The European Medical Technology Industry – in figures

MedTech Europe
from diagnosis to cure

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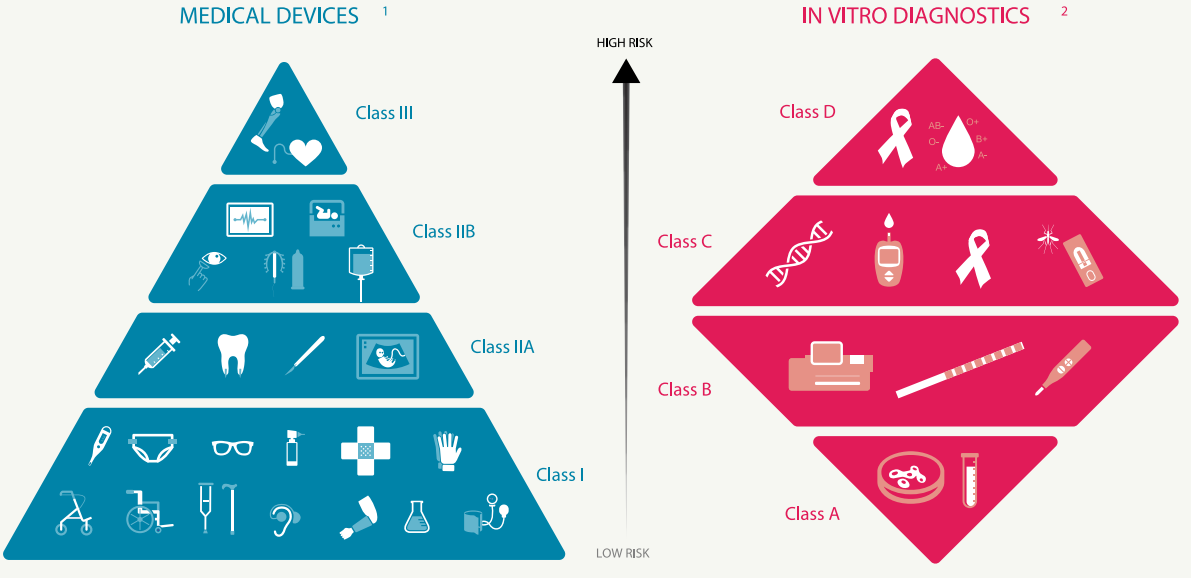
What is Medical Technology?

Medical technology is any technology used to save lives in 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.

Medical technology can be familiar, everyday objects such as 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 total body scanners, blood glucose monitoring devices, ultrasounds, life-supporting machines, implantable devices such as heart valves and pacemakers, neurostimulators and replacement joints for knees and hips. There are more than 500,000 medical technologies currently available and they all share a common purpose: improving, extending and transforming people's lives.

The common thread through all applications of medical technology is the beneficial impact on health, quality of life and society as a whole. Medical technologies all 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.

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	**Anesthetic respiratory technology**	Oxygen mask, gas delivery unit, anesthesia 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 diagnostics 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 hearth valves
15	**Healthcare facility products and adaptations**	Gas delivery systems
16	**Laboratory equipment**	Most IVD which are not reagents

The risk classification ensures that appropriate testing and quality checks are put in place to ensure the safety of a product before it becomes available. It also guarantees that permanent monitoring during the lifetime of high risk devices is conducted by specialised institutions. The number of medical devices receiving CE marking in 2015 is estimated to be around 4,500, around 500 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 healthcare professionals. At the same time, clinical investigations comprised of thousands of patients and interviews with physicians and patients enable the medical technology industry to continuously enhance its technology and provide increased value for money.

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 being 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[5].

■ 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[5].

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 2015, more than 12,400 patent applications were filed with the European Patent Office (EPO) in the field of medical technology – 7.8% 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, with the majority of applications filed from the US (41%).

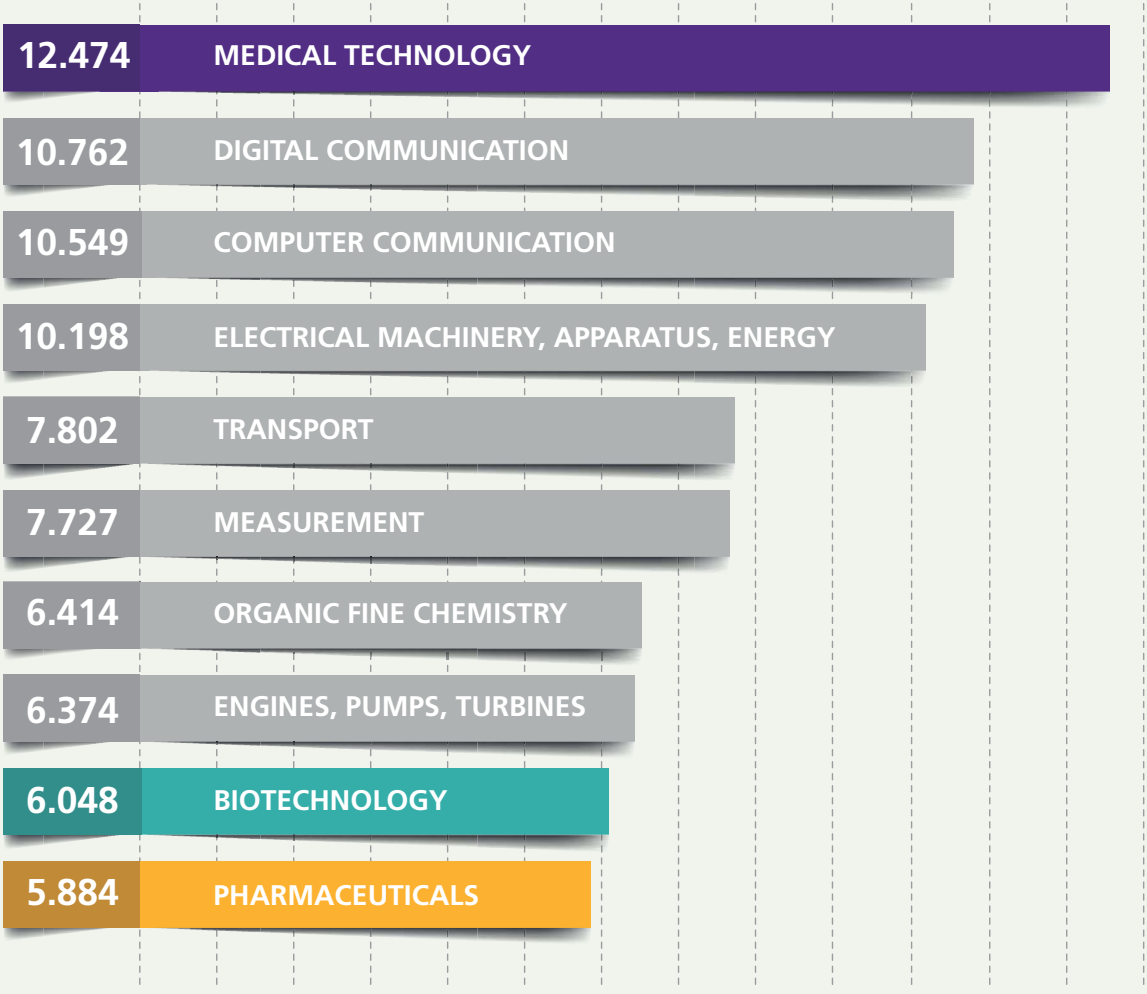
In comparison, around 5,900 applications were filed in the pharmaceutical field and 6,000 in the field of biotechnology. While over the last decade the number of EPO filings in the field of medical technology has doubled, pharma and biotech patent applications were relatively stagnant[6].

