The European

Medical Technology industry

IN FIGURES

MedTech Europe
from diagnosis to cure

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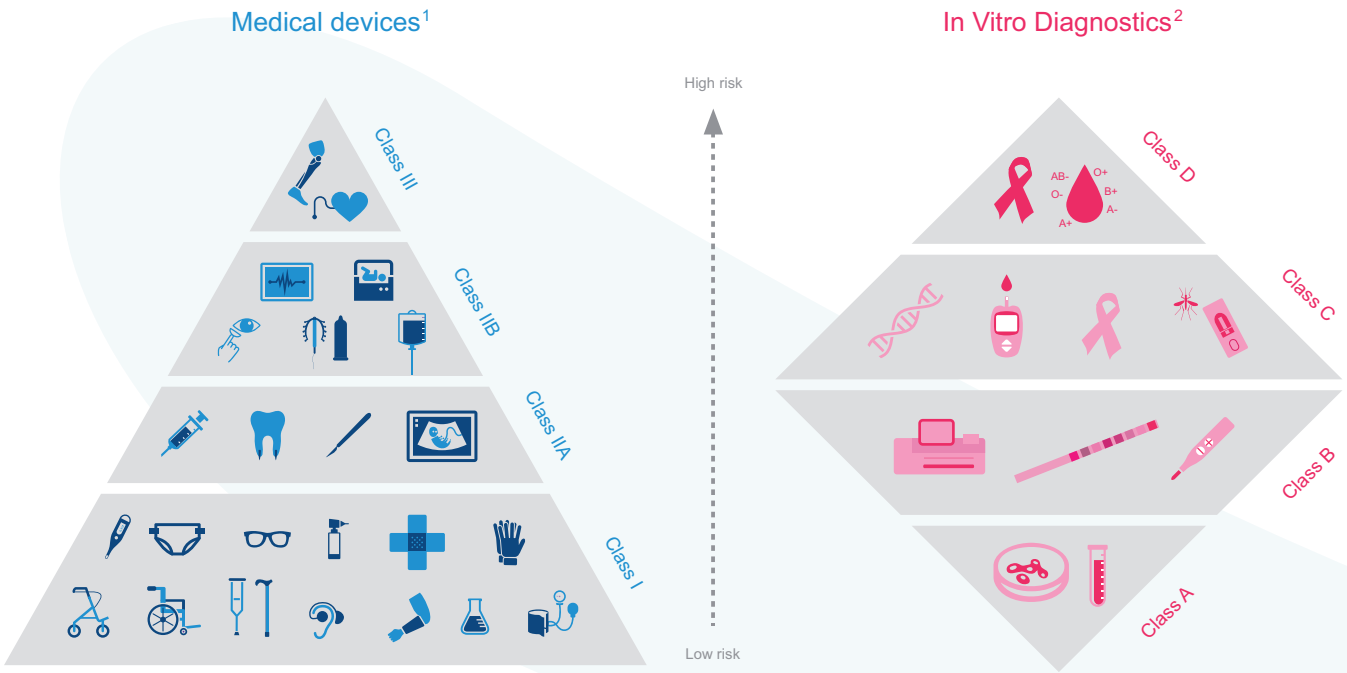
What is Medical Technology?

Medical technology is technology used to ensure health in individuals suffering from a wide range of conditions and is involved in an entire pathway from diagnosis to cure. It extends life and brings healthy life years, reduces symptoms and prevents disease progression, thus playing an essential role in healthcare. Continuous medical technology innovation enhances the quality and effectiveness of care. Billions of patients worldwide depend on medical technology at home, at the doctor's, at hospital and nursing homes. Wheelchairs, pacemakers, orthopaedic shoes, spectacles and contact lenses, insulin pens, hip prostheses, condoms, oxygen masks, dental floss, MRI scanners, pregnancy tests, surgical instruments, bandages, syringes, life-supporting machines: more than 500,000 MedTech products (20,000 generic groups) are available today.

Good health is a prerequisite for well-being and economic prosperity. Medical technology, therapies and services help people live healthier, more productive, socially active, independent lives and reinforce employability. In doing so, medical technology contributes to steering healthcare onto a sustainable path and to ensuring economic growth through better health of the workforce.

Diversity and classification of medical technology



There are more than 500,000 medical technologies registered. These fall within 16 categories of products, as determined by the Global Medical Devices Nomenclature (GMDN) Agency.[3]

CODE	CLASSIFICATION	EXAMPLE
01	Active implantable technology	Cardiac pacemakers, neurostimulators
02	Anaesthetic and respiratory technology	Oxygen mask, gas delivery unit, anaesthesia breathing circuit
03	Dental technology	Dentistry tools, alloys, resins, floss, brushes
04	Electromechanical medical technology	X-ray machine, laser, scanner
05	Hospital hardware	Hospital bed
06	In vitro diagnostic technology	Pregnancy test, genetic test, glucose strip
07	Non-active implantable technology	Hip or knee joint replacement, cardiac stent
08	Ophthalmic and optical technology	Spectacles, contact lenses, intraocular lenses, ophthalmoscope
09	Reusable instruments	Surgical instruments, rigid endoscopes, blood pressure cuffs, stethoscopes, skin electrodes
10	Single use technology	Syringes, needles, latex gloves, balloon catheters
11	Technical aids for disabled	Wheelchairs, walking frames, hearing aids
12	Diagnostic and therapeutic radiation technology	Radiotherapy units
13	Complementary therapy devices	Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups
14	Biological-derived devices	Biological heart valves
15	Healthcare facility products and adaptations	Gas delivery systems
16	Laboratory equipment	Most IVD which are not reagents

This risk classification ensures that appropriate safety measures are put in place before a product becomes available and guarantees that permanent monitoring during the lifetime of the high risk devices is conducted by specialised institutions. In 2012 more than 3,100 medical devices were approved by these institutions in Europe, around 560 of which were class III devices.[4]

Moreover, each technology comes with strict instructions for use and industry continuously invests in hands-on training for physicians. At the same time, clinical investigations comprised of thousands of patients, and interviews with physicians and patients enable the medical technology industry to continuously improve its products.

