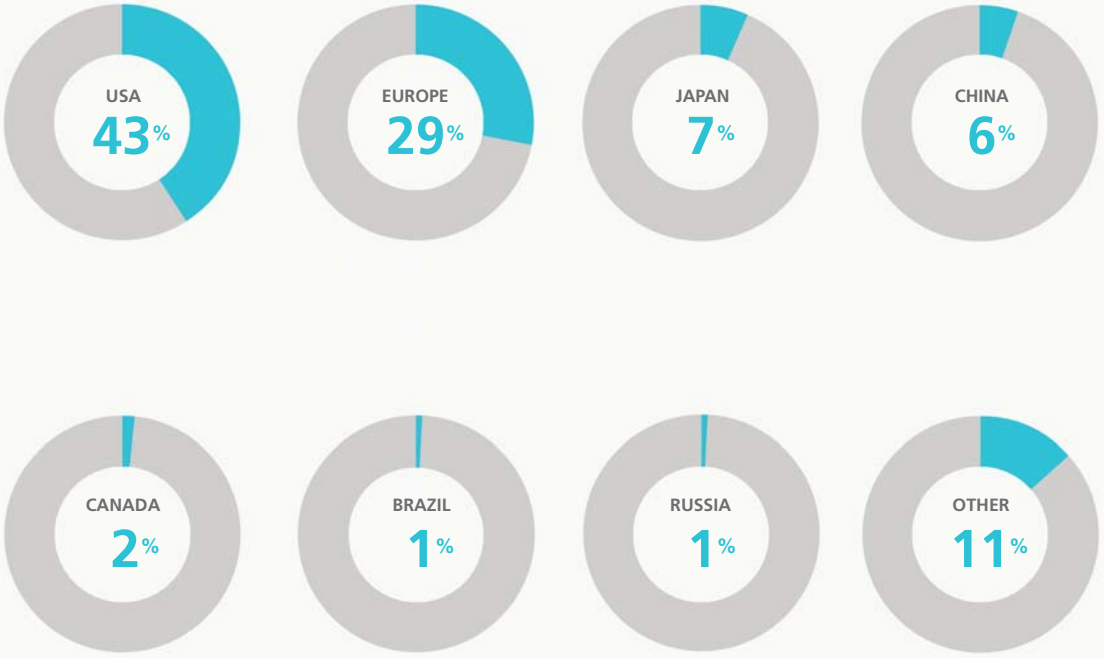


The biggest medtech markets in Europe are Germany, France, the United Kingdom, Italy and Spain[6]. The same countries form the top 5 IVD markets in Europe[7].

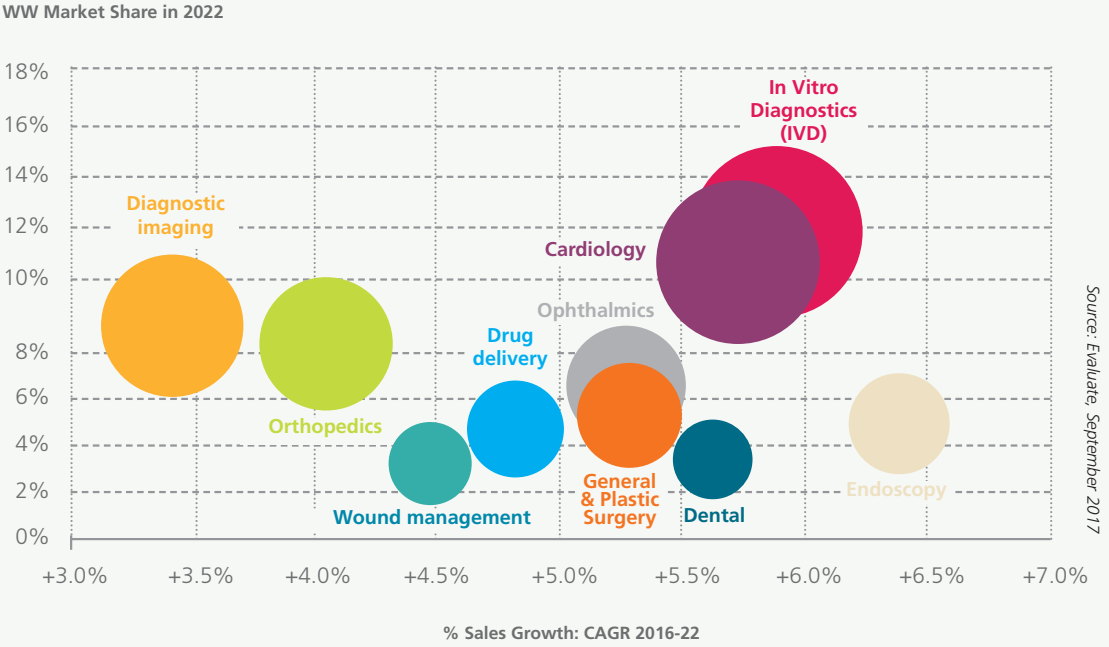
EUROPEAN IVD MARKET BY COUNTRY, 2016 (REF. 7)