PATENT APPLICATION IN MEDICAL TECHNOLOGY FIELD FILLED WITH EPO IN 2015

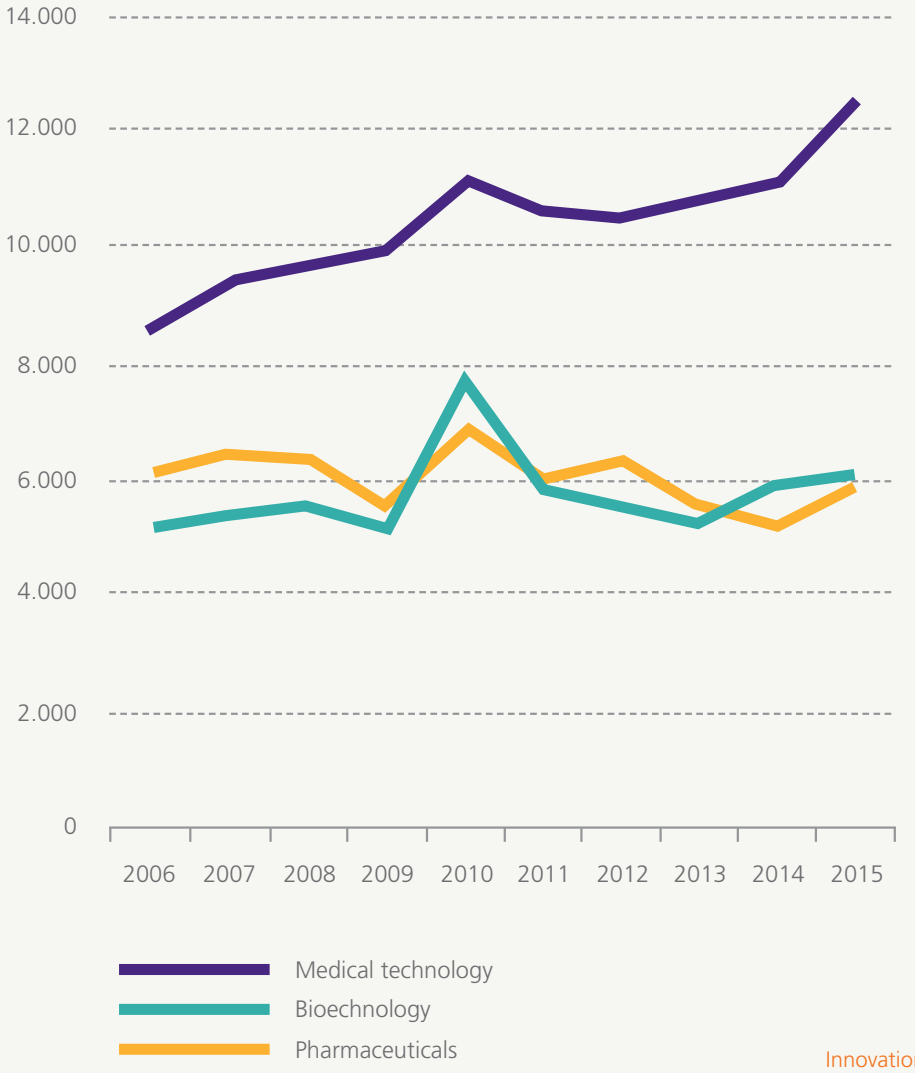
40%
EU28, Norway and Switzerland

60%
Other countries

TOP 10 TECHNICAL FIELDS IN PATENT APPLICATIONS.
NUMBER OF PATENT APPLICATIONS FILED WITH EPO, 2015 (REF. 6)



EVOLUTION OF EUROPEAN PATENT APPLICATIONS BY TECHNICAL FIELD (REF. 6)