Definitions:

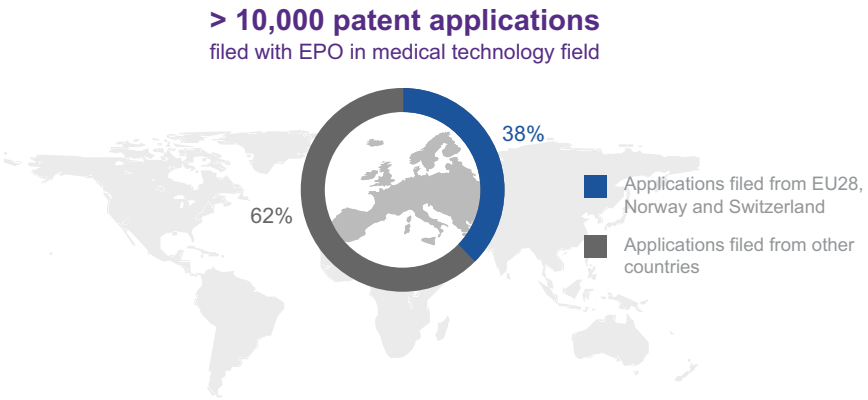
Medical Device - any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.[1]

In Vitro Diagnostics (IVD) – any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: concerning a physiological or pathological state; or concerning a congenital abnormality; or to determine the safety and compatibility with potential recipients; or to monitor therapeutic measures.[2]

Medical Technology (MedTech) – medical devices, in vitro diagnostics, imaging equipment and e-health solutions used to diagnose, monitor, assess predispositions and treat patients suffering from a wide range of conditions.

Innovation

IN EUROPE

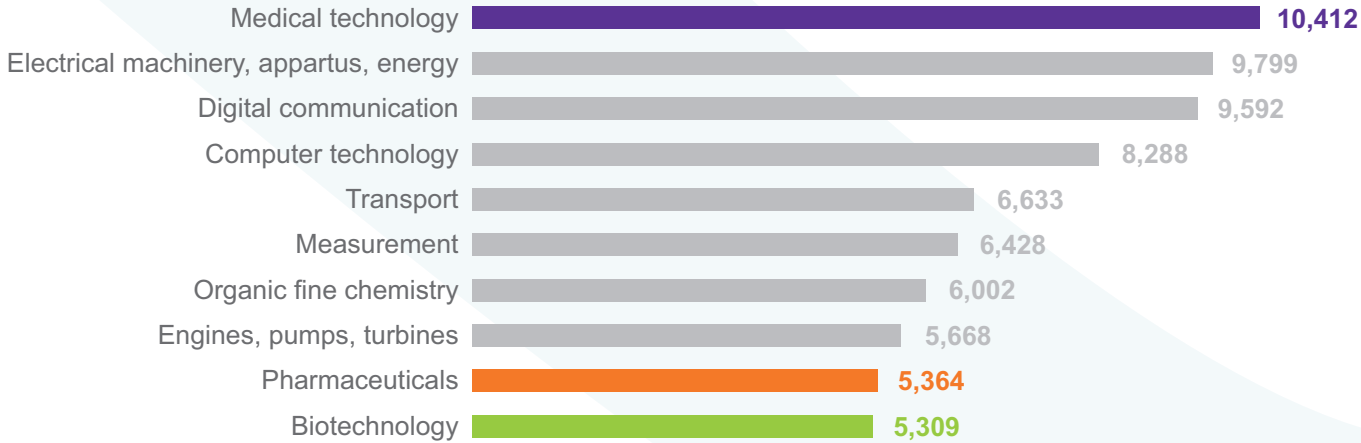


Medical technology is characterised by a constant flow of innovations, which are the result of a high level of research and development within the industry, and of close co-operation with the users. Products typically have a lifecycle of only 18-24 months before an improved product becomes available.

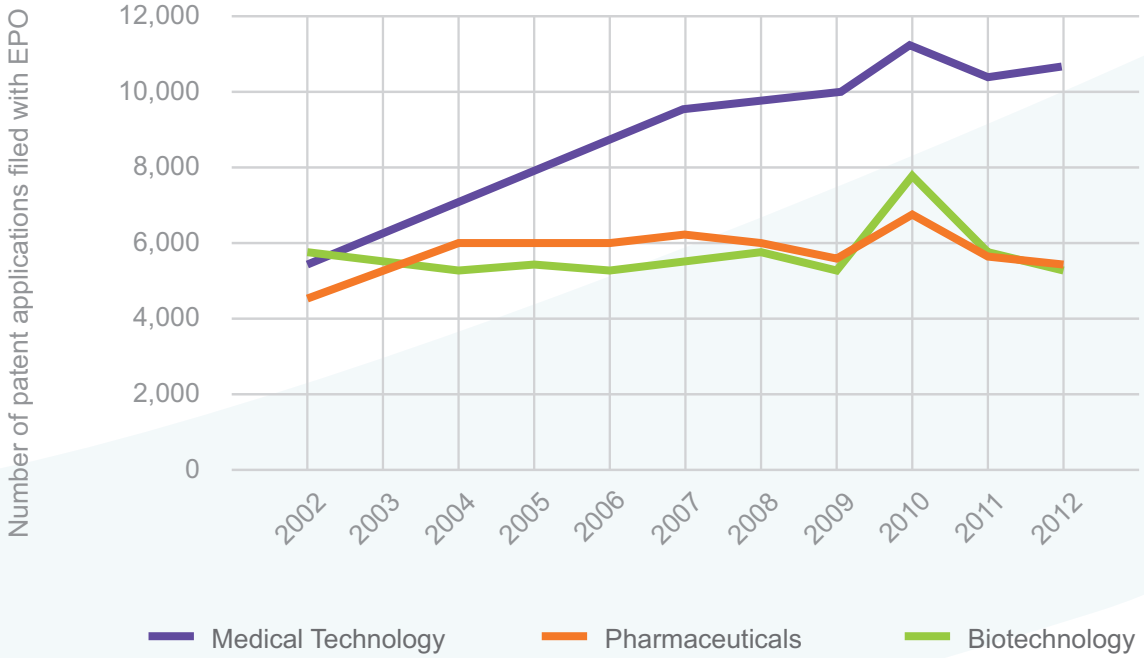
In 2012, more than 10,000 patent applications were filed with the European Patent Office (EPO) in the field of medical technology – equivalent to 7 % of the total number of applications – more than any other technical field. 38% of these patent applications were filed from European countries (EU28, Norway and Switzerland) and 62% from other countries, with the majority of applications filed from US (42%).