WORLD MEDICAL DEVICE MARKET BY REGION BASED UPON MANUFACTURER PRICES, 2016 (REF. 6)



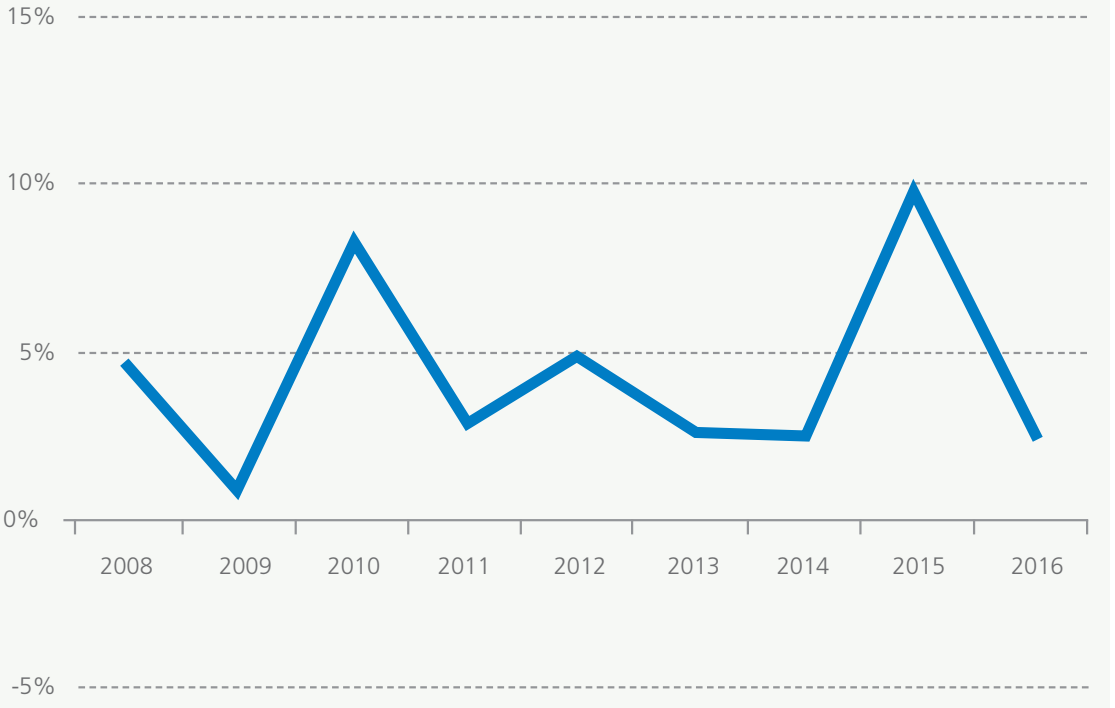
WORLD MEDICAL TECHNOLOGY MARKET BY AREA AND SALES GROWTH, 2016-2022 (REF. 8)



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[8].