Employment

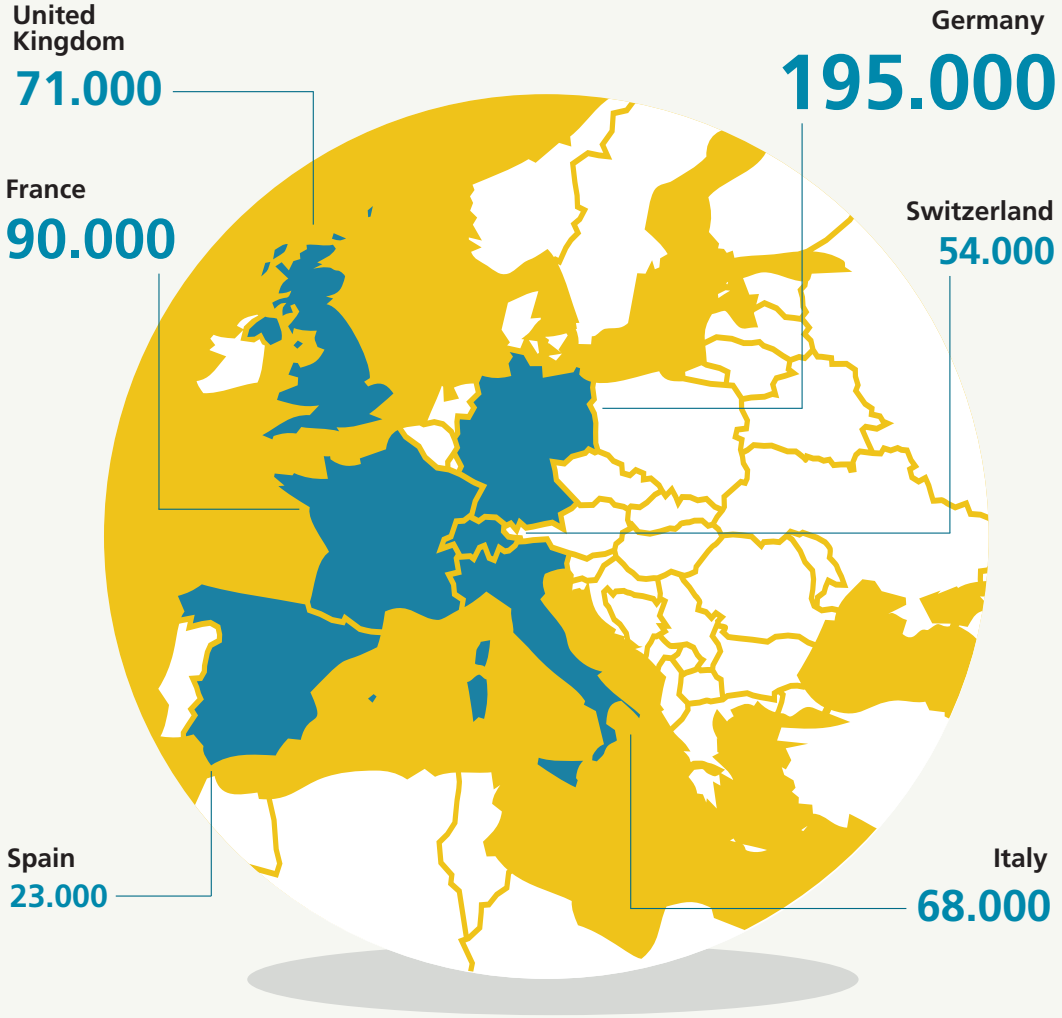
650,000 employees[8]

The European medical technology industry employs more than 650,000 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 Switzerland and Ireland. 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 700,000 people[7].

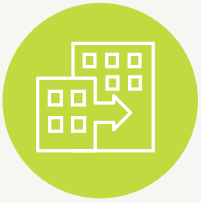
Europe refers to EU 28, Norway and Switzerland unless specified otherwise.

TOP 6 COUNTRIES WITH HIGHEST EMPLOYMENT IN THE MEDICAL TECHNOLOGY INDUSTRY (REF. 8)



NUMBER OF PEOPLE EMPLOYED IN THE MEDICAL TECHNOLOGY INDUSTRY PER 10,000 INHABITANTS (REF. 8)

Companies



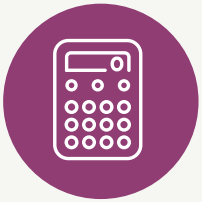
26,000
medical technology companies in Europe

95%
SMEs

There are approximately 26,000 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)[8].

*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

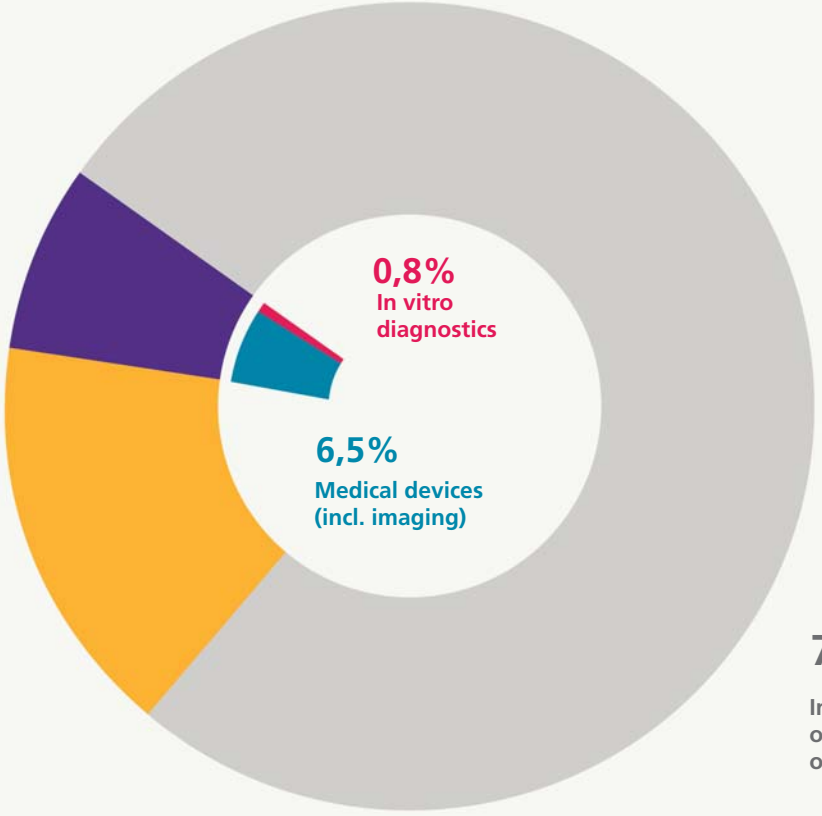


€197

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 7.3% 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[9]. Expenditure on medical technology per capita in Europe is at around €197 (weighted average).

