The European
Medical Technology industry

IN FIGURES

MedTech Europe
from diagnosis to cure

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Foreword

It is with great pleasure that I present to you the 2015 edition of *The European Medical Technology Industry In Figures*.

These new statistics show that the medical technology industry continues to be one of Europe's most diverse and innovative high-tech sectors. It is, in many ways, a model European industry. 95% of Europe's 25,000 medical technology companies are small and medium-sized enterprises (SMEs). The industry invests heavily to continuously improve its technologies and come up with breakthrough innovations. It files more patents than any other sector, provides over 575,000 jobs in Europe and delivers a positive trade balance of €15 billion.

Medical technologies also allow healthcare to be more efficient and effective, playing their part in making health systems more sustainable. We know ageing populations, chronic diseases and comorbidity are challenges to our societies. We know too that health budgets are under pressure. This is why the minds of medical technology innovators are focused on value. This means value for patients and healthcare professionals, but it also means value for payers and policymakers. Healthcare innovation is about more than making people better: it is about making sure people are in good health *and* making the system better.

MedTech Europe represents the diverse needs of our sector in Europe, communicating the value of medical technologies to payers, policymakers and society, and providing our members with valuable intelligence on the regulatory and policy issues that matter to them. With a recovery in progress, we need – now more than ever – for all health stakeholders to support the sometimes disruptive change that medical technology innovations can deliver, and to reward medical technologies when they add value.

Serge Bernasconi
Chief Executive Office MedTech Europe,
EDMA and Eucomed

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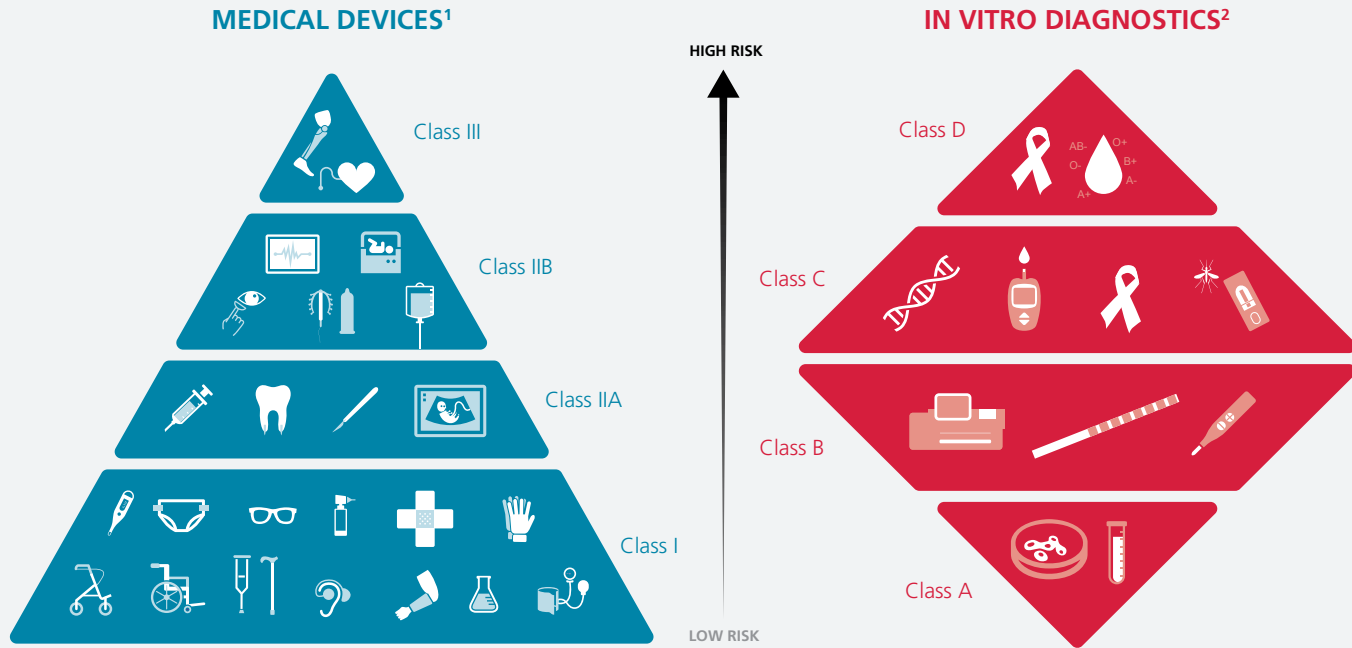
What is Medical Technology?

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 peoples' 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.

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Diversity and classification of medical technology

MEDICAL DEVICES[1]

Class III

Class IIB

Class IIA

Class I

HIGH RISK

LOW RISK

IN VITRO DIAGNOSTICS[2]

Class D

Class C

Class B

Class A

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 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 hearth valves
15	Healthcare facility products and adaptations	Gas delivery systems
16	Laboratory equipment	Most IVD which are not reagents

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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 2014 is estimated to be more than 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].
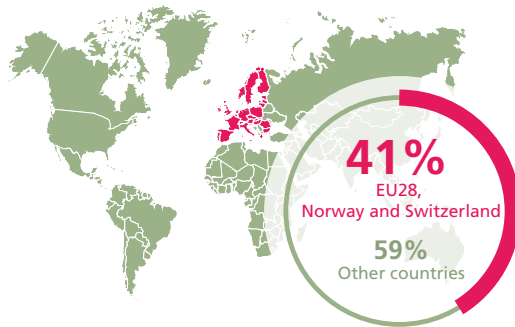
Innovation

Patent applications in medical technology field filled with EPO in 2014

41%
EU28, Norway and Switzerland

59%
Other countries

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 2014, more than 11,000 patent applications were filed with the European Patent Office (EPO) in the field of medical technology – 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, with the majority of applications filed from the US (39%).