In comparison, around 5,400 applications were filed in the pharmaceutical field and 5,300 in the field of biotechnology. While over the last decade the number of EPO filings in the field of medical technology has doubled, biotech and pharma patent applications were relatively stagnant.[5]

Top 10 technical fields in patent applications. Number of patent applications filed with EPO, 2012 [5]



Evolution of European patent applications by technical field [5]



Employment

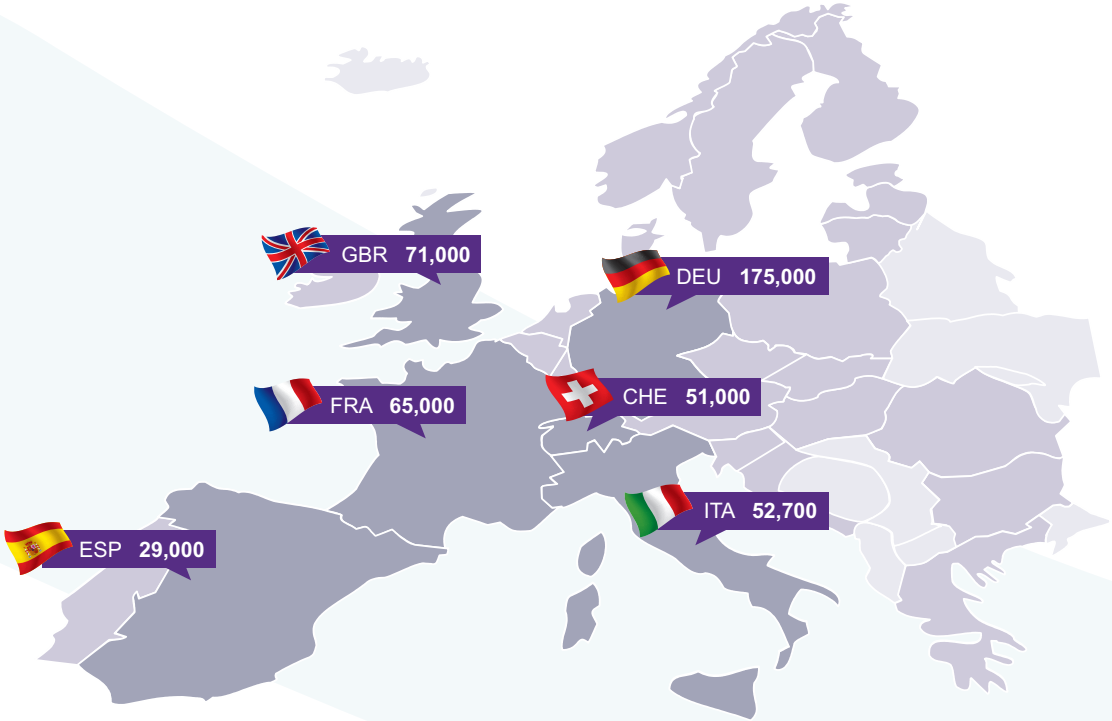
IN EUROPE

> 575,000 employees

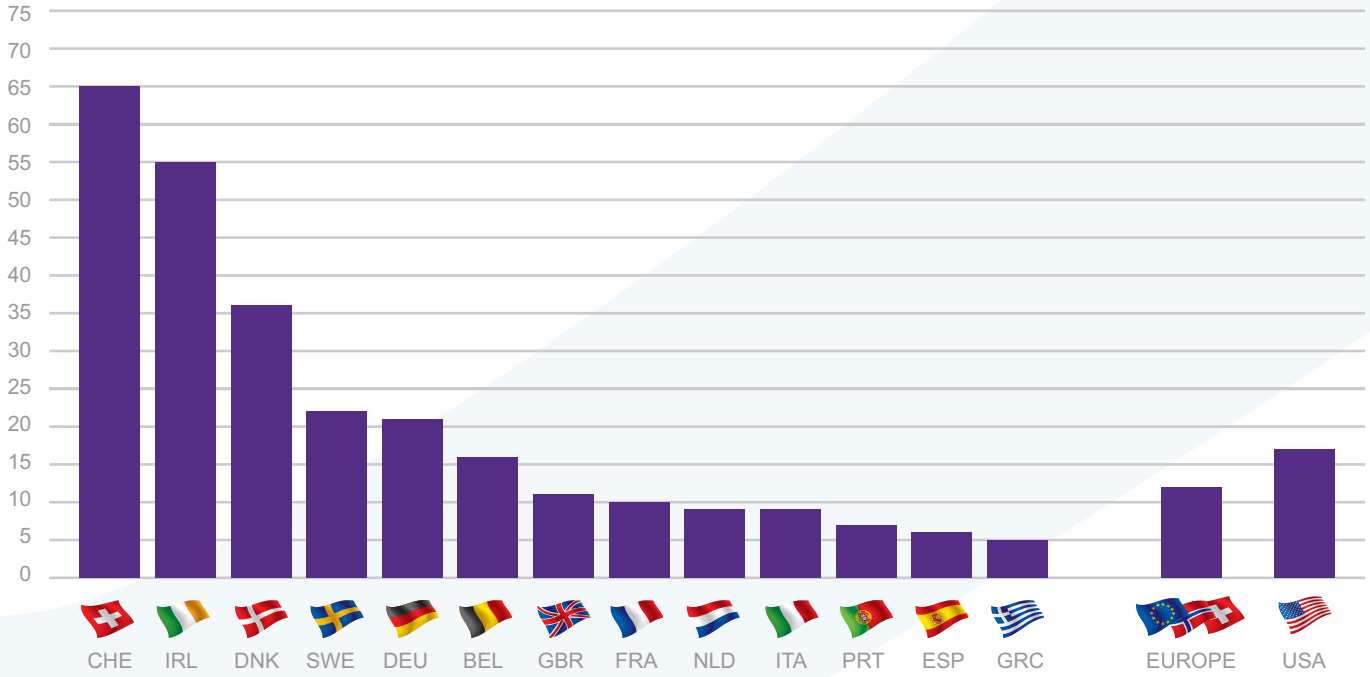
The European medical technology industry employs more than 575,000 people. Germany has the highest absolute number of people employed in the medical technology sector, while the number of MedTech employees per capita is highest in Switzerland and Ireland[6]. This high level of employment shows that the medical technology industry is an important player in the European economy.
In comparison, the US medical technology industry employs around 520,000 people[7] while the European pharmaceutical industry employs 675,000 people[8].

Europe refers to EU28, Norway and Switzerland, unless specified otherwise.