BREAKDOWN OF TOTAL HEALTHCARE EXPENDITURE IN EUROPE (REF. 10)



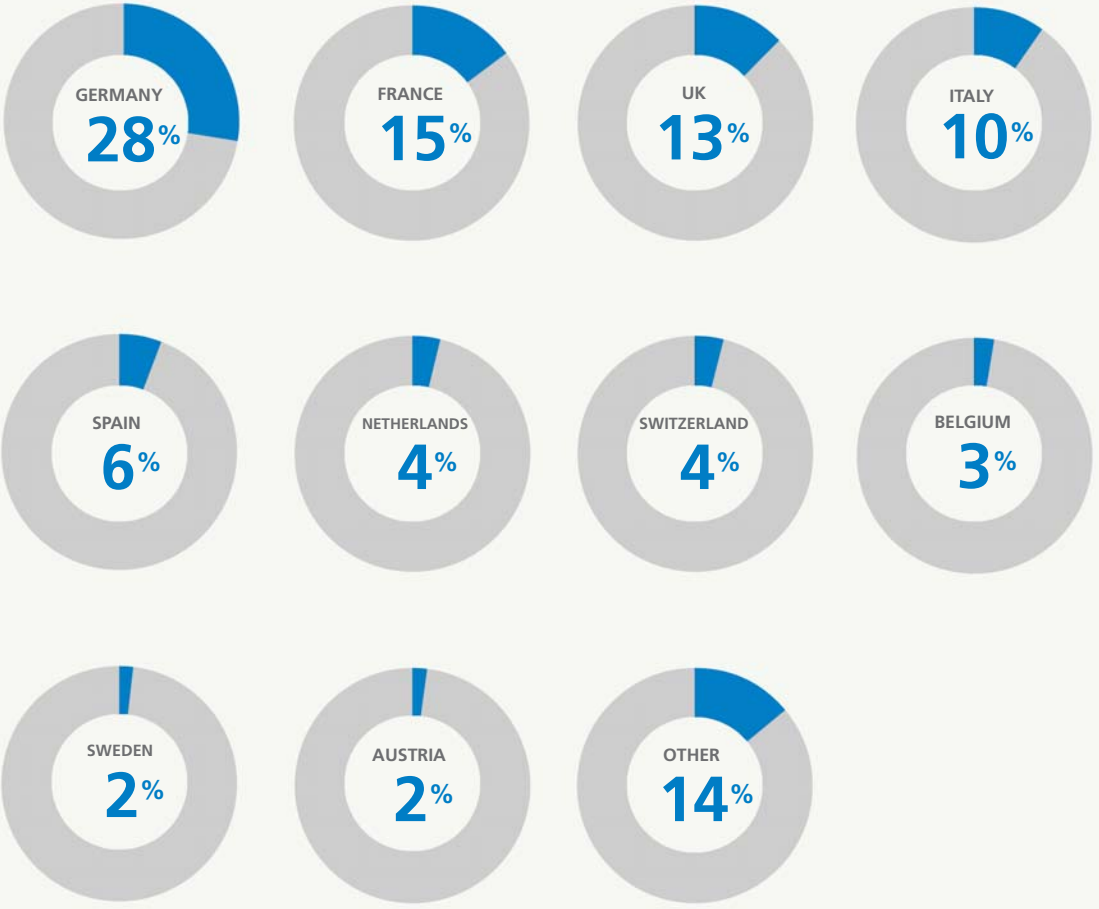
MedTech Market in Europe

€110
billion market

The European medical technology market in 2015 is estimated at roughly €110 billion[11].

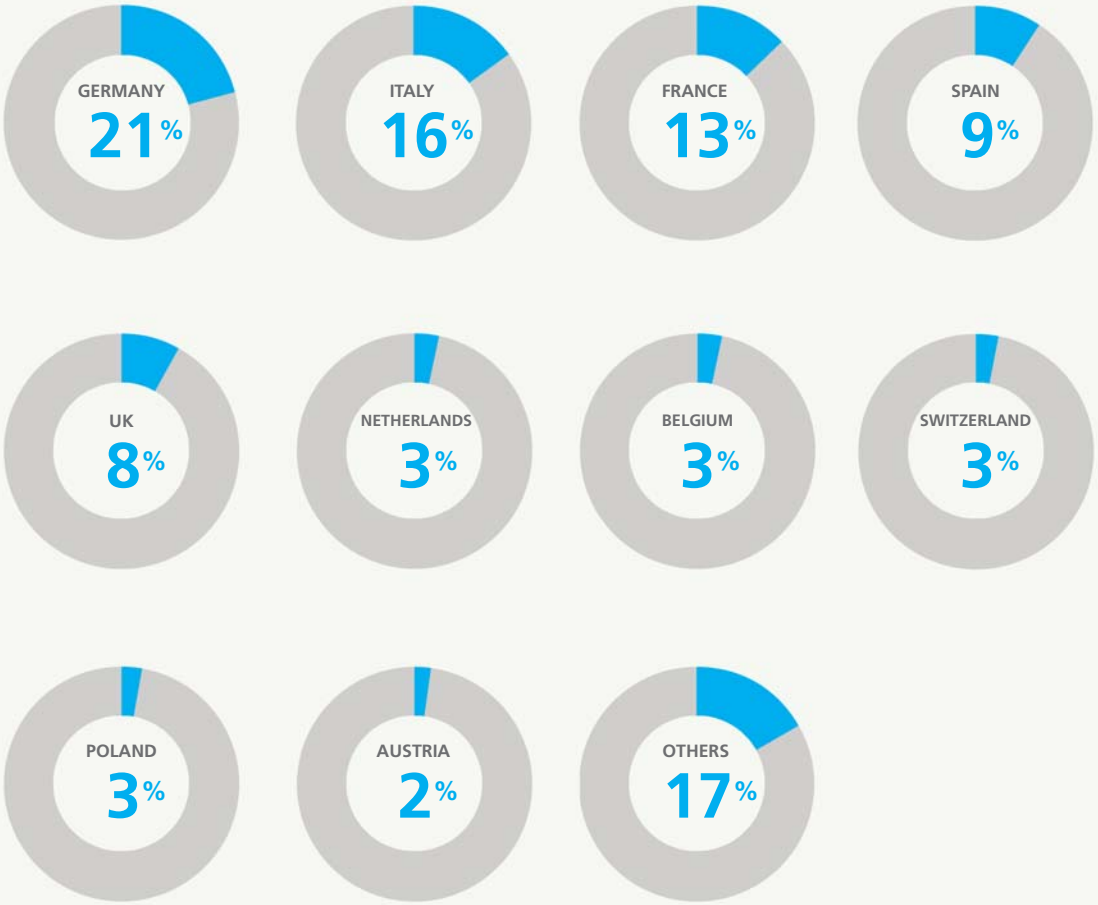
Based upon manufacturer prices the European medical technology market is estimated to make up 28% of the world market. It is the second largest medical technology market after the US (approximately 40%).

