

U.S. Commercial Service Europe

Medical Technology

Best prospects and business opportunities in
the medical technology sector in Europe

2014

Clayallee 170, Berlin, Germany

Medical Technology

OVERVIEW:

The healthcare industry in Europe is highly advanced, and there is a constant demand for cutting-edge, high tech products. In both new and existing technologies, U.S. exporters will find a wealth of opportunities on the European market. The medical technology industry is a leader in innovation, with more than 10,000 patent applications filed with the European Patent Office in 2012. Of these, 42% were filed from the U.S.¹

The European market is estimated to be around 100 billion Euros, constituting approximately one third of the global market, and growing at about 4% annually. This makes it the second largest market for medical technology, after the U.S., which controls 40% market share.² The biggest medical technology markets in Europe are Germany, France, the United Kingdom, Italy, and Spain.

Healthcare is a primary governmental concern across Europe. An average of 10.4% of GDP is spent on healthcare, with 7.5% of this devoted to medical technology.³

The U.S. provides 65% of European imports of medical technology.⁴ While countries with strong medical technology sectors – like Germany, Switzerland, and Ireland – tend to export more of such products than they import, many other European countries rely heavily on imports in this industry. These include Albania, Austria, Belgium, the Czech Republic, Greece, and Norway. U.S. firms will encounter good prospects here. Generally, price tends to be the key factor in these markets, especially in the wake of the financial crisis.

Since the 1990s, regulations on safety and performance of medical devices have been harmonized in the European Union. The following directives comprise the existing legislation for the industry: [Directive 90/385/EEC](#) on active implantable medical devices, [Directive 93/42/EEC](#) on medical devices, and [Directive 98/79/EC](#) on in vitro diagnostic medical devices. Member states are responsible for enforcing this legislation. Other related policies and legislation can be found [here](#).

The bureaucracy regulating approval of medical devices is more time-efficient in Europe than it is in the United States. The approval process by the European Medicines Agency takes about half as long as that of the U.S. Food and Drug Administration.⁵ In addition, products that are correctly CE marked can be marketed throughout the European Union, the European Economic Area, and Switzerland, without further certification. Thus, with one stamp of approval, American technologies can gain access to the

¹ [“The European Medical Technology industry: In Figures,”](#) MedTech Europe, January 2014

² [“The European Medical Technology Industry in Figures,”](#) MedTech Europe, 2013

³ [“The European Medical Technology industry: In Figures,”](#) January 2014

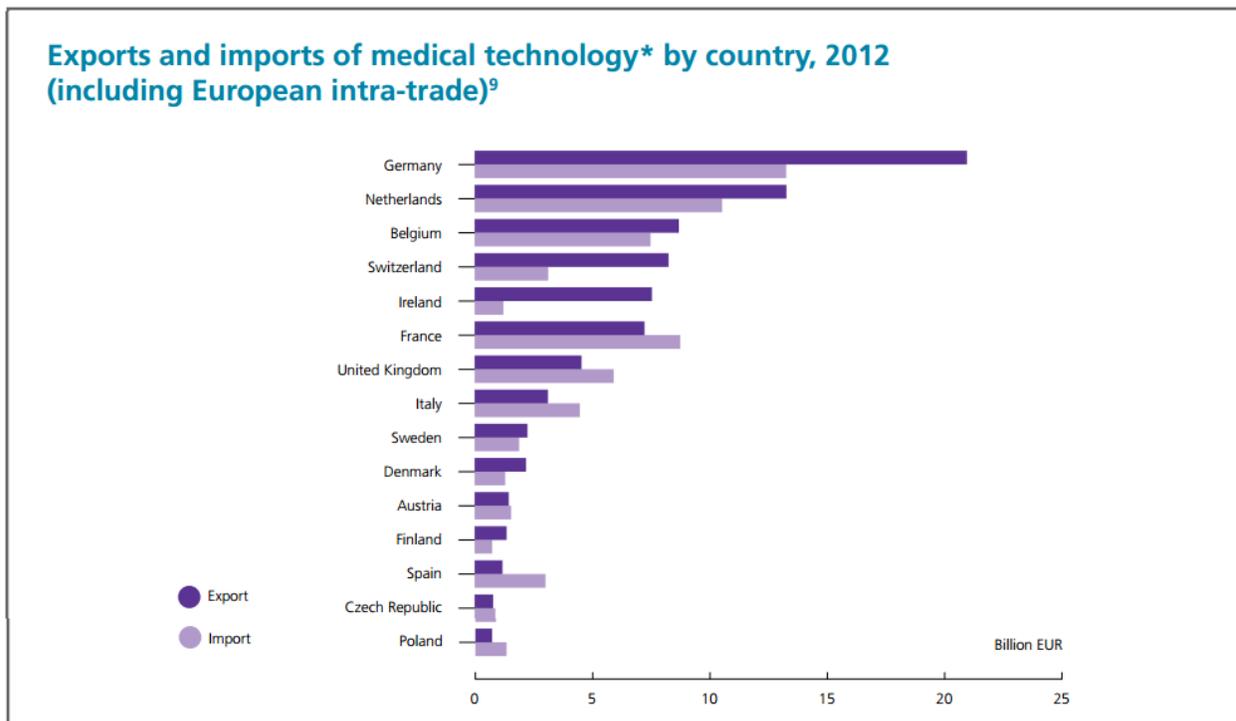
⁴ [“The European Medical Technology Industry in Figures,”](#) 2013