Number of people employed in the medical technology industry [6]



Number of people employed in the medical technology industry per 10,000 inhabitants[6]

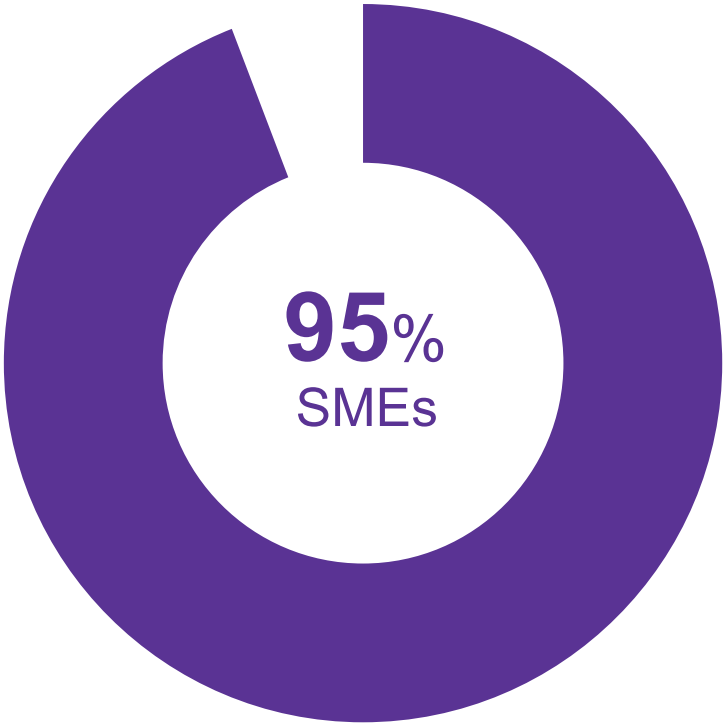


Companies

IN EUROPE

There are almost 25,000 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 almost 95% of the medical technology industry, the majority of which employ less than 50 people (small and micro-sized companies)[9].

* An enterprise is considered to be an 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).



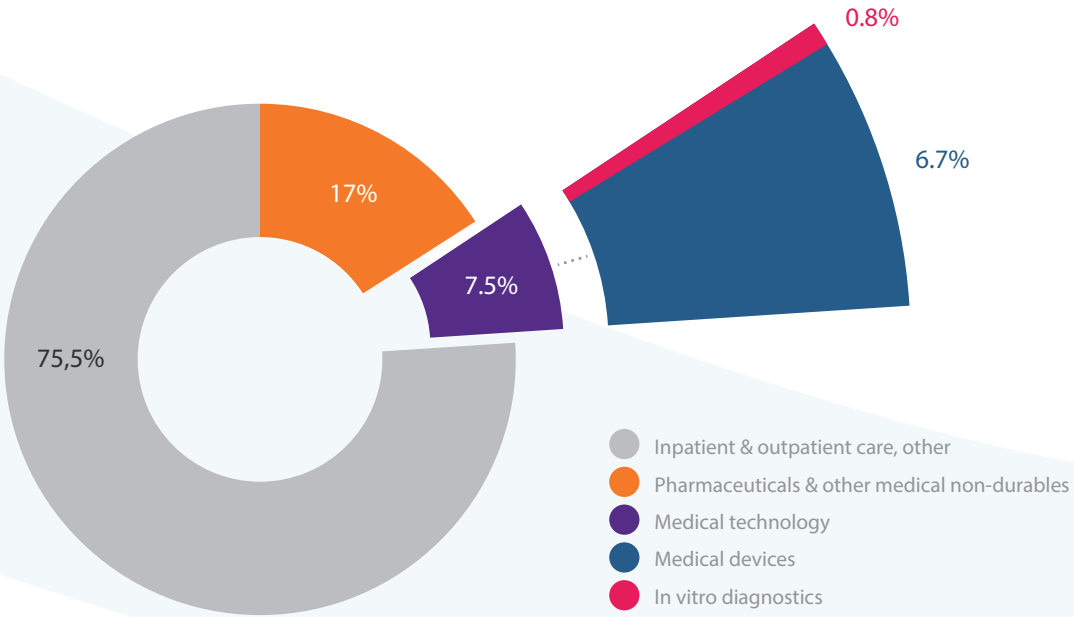
25,000 medical technology companies in Europe.

Expenditure on Medical Technology

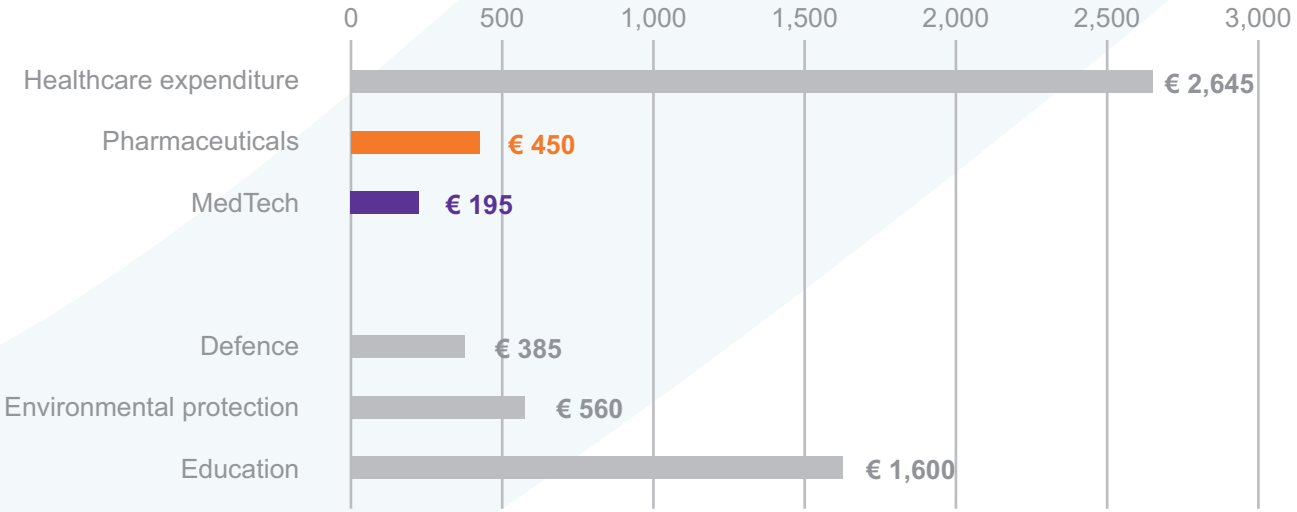
IN EUROPE

In Europe, an average of 10.4% of gross domestic product is spent on healthcare. Of this figure, around 7.5% is attributed to medical technologies. The spending on medical technology varies significantly across European countries, ranging from around 5% to 10% of the total healthcare expenditure[10].
Expenditure on medical technology per capita in Europe is at around €195 (weighted average), compared with €380 in the US[14].