EUROPEAN MEDICAL DEVICE MARKET BY COUNTRY, BASED UPON MANUFACTURER PRICES, 2015 (REF. 11)

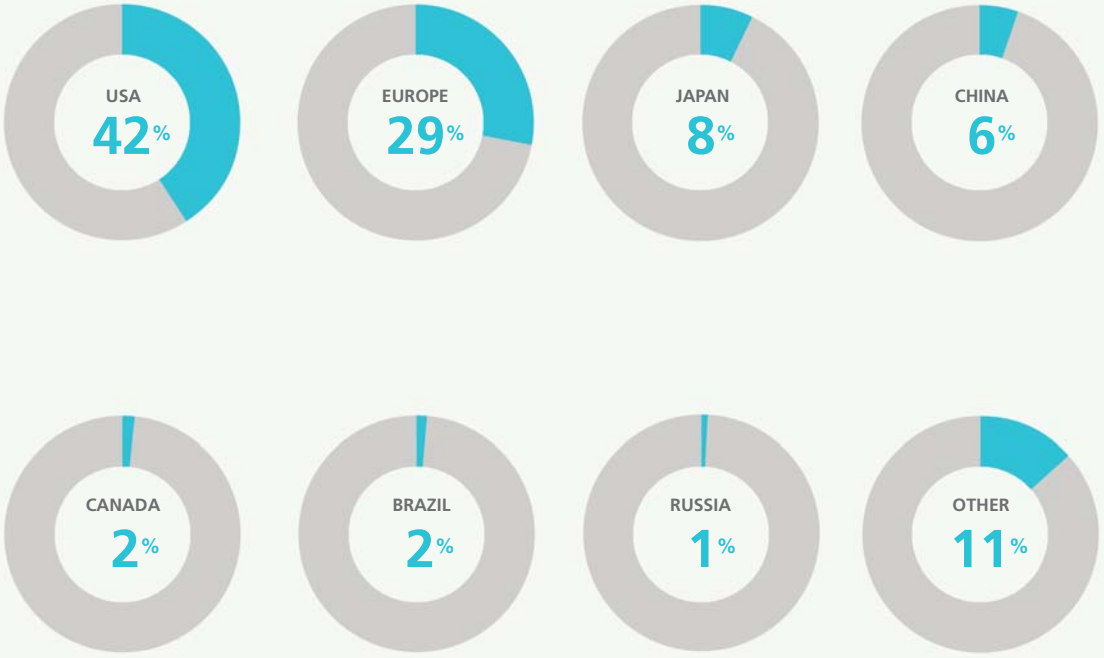


The biggest medtech markets in Europe are Germany, France, the United Kingdom, Italy and Spain[11]. The same countries form the top 5 IVD markets in Europe[12].

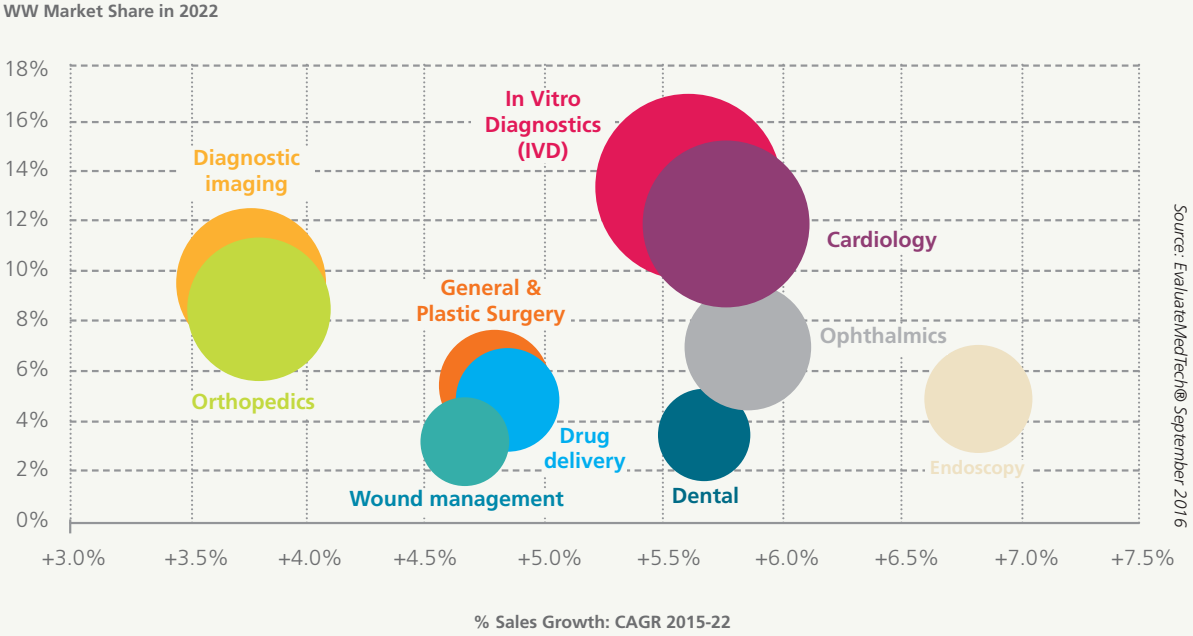
EUROPEAN IVD MARKET BY COUNTRY, 2015 (REF. 12)



WORLD MEDICAL DEVICE MARKET BY REGION BASED UPON MANUFACTURER PRICES, 2015 (REF. 11)



WORLD MEDICAL TECHNOLOGY MARKET BY AREA AND SALES GROWTH, 2015-2022 (REF. 13)