In comparison, around 5,300 applications were filed in the pharmaceutical field and 5,900 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].

Top 10 technical fields in patent applications.
Number of patent applications filed with EPO, 2014[6]

Medical technology
11,124

Electrical machinery,
appartus, energy
10,944

Digital
communication
10,018

Computer
technology
9,869

Transport
7,533

Measurement
7,228

Organic
fine chemistry
6,132

Biotechnology
5,905

Engines,
pumps, turbines
5,318

Pharmaceuticals
5,270
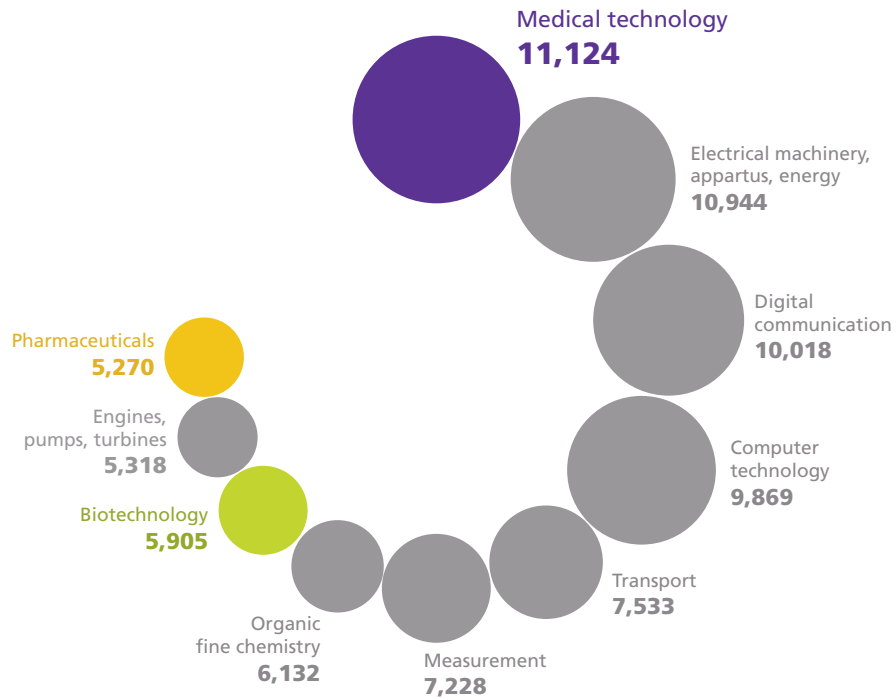
Evolution of European patent applications by technical field[6]

Number of patent applications filed with EPO
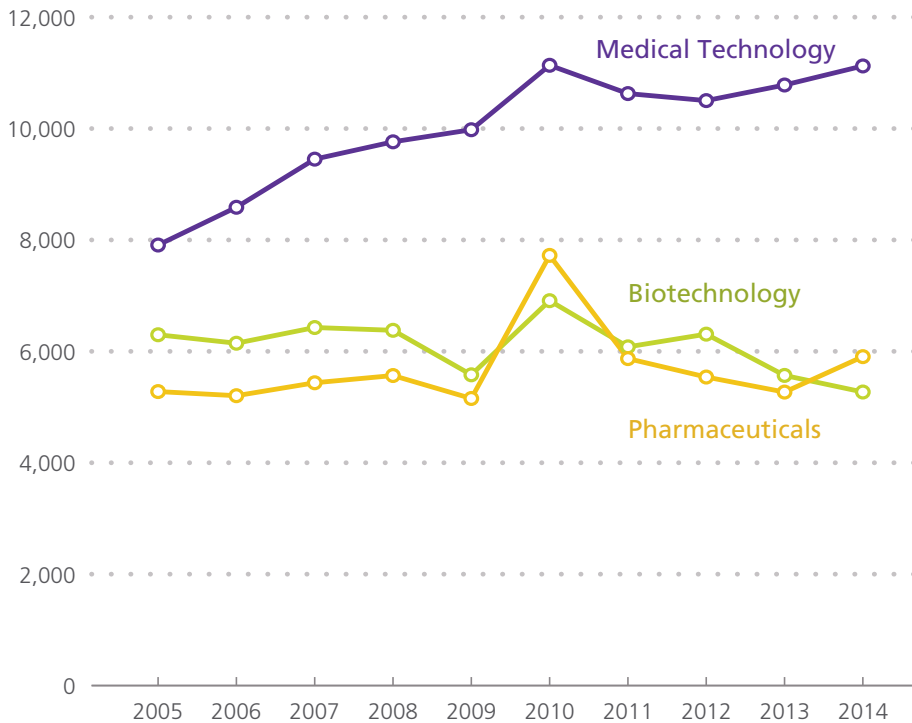
Medical Technology

Biotechnology

Pharmaceuticals

Employment

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. 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 EU 28, Norway and Switzerland unless specified otherwise.