Breakdown of total healthcare expenditure in Europe [15]



Per capita spending on various fields, in €, latest year available [10]



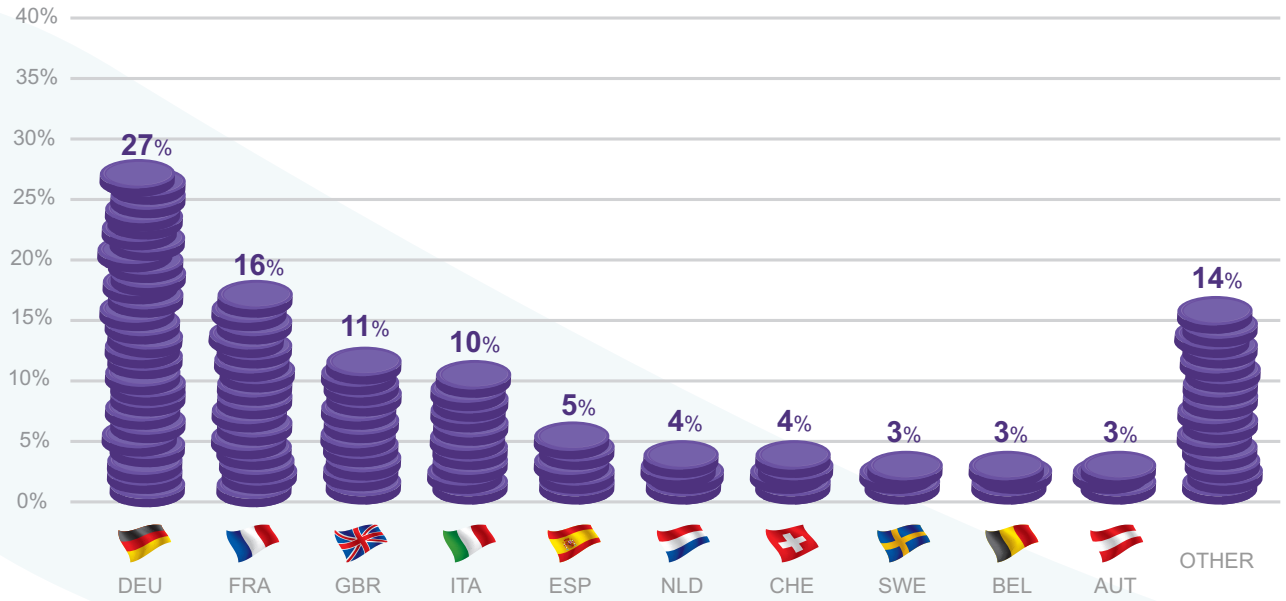
MedTech Market

IN EUROPE

The European medical technology market is estimated at roughly €100 billion.[10]

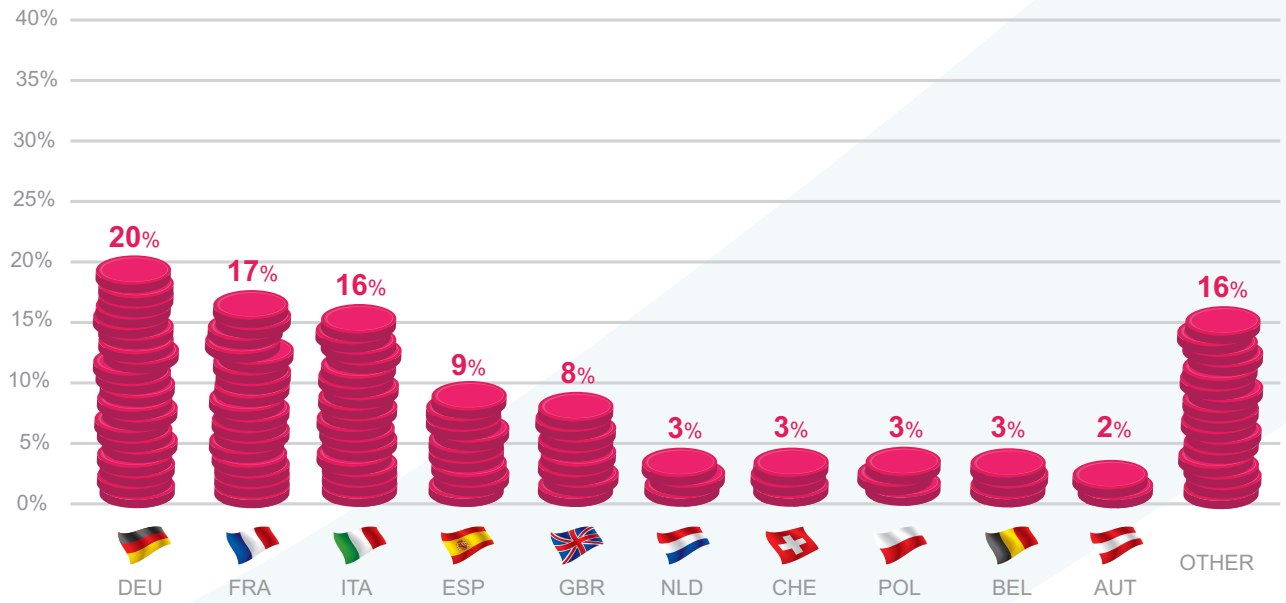
Based upon manufacturer prices the European medical technology market* is estimated to comprise approximately 30%[11] of the world market. It is the second largest medical technology market after US (~40% [11]).

European medical technology market* by country, based upon manufacturer prices, 2012 [11]