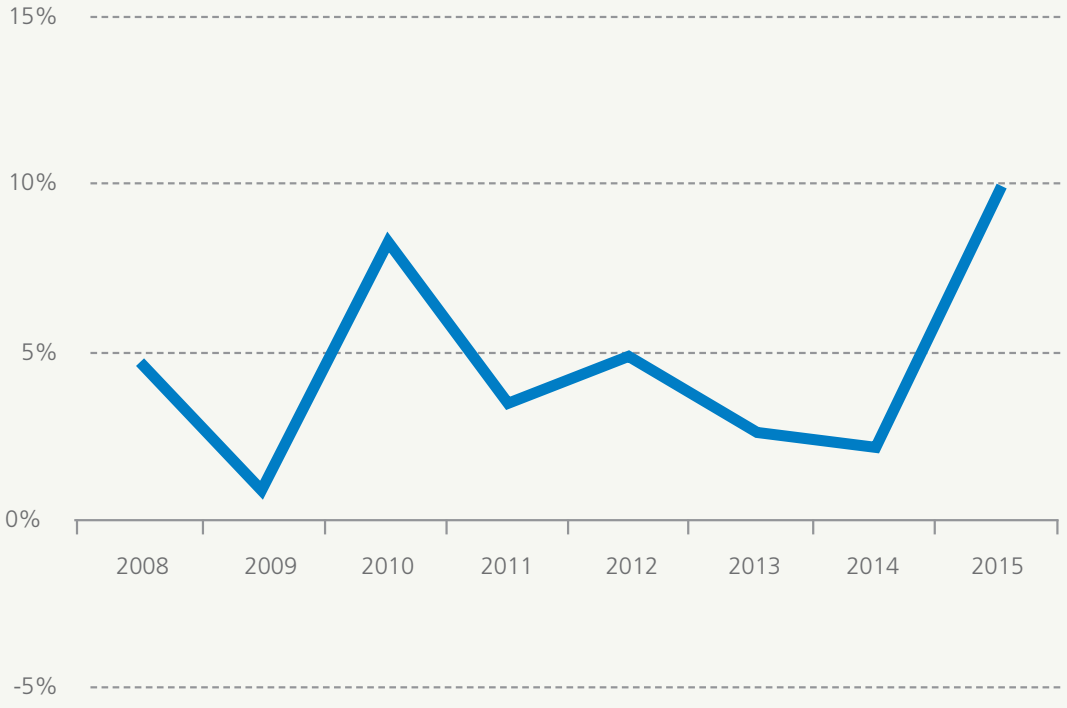


Source: EvaluateMedTech® September 2016

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].

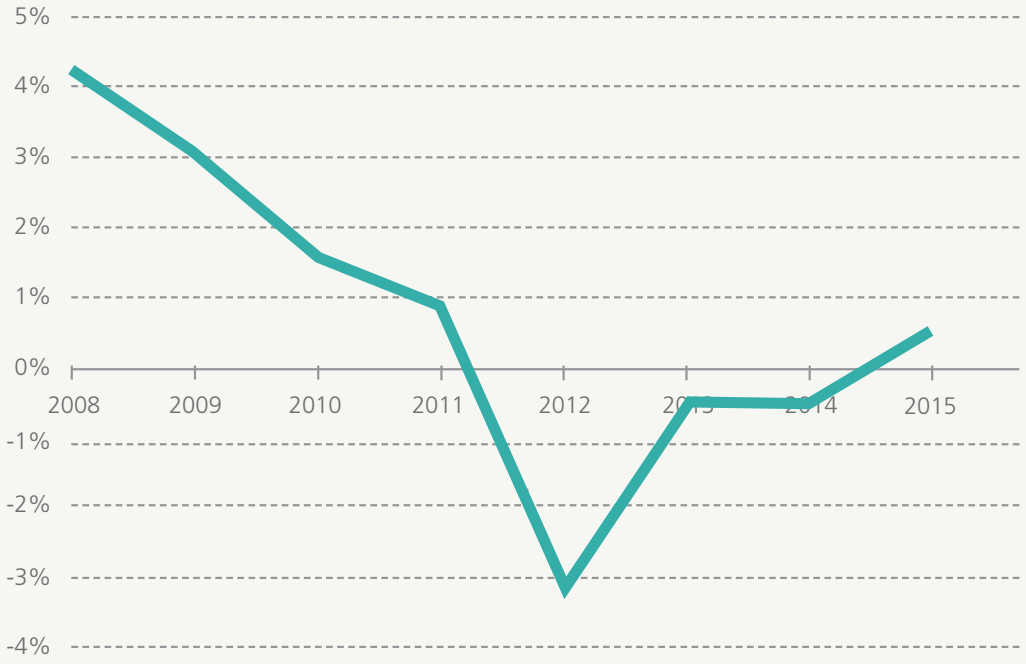
Note: Size of Bubble = WW Sales in 2022

EUROPEAN MEDICAL DEVICE MARKET GROWTH RATES, BASED UPON MANUFACTURER PRICES, 2008-2015 (REF. 11)



The European medical technology market has been growing on average by 4,6% per annum over the past 8 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, 2008-2015 (REF. 12)



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 2015 was around 0.6%.