575,000 employees

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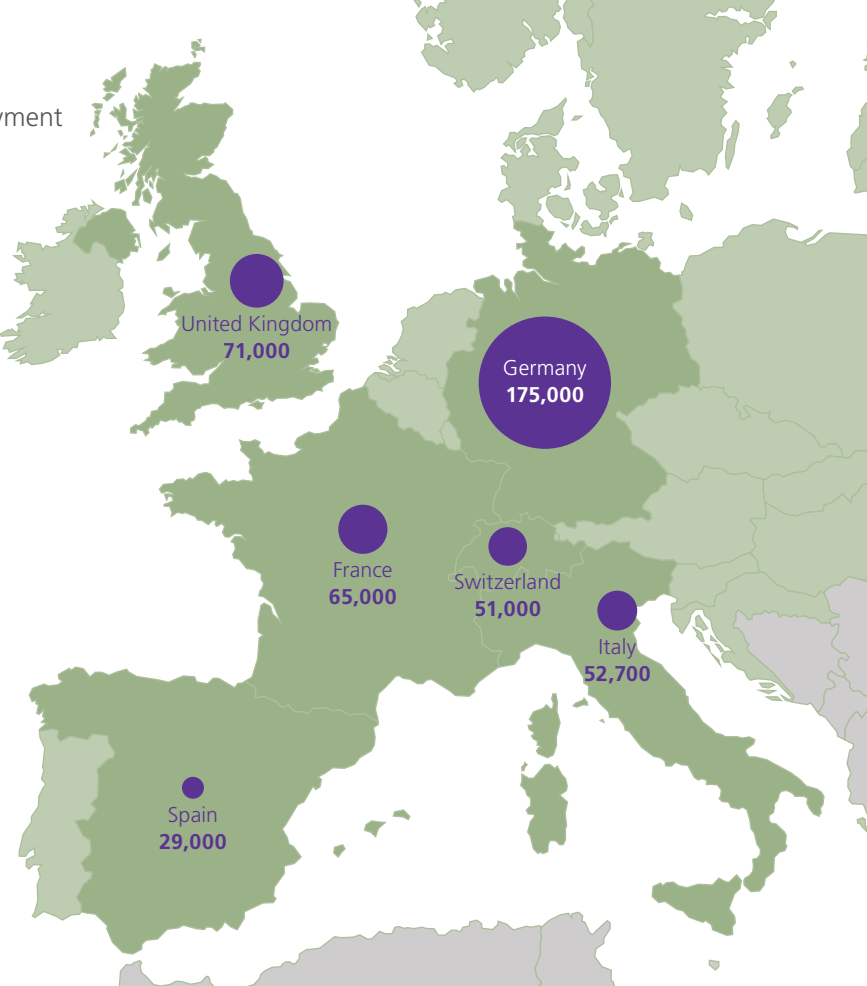Expenditure on Medical Technology

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Top 6 countries with highest employment
in the medical technology industry[9]

United Kingdom
71,000

Germany
175,000

France
65,000

Switzerland
51,000

Italy
52,700

Spain
29,000

Number of people employed in the medical technology
industry per 10,000 inhabitants[9]

65	**55**	**36**	**22**	**21**	**16**	**11**	**10**	**9**	**9**	**7**	**6**	**5**
Switzerland	Ireland	Denmark	Sweden	Germany	Belgium	United Kingdom	France	Netherlands	Italy	Portugal	Spain	Greece

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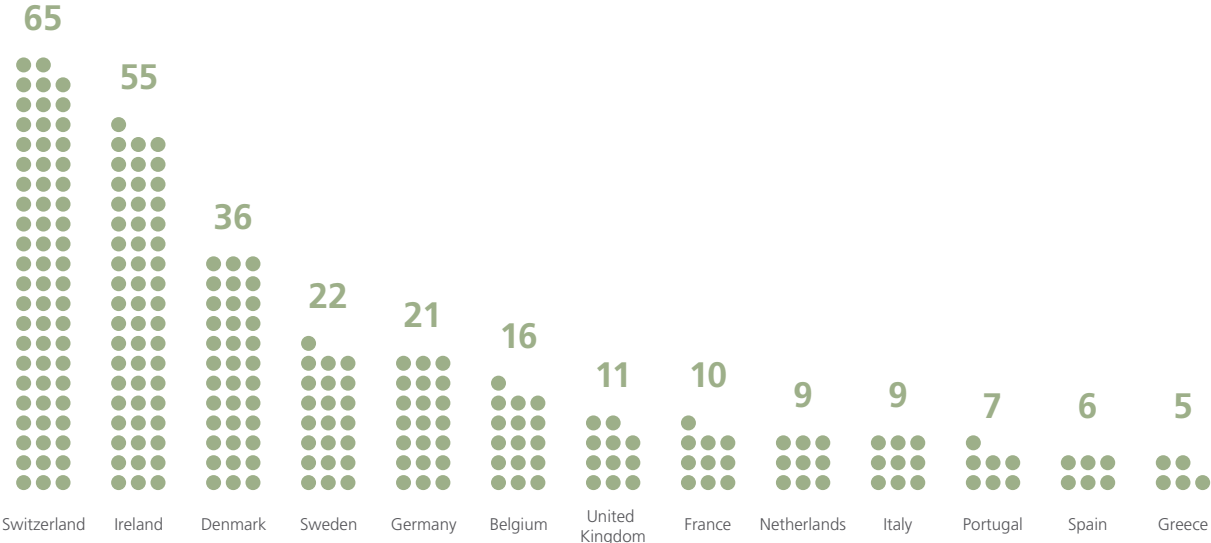About MedTech Europe

Companies

95%
SMEs

25,000
medical
technology
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 a SME if it employs fewer than 250 persons and has an annual turnover not exceeding €50 million (a small or micro-sized company employs fewer than 50 persons and has a turnover of less than €10 million).

Expenditure on Medical Technology

In Europe, an average of 10.4% of gross domestic product (GDP) is spent on healthcare. Of this figure, around 7.5% 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[10]. Expenditure on medical technology per capita in Europe is at around €195 (weighted average), compared with €380 in the US[11].