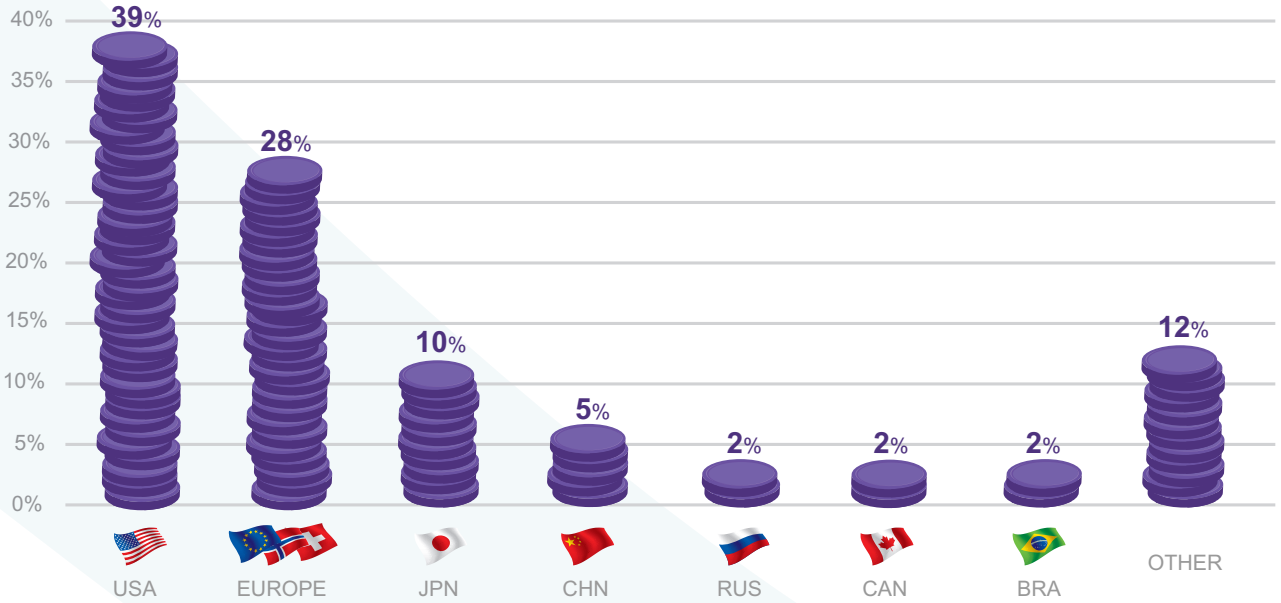


The biggest MedTech markets in Europe are Germany, France, United Kingdom, Italy and Spain[11].
The same countries form the top 5 IVD markets in Europe [12].

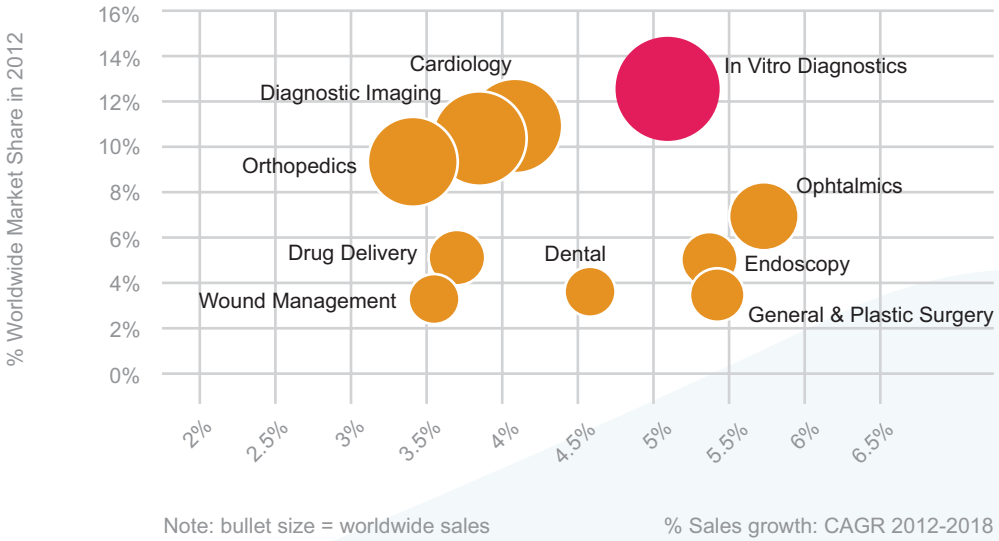
European IVD market by country, 2012 [12]



World medical technology market* by region, based upon manufacturer prices, 2012 [11]



World medical technology market by area and sales growth, 2012-2018 [13]

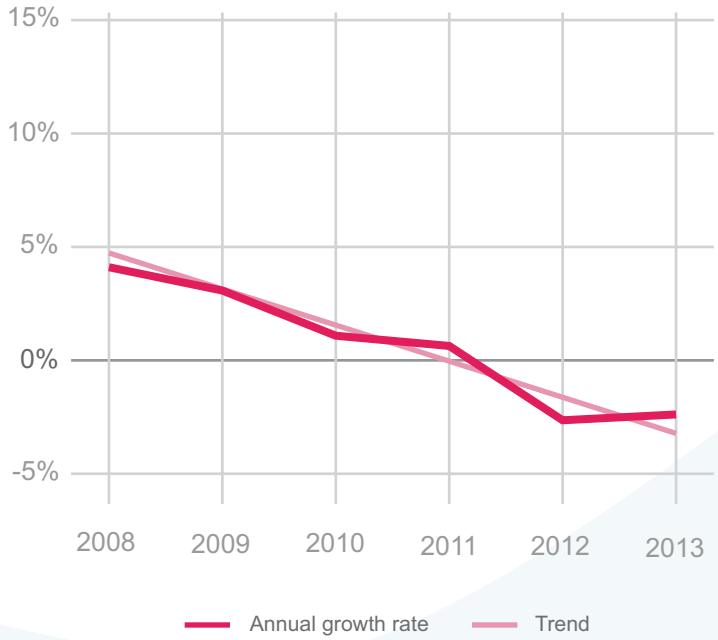


Medical technology offers solutions for many disease areas. On a worldwide perspective, in vitro diagnostics are the largest sector, followed by cardiology and diagnostic imaging[13].

European medical technology market* growth rates, based upon manufacturer prices, 2008-2013 [11]

The European medical technology* market has been growing on average by 4% per annum over the past 6 years. Demand fell in 2009 due to the economic crisis, resulting in the growth rate of only 1%. Market recovered in 2010, but growth rates fell back in 2011[11].

European IVD market growth rates, 2008-2013 [12]



The European IVD market growth has been slowing down over the last 6 years. While annual growth rates in the pre-crisis period were at around 2-4%, in 2012 the European market declined by 2.2% and is expected to have a decrease of around 2% in 2013[12].

* 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. Medical technology not including in vitro diagnostics.