⁵ [“Medical Device Industry Faces ‘Unprecedented Challenges,’](#) AAMI, July 2012

entire European market. However, individual countries have the right to request registration of medical devices.

Many European countries are facing the challenge of an aging population. While currently the ratio of pensioners to the working age population is 1:4, by 2050 it is expected to be a startling 1:2.⁶ This creates new demands for health care, straining the existing infrastructures, and simultaneously means that the taxpayer base is shrinking. This problem is further complicated by the tight financial situation in Europe, putting pressure on public spending. As a result, the European medical technology must restructure, with a focus on value-based innovation. To address this challenge, Eucomed (the European Medical Technology Industry Association) and EDMA (the European Diagnostics Manufacturer's Association) have come together to promote the [Contract for a Healthy Future](#), which charts the way forward for the European medical technology industry through bold thinking and collaboration. An increasingly aged population throughout Europe is not only a policy challenge, but also a potential opportunity for efficient technologies and new forms of healthcare. Demand for home care and hospice products is on the rise, and innovative technologies to address the needs of pensioners will be well received.

Trends on the European healthcare market are moving towards miniaturization of technology, nanotechnology, and e-Health solutions. Innovative solutions and the latest technology have potential across Europe.



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⁶ ["Common Challenges; Shared Solutions,"](#) MedTech Europe, accessed January 2014

⁷ ["The European Medical Technology Industry in Figures,"](#) 2013

TARGET COUNTRIES:

[Albania](#), [Austria](#), [Belgium](#), [Bosnia & Herzegovina](#), [Bulgaria](#), [Czech Republic](#), [Finland](#), [France](#), [Germany](#), [Greece](#), [Hungary](#), [Ireland](#), [Italy](#), [Macedonia](#), [Montenegro](#), [the Netherlands](#), [Norway](#), [Poland](#), [Portugal](#), [Romania](#), [Serbia](#), [Slovakia](#), [Slovenia](#), [Spain](#), [Sweden](#), [Ukraine](#), [United Kingdom](#)

Click on link for corresponding Country Commercial Guide.

CERTIFICATION:

CE conformity:

The distinguishing feature of new approach directives is CE marking, which is a conformity mark, affixed to the product, the instructions for use and the packaging, an indication to inspection authorities that the product complies with the directives. While CE marking is generally required on all medical devices, there are a few exceptions. In general, devices shown at trade fairs, exhibits, for demonstrations etc do not need to have CE marking. However, it is recommended to indicate clearly that non-CE marked devices are for demonstration purposes only.

SUB-SECTORS

Dental healthcare:

Junior dental healthcare: Bulgaria

Dental mechanical tools and instruments: Albania, Bulgaria, Norway, Ukraine

Dental surgery services: Bulgaria

Teeth whitening systems: Hungary

Root canal treatment: Hungary

Computer-controlled injection devices for anesthetization: Hungary

Orthodontics devices: Hungary

Implant instruments: Hungary, Slovakia

Cosmetic/aesthetic dentistry: Slovakia

Laboratory equipment:

Laboratory and testing equipment: Albania, Austria, Bosnia & Herzegovina, Bulgaria, Macedonia, Montenegro, Norway, Serbia, Slovenia, Ukraine

Laboratory diagnostics: Hungary

Clinical chemistry: Hungary

Image Cytometry (microscopic cell measuring): the Netherlands

In-vitro diagnostic products: Austria, Bulgaria, Finland

Handicaps:

Hearing aids: Hungary, Slovakia

Innovative prosthesis: France, Slovakia, Sweden, United Kingdom

Physiotherapy and rehabilitation equipment: Bulgaria, Germany, Ireland, Serbia, Ukraine, United Kingdom

Scanning and imaging:

Scanning units: Austria, Bosnia & Herzegovina, Montenegro, Serbia, Slovenia

Diagnostic imaging equipment: Albania, Bosnia & Herzegovina, Bulgaria, France, Italy, Montenegro, Serbia, Ukraine

Sophisticated digitalized x-ray equipment: Albania, Austria, Bosnia & Herzegovina, Bulgaria, Finland, Hungary, Macedonia, Norway, Poland, Portugal, Slovakia

Digital image processing: Czech Republic, Finland, Portugal

Magnetic resonance imaging (MRI) equipment: Albania, Austria, Bosnia & Herzegovina, Bulgaria, Finland, Macedonia, Montenegro, the Netherlands, Portugal, Serbia, Slovenia, Ukraine

Magnetic Resonance Angiogram (MRA): Spain

Image networking capabilities: Austria, France

Nuclear imaging (PET, Gamma camera): Hungary

Computer tomography imaging systems: Albania, Austria, Macedonia, Slovenia, Ukraine

Position Emission Tomography (PET): the Netherlands

Single Photon Emission Computer Tomography (SPECT): the Netherlands

Picture archiving: Finland, the Netherlands, Portugal

Ultrasound equipment: Albania, Austria, Bosnia & Herzegovina, Bulgaria, Czech Republic, Hungary, Macedonia, Montenegro, the Netherlands, Norway, Serbia, Ukraine

Echographic units: Austria

CT scan: Spain

Miscellaneous equipment:

Nuclear medical equipment: Austria, Bosnia & Herzegovina, Poland, Serbia

Endoscopes: Albania, Austria, Bosnia & Herzegovina, Czech Republic, Finland, Italy, Montenegro, the Netherlands, Portugal, Serbia

Abrasive tools: Bulgaria

Needles: Albania

Catheters: Albania, Hungary

Intensive care equipment: Albania, Bosnia & Herzegovina, France, Montenegro, Romania, Serbia

Stents: Macedonia, Serbia

Biosensors: the Netherlands

Tissue and blood bank related equipment: Albania, Bosnia & Herzegovina, Bulgaria, Montenegro, Serbia

Diagnostics:

Diagnostic equipment and instruments: Germany, Hungary, Ireland, Norway, Poland, Slovenia, Ukraine, United Kingdom

Diagnostic point-of-care tests: Ukraine

Gynecology diagnostic systems: Austria

Cardiology:

Pacemakers: Albania, Austria, Bosnia & Herzegovina, Hungary, Macedonia, Serbia

Electrocardiography equipment: Albania, Austria, Bosnia & Herzegovina, Italy, Macedonia, Montenegro

Echocardiography systems: Austria

Cardiology equipment: Austria, Ireland, Macedonia, Spain

Cardiography: Norway

Implantable cardiac devices: Ukraine

Stimulators and defibrillators: Italy, Macedonia, the Netherlands,

Cardiovascular diagnostic equipment: Albania, Bosnia & Herzegovina, Germany, Montenegro, Serbia

Cardiovascular surgical devices: Poland, Germany

Oncology:

Oncology equipment: Macedonia, Poland, Romania, United Kingdom

Radiation therapy: Albania, Bosnia & Herzegovina, Montenegro, Serbia

Urology:

Urology equipment: Albania, Bosnia & Herzegovina, Bulgaria, Macedonia, Montenegro, Serbia

Equipment for kidney treatment: Bulgaria

Equipment for hemodialysis: Bulgaria

Dialysis equipment: Austria, Bosnia & Herzegovina, Germany

Urology diagnostic systems: Austria, Germany

Radiology:

Interventionism radiology: Austria

Radiology information systems: Greece

Miscellaneous:

Obesity and diabetes products: Belgium, Sweden, United Kingdom

Specialized wound care: Germany, Spain

Neurology technologies: Spain

Homecare products: Belgium, Bulgaria, Czech Republic, France, Germany, Ireland, Poland, Serbia, Sweden, United Kingdom

Pathology instruments and equipment: Norway

Electro-medical instruments: Germany, Hungary, Ireland, the Netherlands

Ophthalmic equipment: Italy

Surgical equipment:

Non-invasive and minimally invasive surgical equipment: Albania, Belgium, Bosnia & Herzegovina, Bulgaria, France, Germany, Italy, Macedonia, Montenegro, Poland, Serbia, Sweden

Surgical equipment: Bulgaria, Ireland, Macedonia, Norway, Poland, Portugal, Slovakia

Maxillary surgery: Bulgaria

Anesthetics and anesthesiology equipment: Albania, Bosnia & Herzegovina, Bulgaria, Italy, Montenegro, Romania, Serbia, Spain