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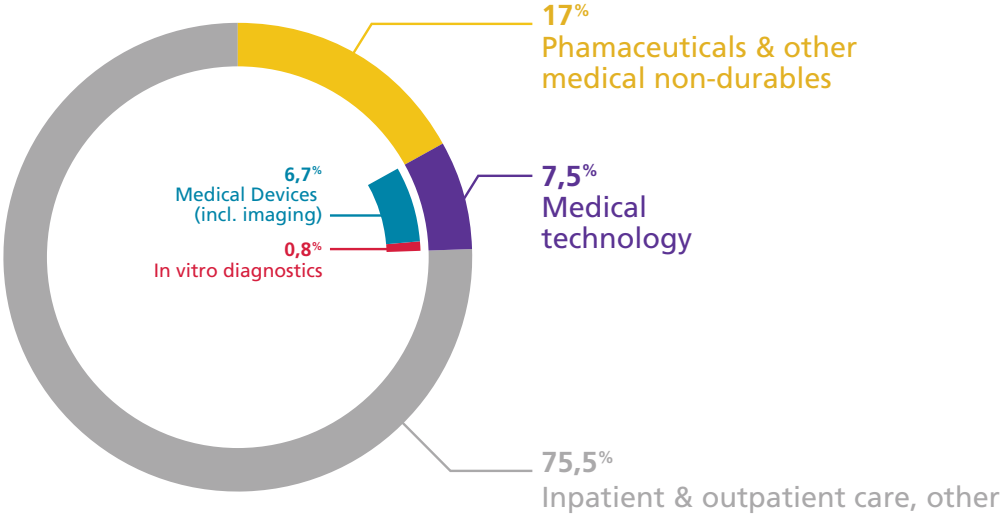Expenditure on Medical Technology

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Breakdown of total healthcare expenditure in Europe[12]

17% Phamaceuticals & other medical non-durables

7,5% Medical technology

6,7% Medical Devices (incl. imaging)

0,8% In vitro diagnostics

75,5% Inpatient & outpatient care, other

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

€ 2,645 — Healthcare expenditure

€ 450 — Pharmaceuticals

€ 195 — MedTech

€ 385 — Defence

€ 560 — Environmental protection

€ 1,600 — Education
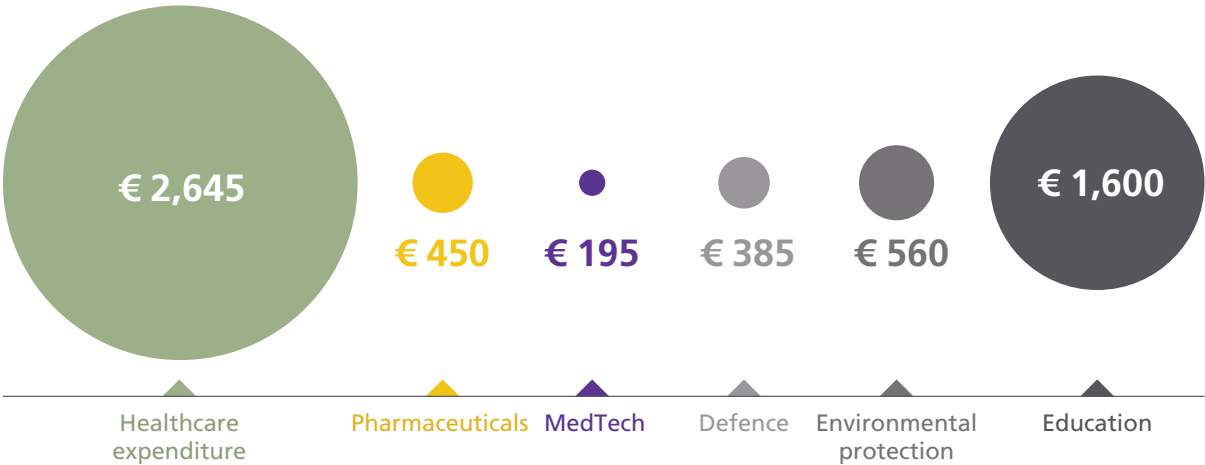
MedTech Market in Europe

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

Based upon manufacturer prices the European medical technology market is estimated to make up 31% of the world market. It is the second largest medical technology market after the US (± 40%)[13].

€100 billion market

European medical technology market by country,
based upon manufacturer prices, 2014[13]

GERMANY
28%

FRANCE
16%

UNITED KINGDOM
12%

ITALY
10%

SPAIN
5%

NETHERLANDS
4%

SWITZERLAND
3%

SWEDEN
3%

BELGIUM
3%

AUSTRIA
2%

OTHER
14%

The biggest medtech markets in Europe are Germany, France, the United Kingdom, Italy and Spain[13]. The same countries form the top 5 IVD markets in Europe[14].

European IVD market by country, 2014[14]