Trade

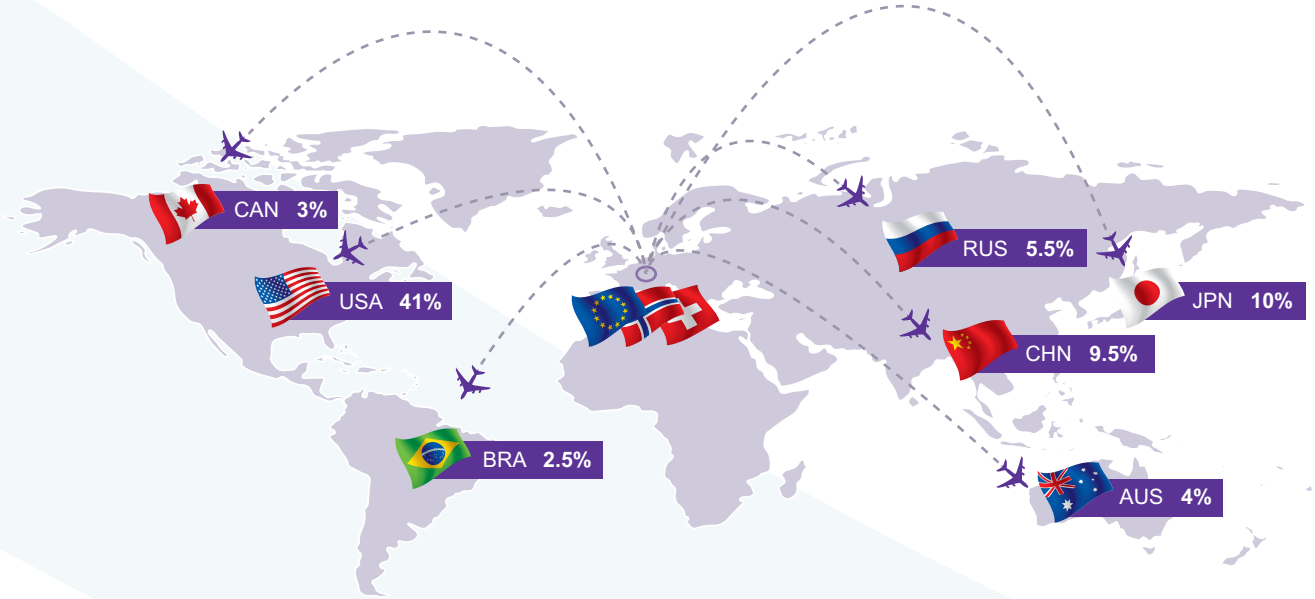
IN EUROPE

Europe has a positive medical technology trade* balance of €15.5 billion (2012), more than a twofold increase since 2006. In comparison, US medical technology trade surplus is at €5.3 billion. Main European MedTech trade partners are US, China and Japan[11].

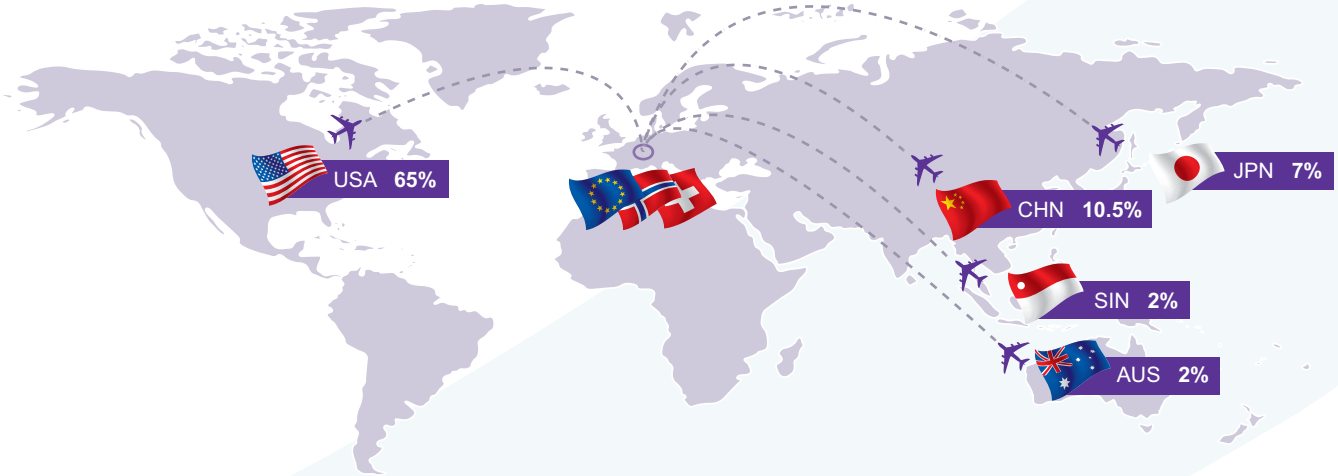
*Trade section does not include in vitro diagnostics in the figures for medical technology.

Europe's trade surplus is estimated at €15.5 billion.

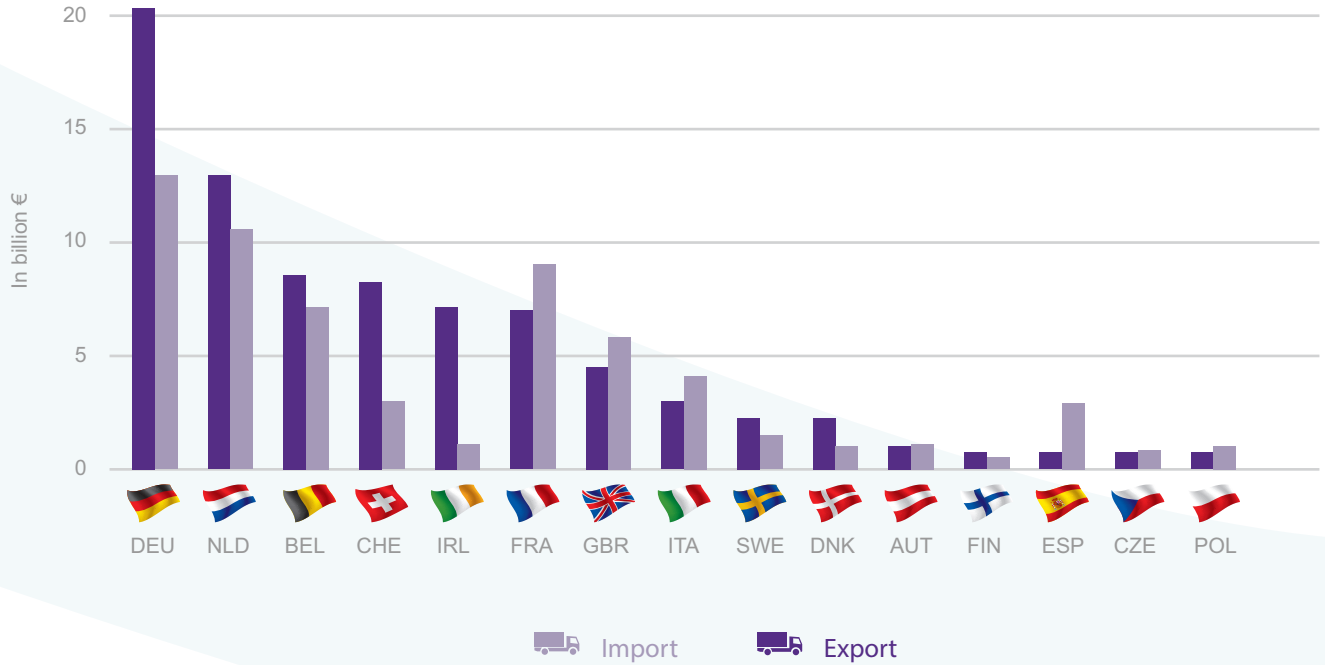
Top European medical technology export destinations, 2012 [11]