* 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

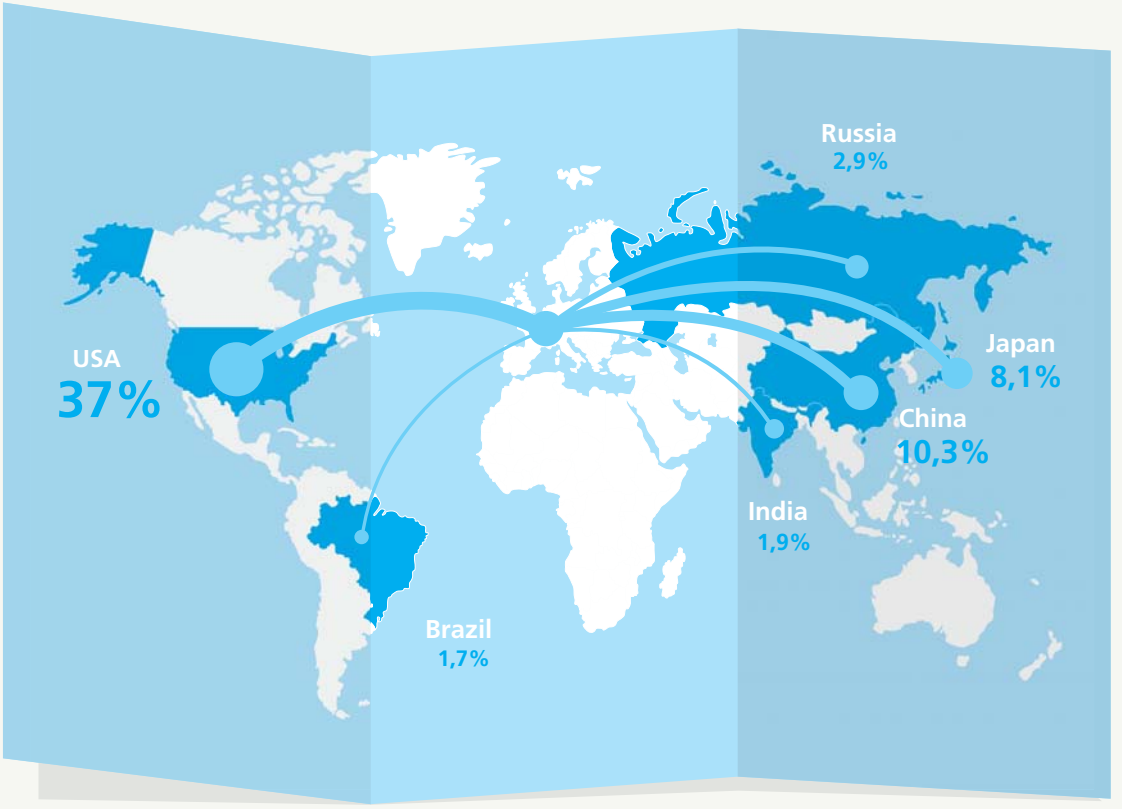
€14.1 billion

Estimation of Europe's trade surplus in 2015

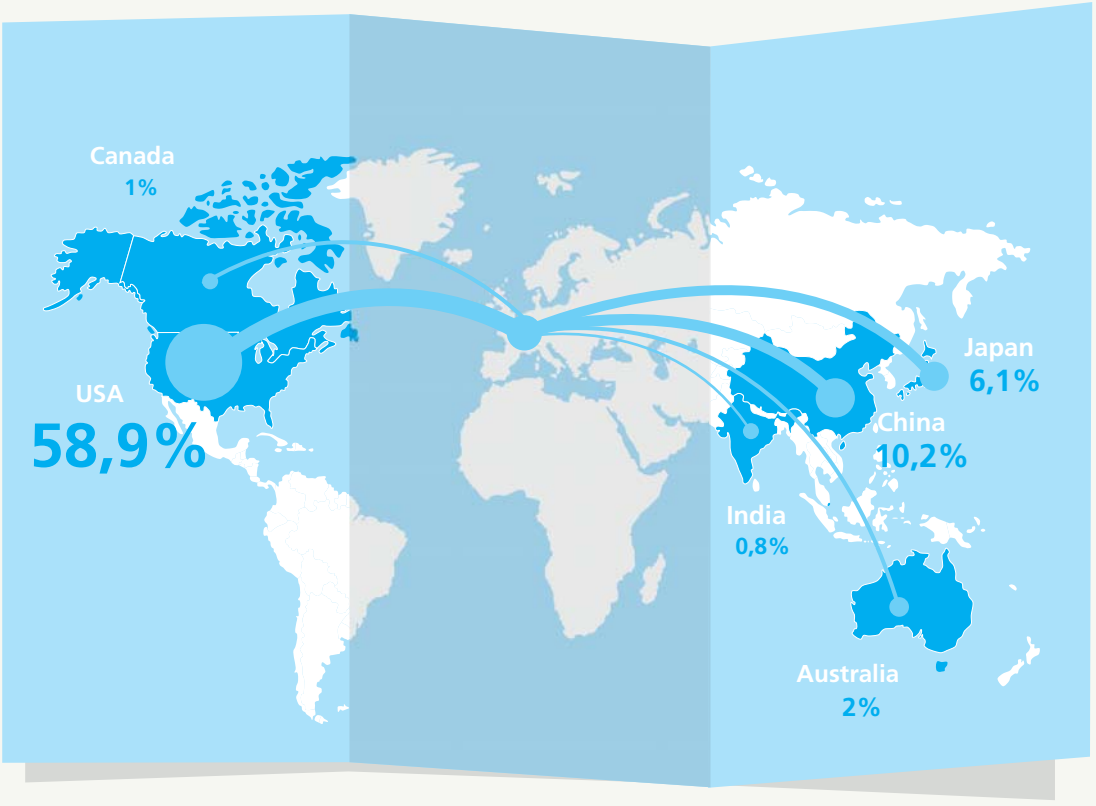
Europe has a positive medical technology trade* balance of 14.1 billion (2015) and this still represents a twofold increase since 2006. In comparison, the US medical technology trade surplus is at €5 billion. Compared to 2012, the main European medtech trade partners remain the same: the US, China and Japan (Ref 11).

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

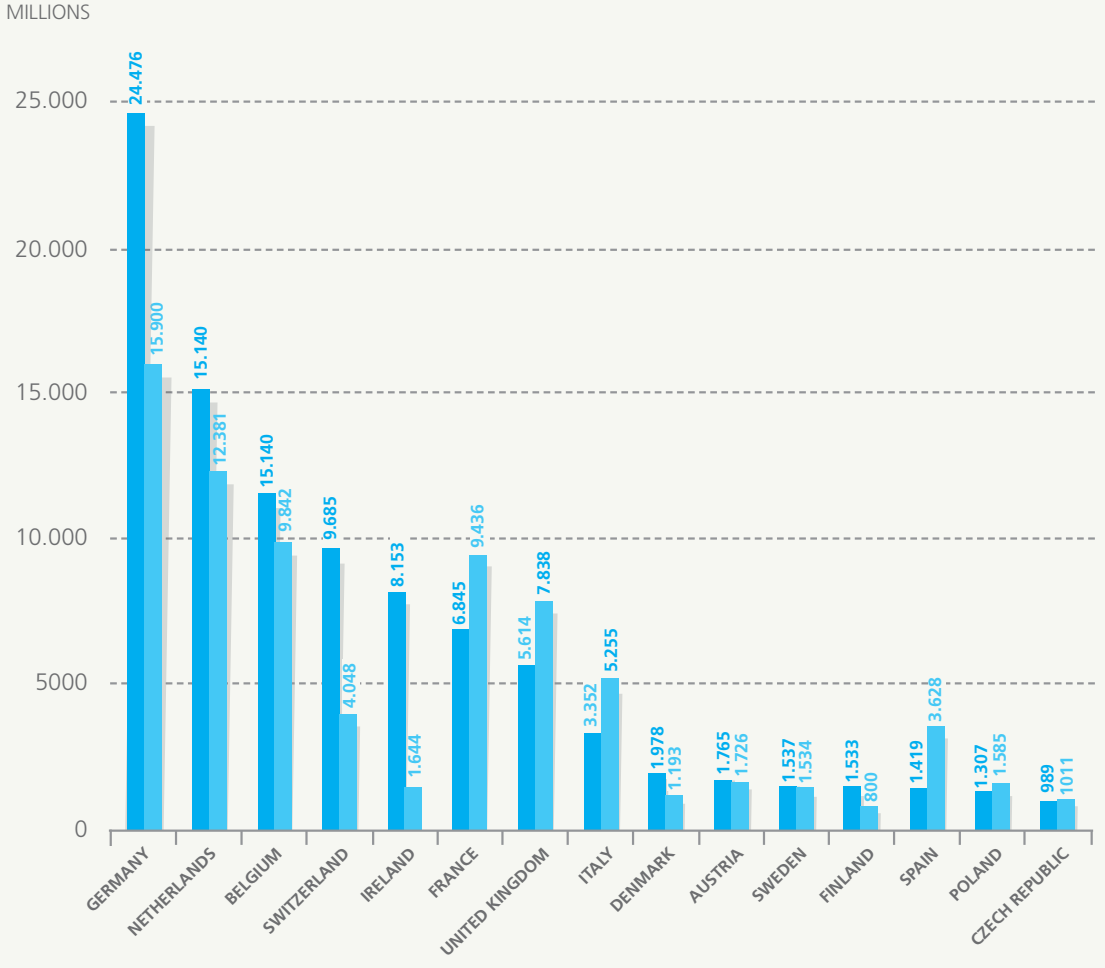
TOP EUROPEAN MEDICAL DEVICE EXPORT DESTINATIONS, 2015 (REF. 11)