GERMANY 20%

FRANCE 17%

ITALY 16%

SPAIN 9%

UNITED KINGDOM 8%

NETHERLANDS 3%

SWITZERLAND 3%

POLAND 3%

BELGIUM 3%

AUSTRIA 2%

OTHER 16%

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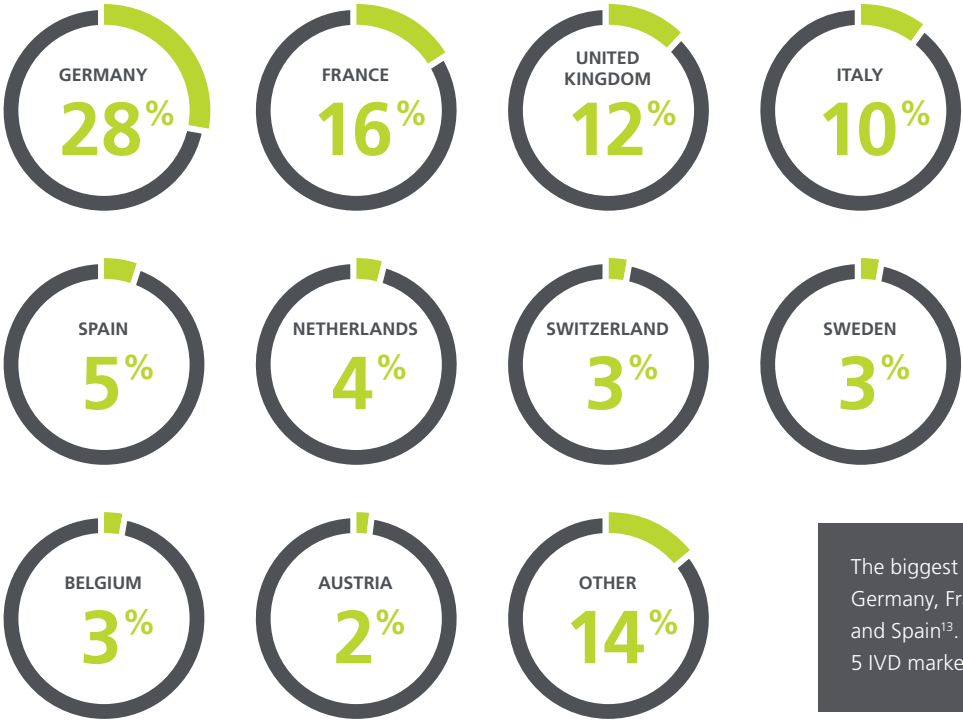Expenditure on Medical Technology

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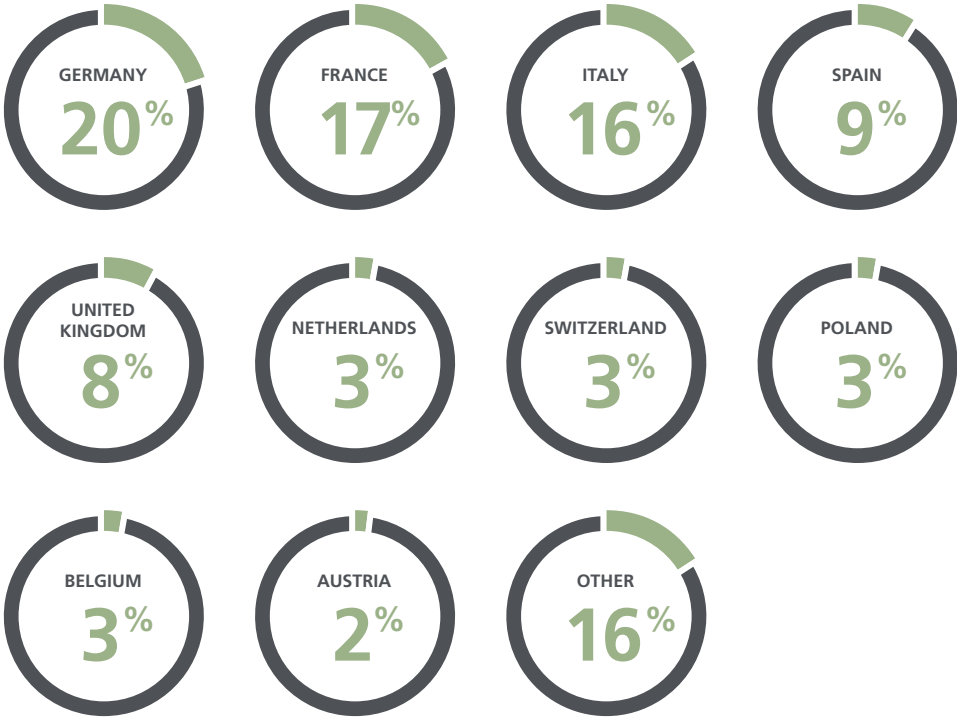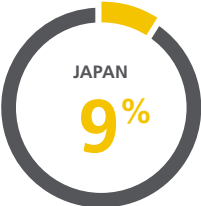About MedTech Europe

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World medical technology market by region
based upon manufacturer prices, 2014[13]

USA
39%

EUROPE
31%

JAPAN
9%

CHINA
6%

RUSSIA
2%

CANADA
2%

BRAZIL
2%

OTHER
9%
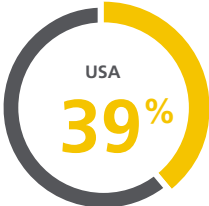
World medical technology market by area and sales growth, 2014-2020[15]

WW Market Share in 2020

% Sales Growth: CAGR 2014-20

Bubbles (left to right, approximate):
- Diagnostic Imaging
- Orthopedics
- Drug Delivery
- Wound Management
- General & Plastic Surgery
- Dental
- Cardiology
- Ophthalmics
- Endoscopy
- In Vitro Diagnostics (IVD)