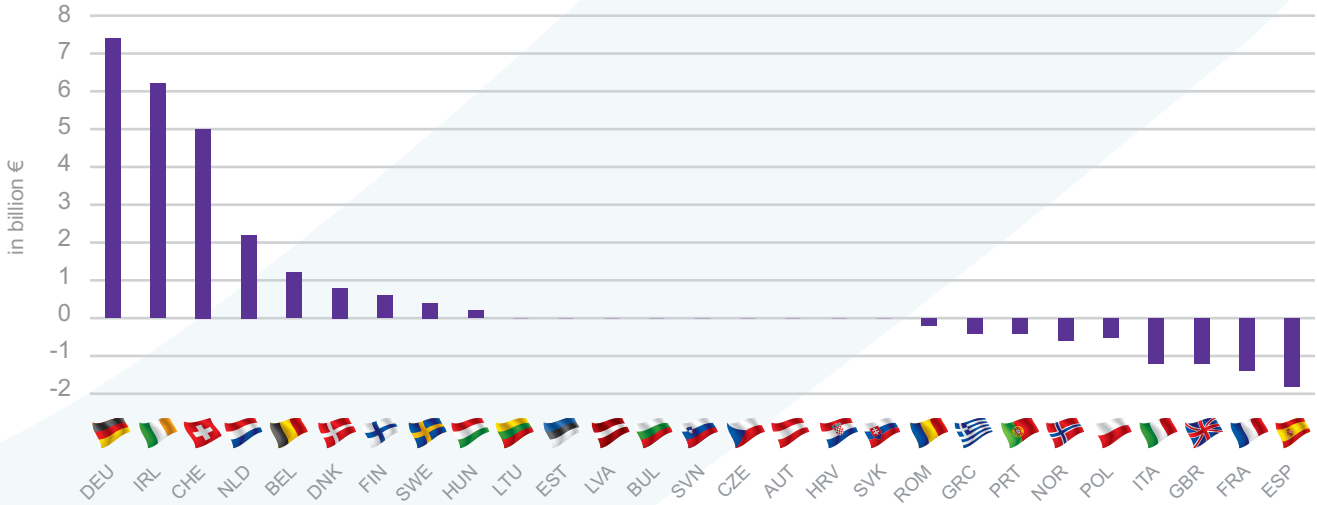
Top suppliers to European medical technology market (imports), 2012 [11]



Exports & imports of medical technology by country, 2012 (including European intra-trade) [11]



Medical technology trade balance by country, 2012 [11]



About MedTech Europe

MedTech Europe is an Alliance of European medical technology industry associations. The Alliance was founded in October 2012 and currently has two members being EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry.

The Alliance was established to represent the common policy interests of its members more effectively and efficiently. Its mission is to make value-based, innovative medical technology available to more people, while supporting the transformation of healthcare systems onto a sustainable path. As such, the medical devices and in vitro diagnostics industries are jointly executing their industry strategy.

In 2012 MedTech Europe published the "Contract for a Healthy Future", the MedTech industry's 5-year strategy, and "Creating Value in European Healthcare". "Contract for a Healthy Future" details the role of Europe's medical technology industry in steering healthcare systems onto a sustainable path, while the "Creating Value in European Healthcare"- publication explains how Europe's medical technology industry is delivering on the promise of the "Contract". Both publications are available at www.reforminghealthcare.eu

References

[1] European Commission. The classification of medical devices is a 'risk based' system based on the vulnerability of the human body taking account of the potential risks associated with the devices. The classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device.

[2] European Commission. IVD classification is based on the degree of health risk posed to an individual and public, and is related to the risk of an incorrect result arising from the use of the IVD.

[3] Global Medical Devices Nomenclature (GMDN) Agency, 2010.

[4] The European Association for Medical Devices of Notified Bodies - Medical Device Survey 2012: data from 28 Notified Bodies. CE mark is a verification that a device meets all regulatory requirements of the Directives which apply to it.

[5] European Patent Office, Eucomed calculations. Medical technology as defined by World Intellectual Property Organization (based on the WIPO IPC-Technology concordance as revised in August 2012). European countries refer to EU + Norway, Switzerland. Patents are attributed by the country of residence of the applicant.

[6] Eurostat, Eucomed calculations based on the data obtained from National Associations of 15 countries for the latest year available. Countries with (partially) provided data: Belgium, Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, Netherlands, Poland, Portugal, Spain, Sweden, UK, Switzerland. Europe refers to EU + Norway, Switzerland.

[7] S. Tripp, M. Grueber, R. Helwig - The Economic Impact of the U.S. Advanced Medical Technology Industry, Battelle Technology Partnership Practice, March 2012.

[8] EFPIA – The Pharmaceutical Industry in Figures. Key Data 2013. Europe refers to EU + Norway, Switzerland.

[9] Eucomed calculations based on the data obtained from National Associations of 15 countries for the latest year available. Europe refers to EU + Norway, Switzerland.

[10] WHO Global Health Expenditure Database, Eurostat, Eucomed calculations based on the data obtained from National Associations of 15 countries for the latest year available. Countries with (partially) provided data: Belgium, Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, Netherlands, Poland, Portugal, Spain, Sweden, UK, Switzerland. Europe refers to EU + Norway, Switzerland.

[11] Espicom, Eucomed calculations. Manufacturer prices. Medical technology excluding in vitro diagnostics. Europe refers to EU (excluding Cyprus, Luxembourg, Malta) + Norway, Switzerland.

[12] EDMA - European IVD Market Statistics Report 2012
http://www.edma-ivd.eu/uploads/Market%20Intelligence/2011_EU_IVD_Market_Statistics_Report-2.pdf

[13] World Preview 2013, Outlook to 2018: The Future of Medtech, EvaluateMedTech™, September 2013. www.evaluategroup.com/MedTechWP2013

[14] WHO; G. Donahoe and G.King - Estimates of Medical Device Spending in the United States, F.S.A., M.A.A.A. AdvaMed, 2012.

[15] WHO, Eurostat, EFPIA, EDMA, Eucomed calculations. Europe refers to EU + Norway, Switzerland

Notes

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