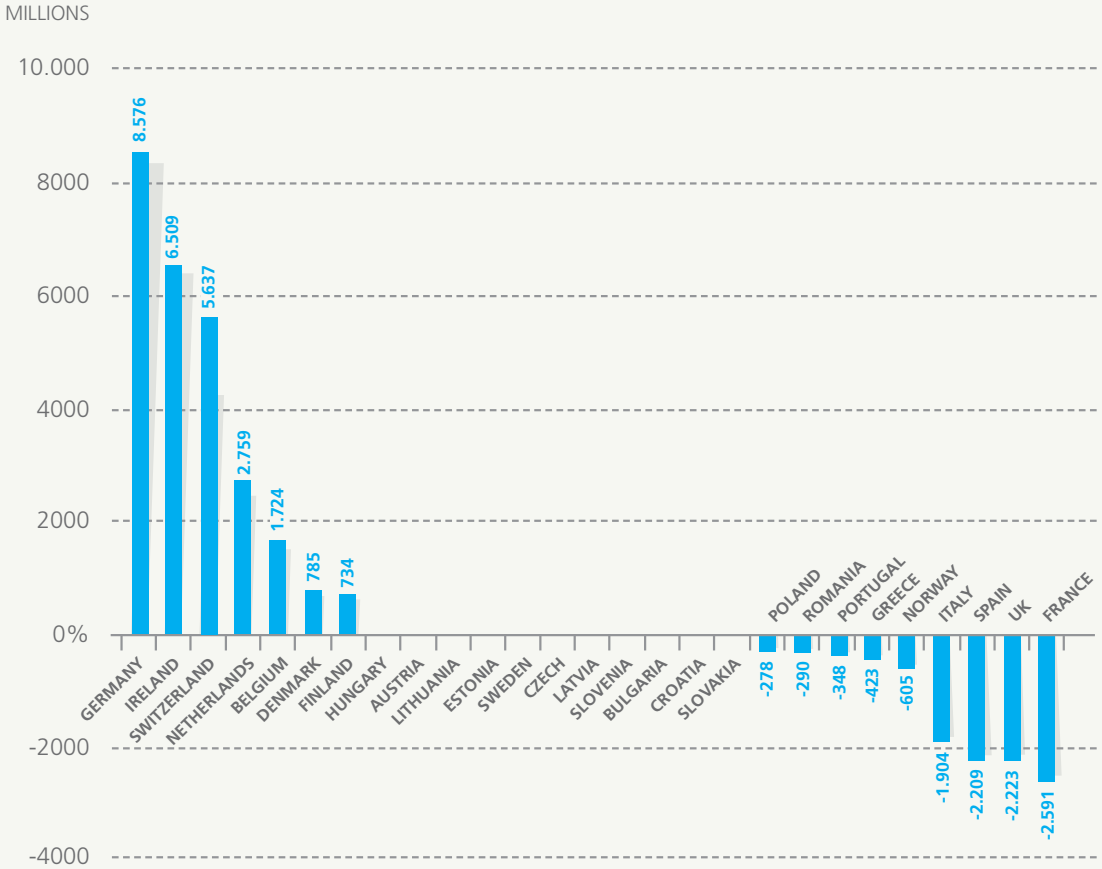
TOP SUPPLIERS TO EUROPEAN MEDICAL DEVICE MARKET (IMPORTS), 2015 (REF. 11)



EXPORT AND IMPORTS OF MEDICAL DEVICE BY COUNTRY 2015 (INCLUDING INTRA-COMMUNITY TRADE, MILLION EUROS) (REF. 11)



MEDICAL DEVICE TRADE BALANCE BY COUNTRY (INCLUDING INTRA-COMMUNITY TRADE, MILLION EUROS) , 2015 (REF. 11)



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 Commission. The classification of medical devices is a 'risk based' system based on the vulnerability of the human body taking into 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 2015: data from 25 Notified Bodies. CE mark is a verification that a device meets all regulatory requirements of the Directives which apply to it.

5 Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices – January 2012.

6 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 2015). European countries refer to EU + Norway, Switzerland. Patents are attributed by the country of residence of the applicant.

7 EFPIA – The Pharmaceutical Industry in Figures. Key Data 2015. Europe refers to EU + Norway, Switzerland.

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

9 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.

10 WHO, Eurostat, EFPIA, EDMA, Eucomed calculations. Europe refers to EU + Norway, Switzerland.

11 Espicom, Eucomed calculations. Manufacturer prices. Medical technology excluding in vitro diagnostics. Europe.

12 EDMA- European IVD Market Statistics Report 2015.

13 EvaluateMedTech® World Preview 2016, Outlook to 2022 (October 2016)
http://www.evaluategroup.com/public/Reports/EvaluateMedTech-World-Preview-2016.aspx

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