Note: Size of Bubble = WW Sales in 2020

Source: EvaluateMedTech® September 2015
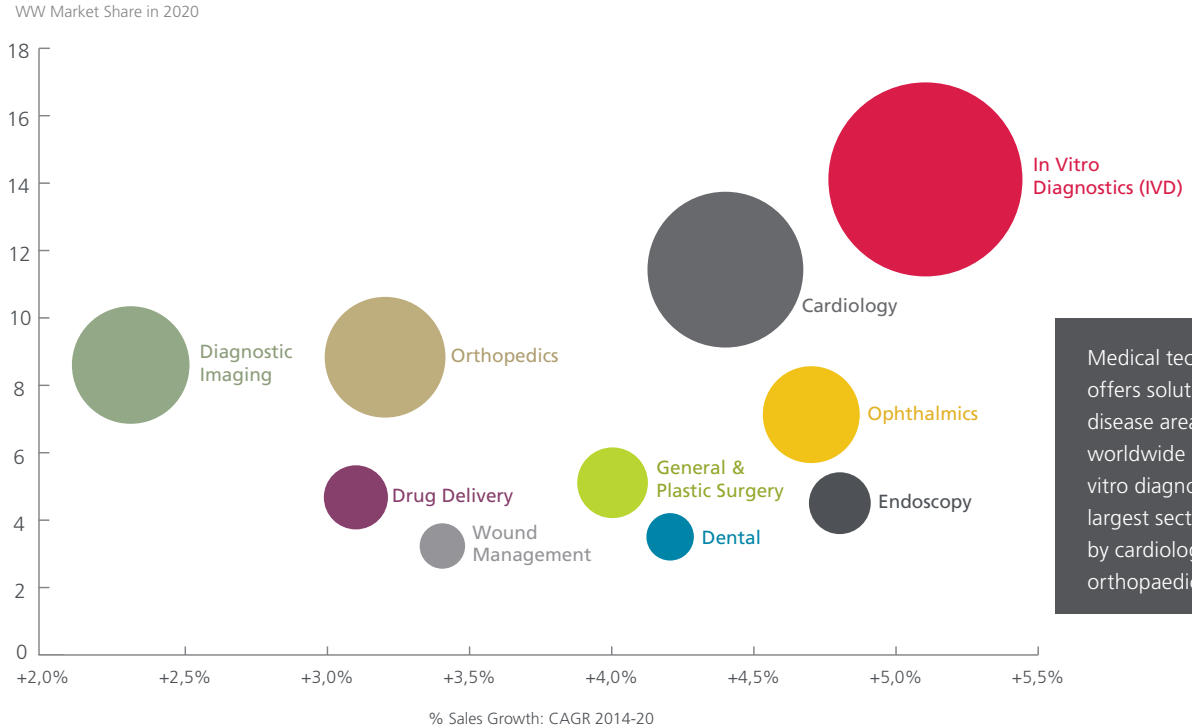
Medical technology offers solutions for many disease areas. On a worldwide perspective, in vitro diagnostics are the largest sector, followed by cardiology and orthopaedics[15].

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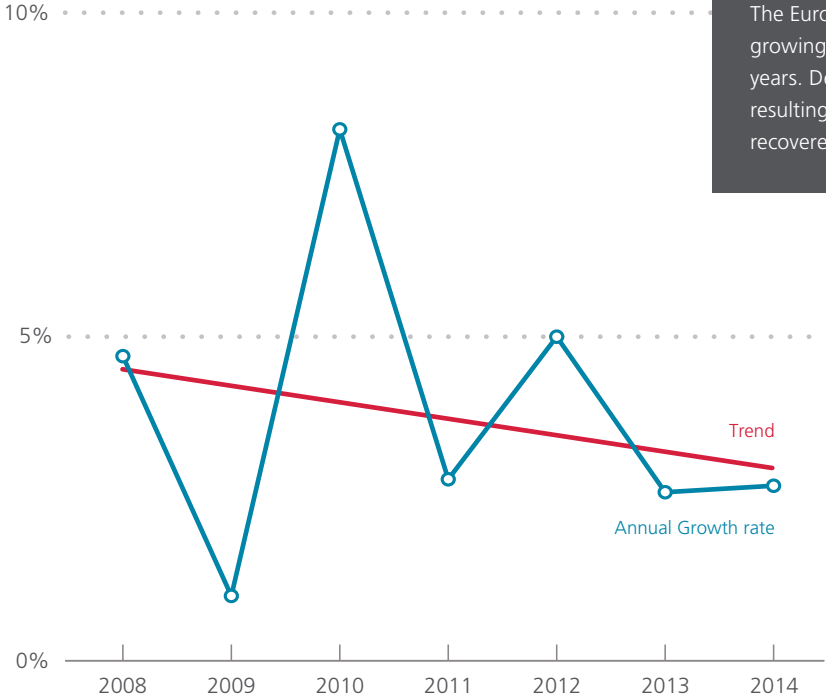
European medical technology market growth rates, based upon manufacturer prices, 2008-2014[13]

The European medical technology* market has been growing on average by 4% per annum over the past 7 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[11].

Trend

Annual Growth rate

European IVD market growth rates, 2008-2014[14]

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 2014 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. Medical technology not including in vitro diagnostics.

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Trade
in Europe

Europe has a positive medical technology trade* balance of €14 billion (2014). This is less than in 2013 (€15.2 billion), but still represents a twofold increase since 2006. In comparison, 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.[13]