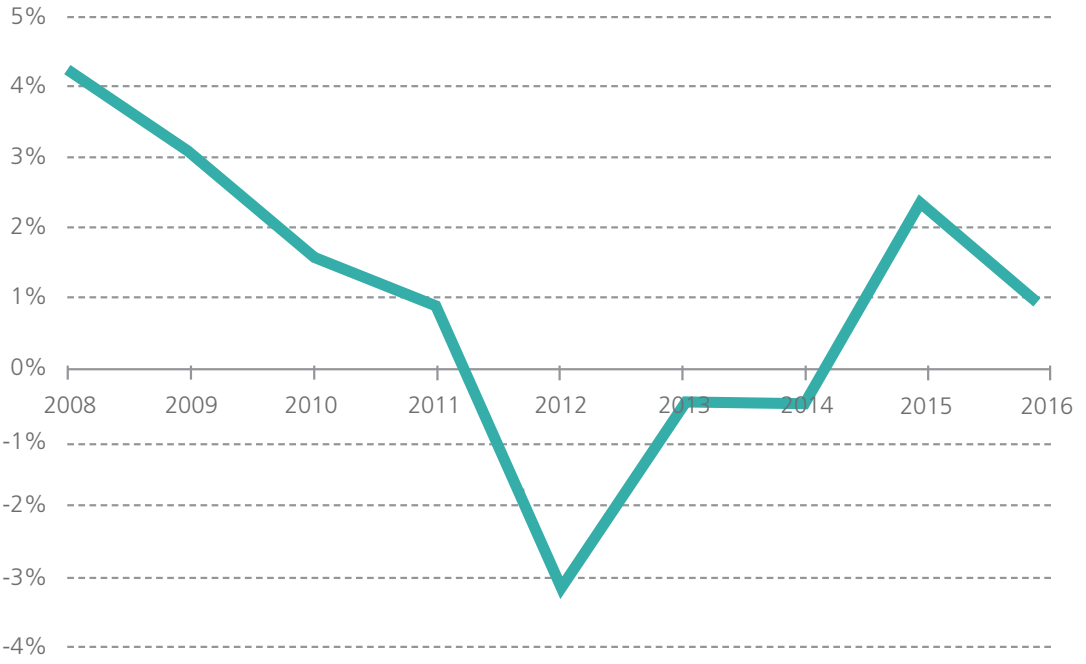
Note: Size of Bubble = WW Sales in 2022

EUROPEAN MEDICAL DEVICE MARKET GROWTH RATES, BASED UPON MANUFACTURER PRICES, 2008-2016 (REF. 6)



The European medical technology market has been growing on average by 4,4% per annum over the past 9 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.

EUROPEAN IN VITRO DIAGNOSTICS MARKET GROWTH RATES, BASED UPON MANUFACTURER PRICES, 2008-2016 (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 2016 was around 1%.

* Market size estimated in manufacturers' prices, not including margins, such as value added in the wholesaling and retailing, transportation costs, some taxes included in the final price, etc.