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

Europe's trade surplus is estimated at €14 billion

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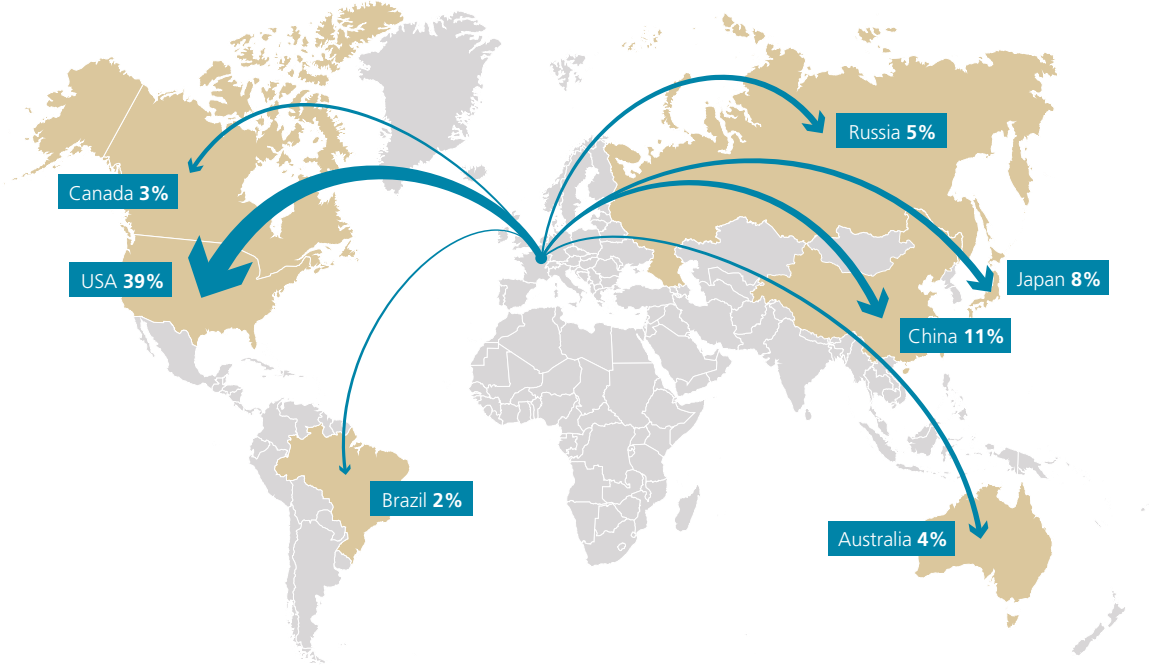
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Top European medical technology export destinations, 2013[13]

Canada **3%**

USA **39%**

Brazil **2%**

Russia **5%**

Japan **8%**

China **11%**

Australia **4%**

Top suppliers to European medical technology market (imports), 2013[13]

USA **63%**

Japan **6%**

China **10%**

Singapore **2%**

Australia **2%**

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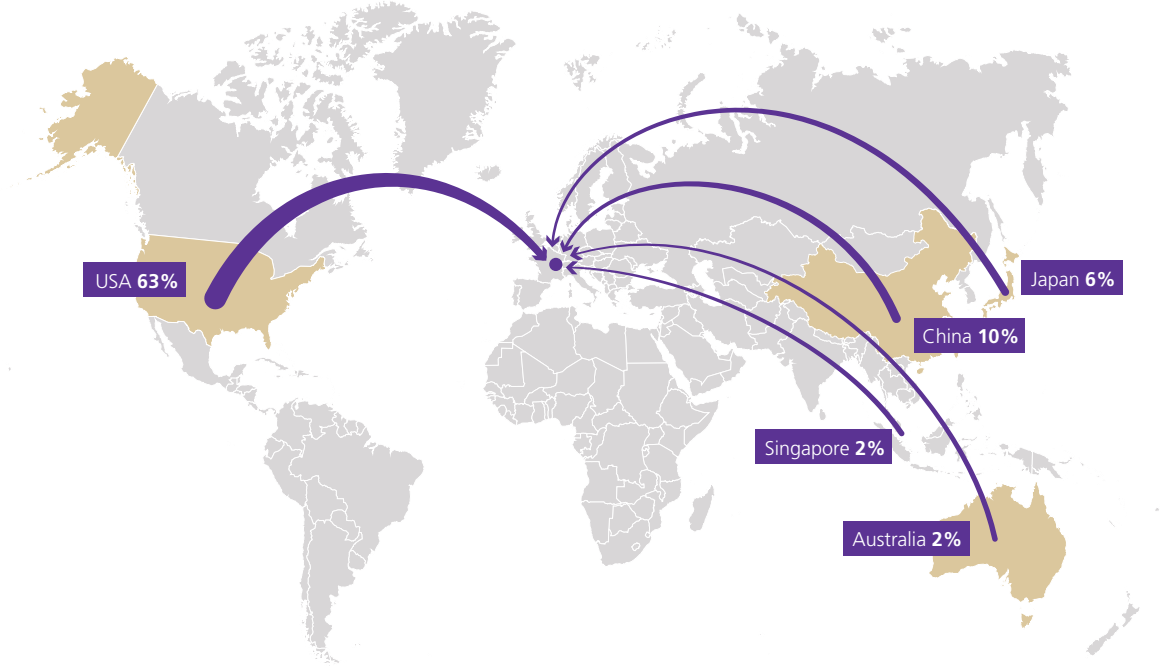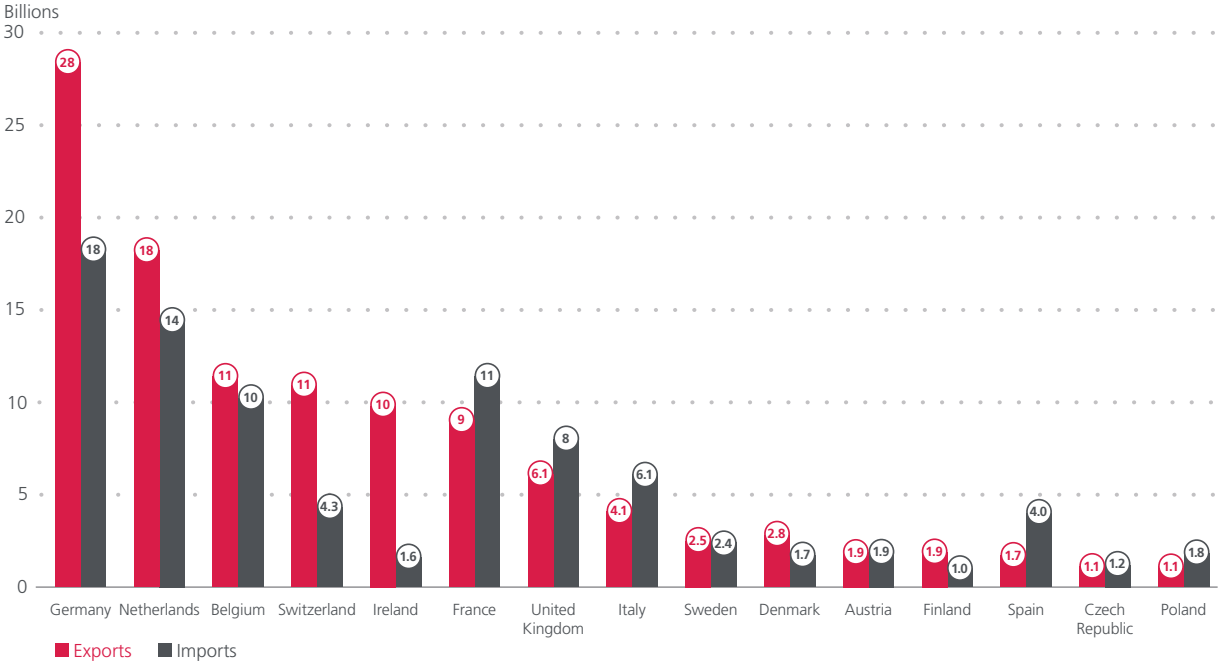About MedTech Europe