Trade in Europe

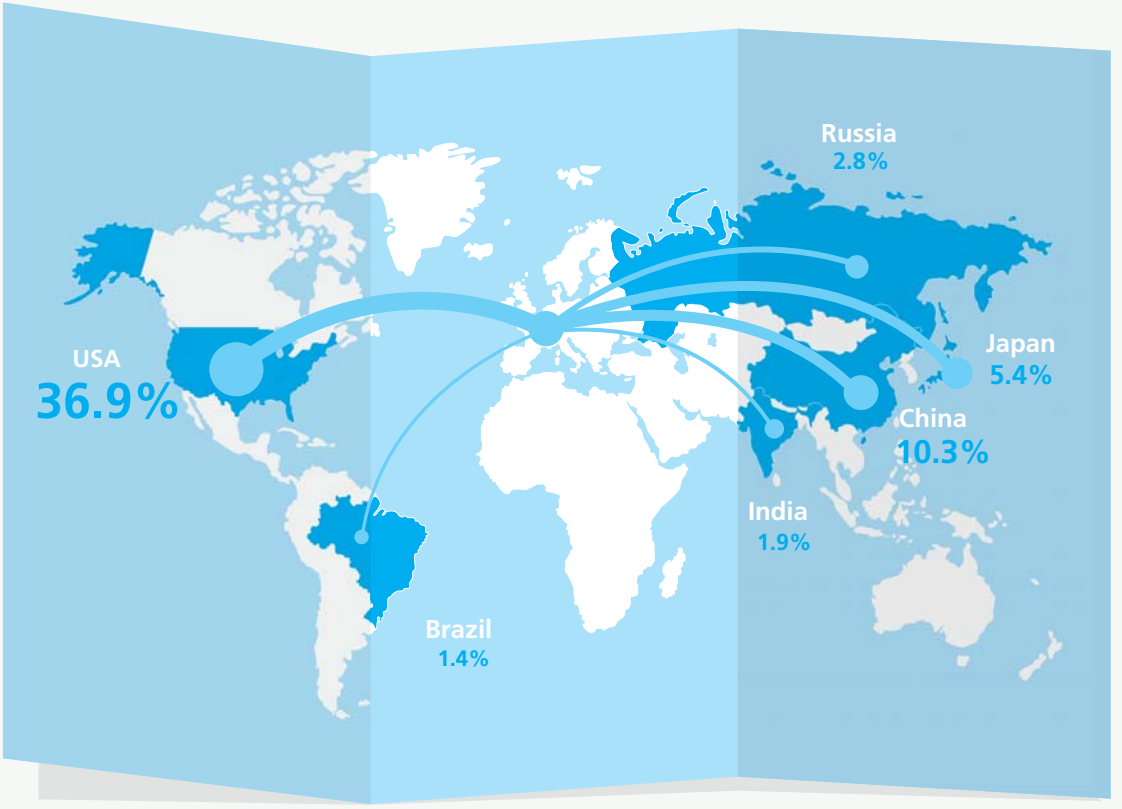
€17.5 billion

Estimation of Europe's trade surplus in 2016

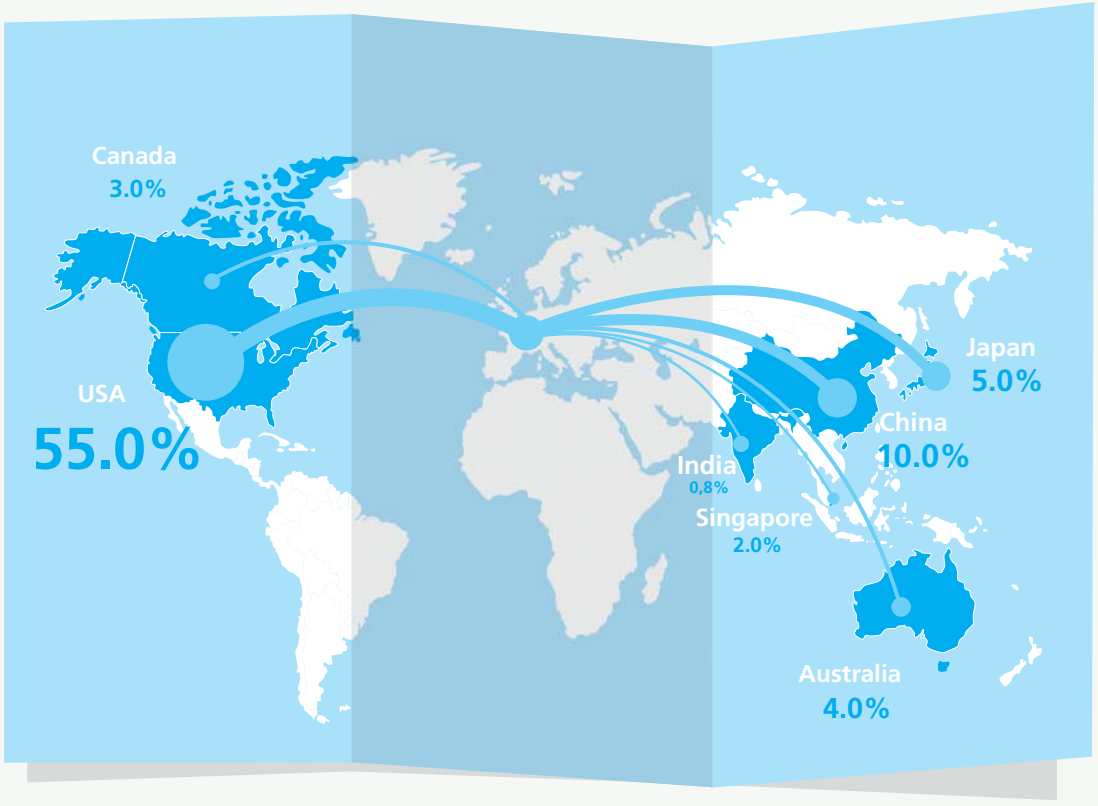
Europe has a positive medical technology trade* balance of €17.5 billion (2016) and this represents a more than twofold increase since 2006. In comparison, the US medical technology trade surplus is at €5 billion. Compared to 2012, the main European medtech trade partners remain the same: the US, China and Japan (Ref 6).

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

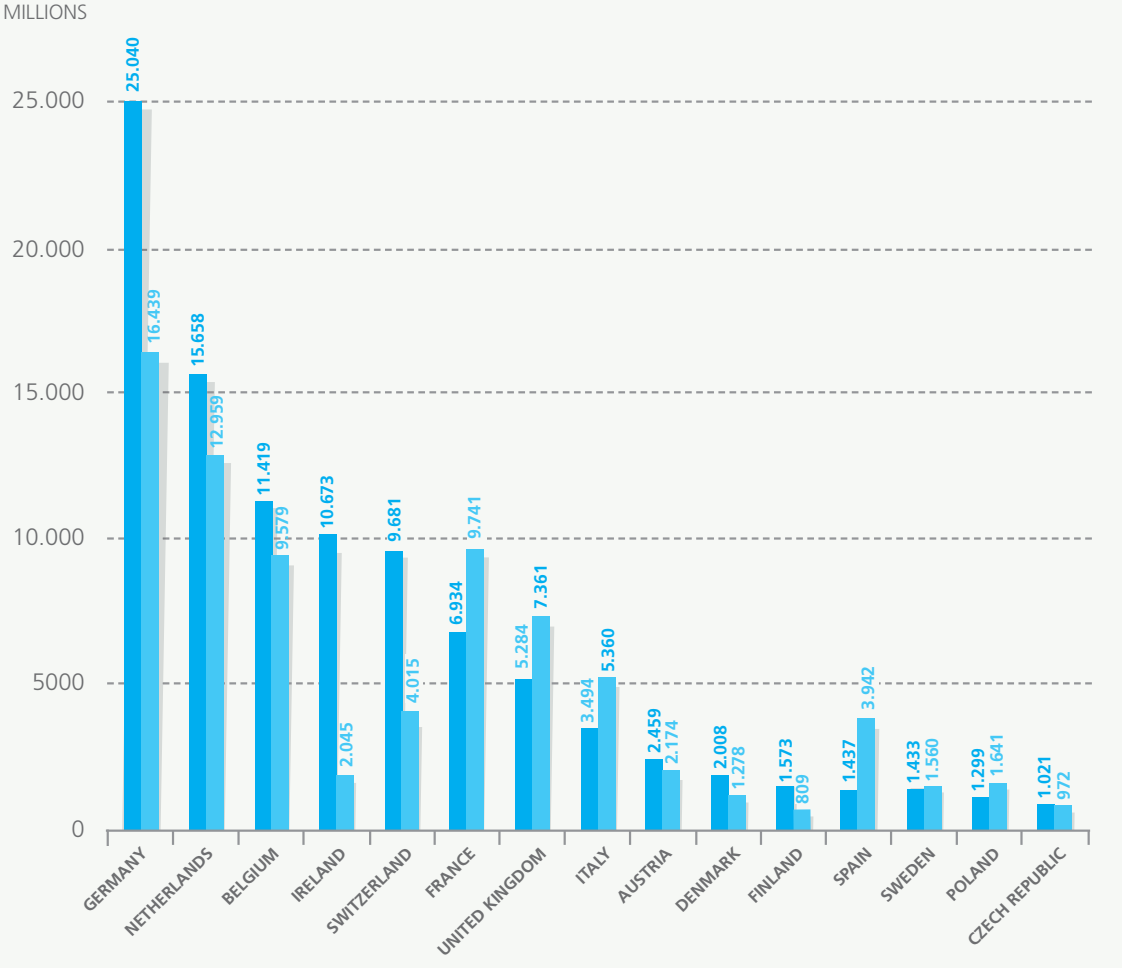
TOP EUROPEAN MEDICAL DEVICE EXPORT DESTINATIONS, 2016 (REF. 6)