Export and imports of medical technology by country, 2014 (including European intra-trade)[13]
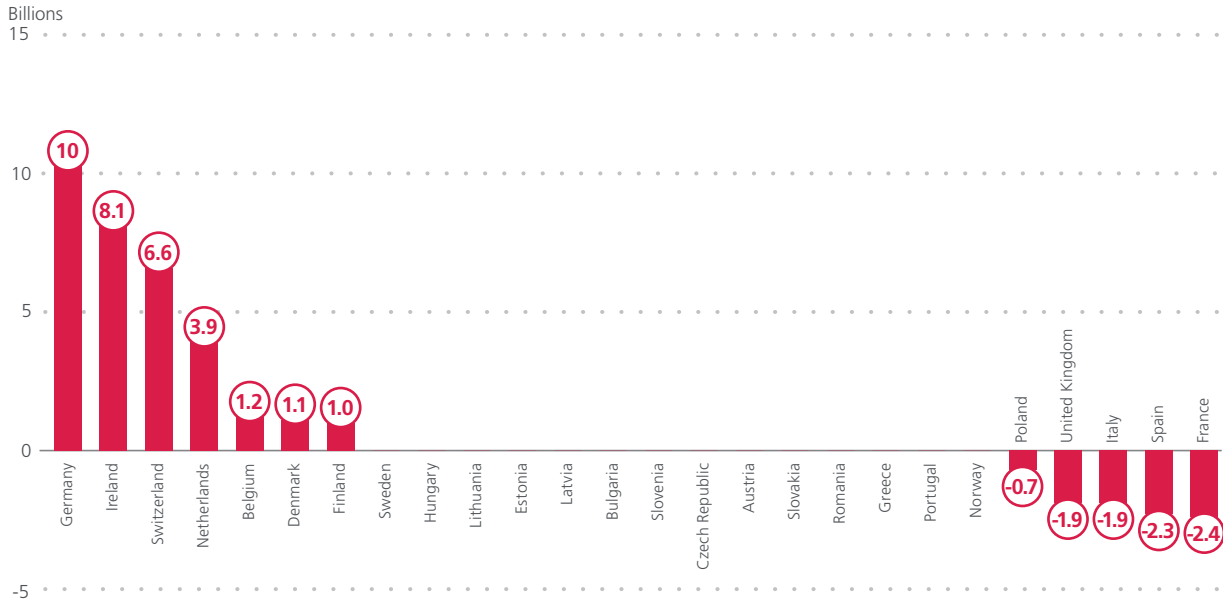
Billions

Country	Exports	Imports
Germany	28	18
Netherlands	18	14
Belgium	11	10
Switzerland	11	4.3
Ireland	10	1.6
France	9	11
United Kingdom	6.1	8
Italy	4.1	6.1
Sweden	2.5	2.4
Denmark	2.8	1.7
Austria	1.9	1.9
Finland	1.9	1.0
Spain	1.7	4.0
Czech Republic	1.1	1.2
Poland	1.1	1.8

■ Exports ■ Imports

Top suppliers to European medical technology market (imports), 2013[13]

Billions

Country	Value
Germany	10
Ireland	8.1
Switzerland	6.6
Netherlands	3.9
Belgium	1.2
Denmark	1.1
Finland	1.0
Sweden	
Hungary	
Lithuania	
Estonia	
Latvia	
Bulgaria	
Slovenia	
Czech Republic	
Austria	
Slovakia	
Romania	
Greece	
Portugal	
Norway	
Poland	-0.7
United Kingdom	-1.9
Italy	-1.9
Spain	-2.3
France	-2.4

About
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From diagnosis to cure

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

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.

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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 2014: 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 2014). European countries refer to EU + Norway, Switzerland. Patents are attributed by the country of residence of the applicant.

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 calculation based on the data obtained from National Associations of 15 countries for the latest year available. Europe refers to EU + Norway, Switzerland. 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 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 WHO; G. Donahoe and G. King – Estimates of Medical Device Spending in the United States, F.S.A., M.A.A.A., AdvaMed, 2012.

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

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

14 EDMA- European IVD Market Statistics Report 2014

15 EvaluateMedTech® World Preview 2015, Outlook to 2020 (October 2015) - http://info.evaluategroup.com/evaluatemedtech-world-preview-2015

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