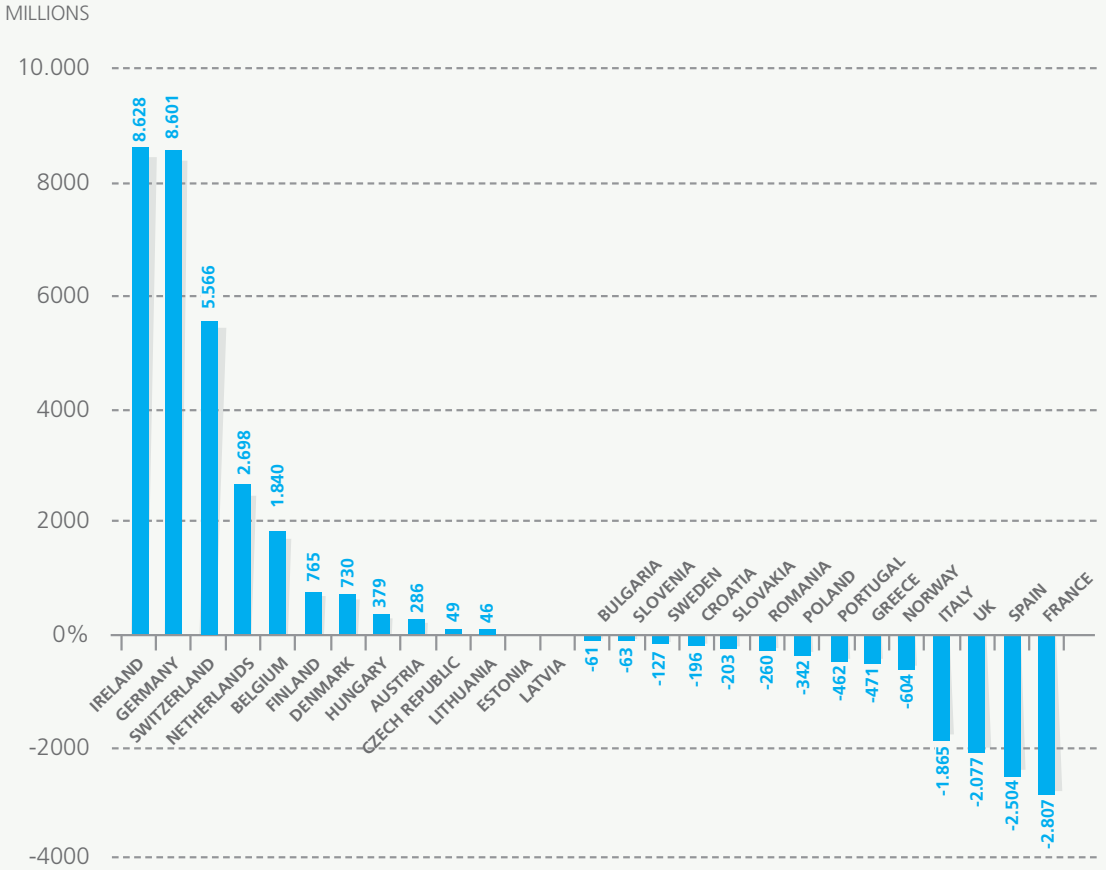
TOP SUPPLIERS TO EUROPEAN MEDICAL DEVICE MARKET (IMPORTS), 2016 (REF. 6)



EXPORT AND IMPORTS OF MEDICAL DEVICE BY COUNTRY 2016 (INCLUDING INTRA-COMMUNITY TRADE, MILLION EUROS) (REF. 6)



MEDICAL DEVICE TRADE BALANCE BY COUNTRY (INCLUDING INTRA-COMMUNITY TRADE, MILLION EUROS), 2016 (REF. 6)



About MedTech Europe

MedTech Europe is the European trade association representing the medical technology industry from diagnosis to cure. We represent In-Vitro 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 promotes a balanced policy environment that helps the medical technology industry meet Europe's growing healthcare needs and expectations. We also promote medical technology's value for Europe through our five-year industry strategy, which focuses on value-based innovations that support more sustainable healthcare systems.

We use economic research to show the benefits of medical technology and we organise many initiatives to explain the value we bring to Europe. We bring stakeholders together to discuss trends, issues and opportunities. Each year we also organise the European MedTech Forum, the largest health and industry policy conference in Europe, to engage with stakeholders on common topics of interest.

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 2017. 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 2016.

8 Worldwide Medtech Sales by EvaluateMedTech® Device Area: Top 15 Categories & Total Market (2016 & 2022)- http://info.evaluategroup.com/MTWP2017-EMF.html

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