Sterilizing equipment: Bulgaria

Mini invasive surgery systems (MIS): Czech Republic, Finland, Italy, Poland, Portugal, Ukraine

Day surgery equipment: Finland, France

Surgery training and planning system: Greece

Surgical navigation systems: Ukraine

Laser surgery instruments: Albania, Bulgaria, Germany, Italy, Serbia, Ukraine

Orthopedic products: Belgium, France, Germany, Hungary, Ireland, Norway, Slovakia, Spain, Sweden, United Kingdom

Neurostimulation systems: Ukraine

Hospital management:

Hospital management systems: Bulgaria, Greece

Improvement of emergency care: Bulgaria, Ukraine

Hospital procurement based on Electronic Data Interchange Systems (EDI): Greece

Ambulances: Ukraine

Operating rooms: Poland, Ukraine

Hospital management training: Greece, Slovenia

Specialist consultations within the ear-nose-throat field (video conferencing): Norway

Specialist consultations in dermatology (e.g. video conferencing and still picture technology): Norway

Introduction of internal and clinical audits as well as analytical cost accounting systems: Greece

Health IT:

Information systems: Greece, Sweden

e-Prescription, e-Referral, and e-Labs systems: Greece, Italy, Romania, Slovakia

Electronic health records: Greece, Finland, Italy, Norway, Romania

Digital drug management: Italy

Cloud computing: Italy

Computer assisted diagnoses: Greece

Computerized systems for cosmetic, aesthetic, and restorative medicine: Bulgaria

Electronic insurance cards: Greece, Romania

Medical software: Belgium

Telemedicine: Belgium, Bulgaria, France, Greece, Ireland, Italy, Norway, Sweden, Ukraine, United Kingdom

Wearable and wireless medical technologies: Germany

E-Health: Belgium, Bulgaria, Germany, Greece, Hungary, Norway, Romania, Slovakia, Sweden, United Kingdom

Patient monitoring systems: Austria, Bulgaria, Czech Republic, Finland, Hungary, Italy, Norway, Poland, Portugal, Serbia, United Kingdom

TRADE EVENTS:

[Compamed](#) (Dusseldorf, Germany)

High tech solutions for medical technology

[Dental World](#) (Budapest, Hungary)

International dental exhibition

[Exposanita](#) (Bologna, Italy)

International health care exhibition

[FIBO](#) (Cologne, Germany)

The world's leading trade show for fitness, wellness, and health

[Finnish Dental Congress and Exhibition](#) (Helsinki, Finland)

Finland's leading event for dentistry professionals

[Health & Rehab Scandinavia](#) (Copenhagen, Denmark)

Trade fair for disability-related products and services as well as healthcare and hospital equipment

[IN³ Medical Device 360° Dublin](#) (Dublin, Ireland)

Partnering Europe's MedTech innovators with investors and corporate acquirers

[International Dental Show](#) (Cologne, Germany)

Trade fair for the dental industry

[Lab](#) (Oslo, Norway)

Laboratory equipment

[Medica](#) (Dusseldorf, Germany)

International fair for medical equipment

[Medical Devices Summit](#) (Dublin, Ireland)

Panels, presentations and networking opportunities with high-level individuals from across the industry

[Medical Fair Brno](#) (Brno, Czech Republic)

International fair for medical technology and healthcare

[Medic Expo](#) (Athens, Greece)

[Medtec Ireland](#) (Galway, Ireland)

Event for medical device manufacturers

[Medtec UK](#) (London, UK)

The UK's leading event for medical device manufacturers

[Nordental](#) (Oslo, Norway)

Dental equipment

[OTWorld](#) (Leipzig, Germany)

The orthopedic and rehabilitation industry's leading event worldwide

[*Pragodent*](#) (Prague, Czech Republic)

Dental care, services, and hygiene

[*Praqomedica*](#) (Prague, Czech Republic)

Medical fair, organized together with a specialized fair for the handicapped

[*Public Health*](#) (Kyiv, Ukraine)

The largest medical equipment and pharmaceuticals trade show in Ukraine

[*REHACARE*](#) (Dusseldorf, Germany)

Europe's premier rehabilitation and care event

[*ROMMEDICA*](#) (Bucharest, Romania)

International trade fair for medical instruments and equipment

[*Salmed*](#) (Poznan, Poland)

Poland's largest event for the healthcare/medical industry sector

[*Salons Santé Autonomie*](#) (Paris, France)

Health and independence trade shows

[*Scandefa*](#) (Copenhagen, Denmark)

Trade fair focused on the dental industry

[*Slovak Dental Days*](#) (Bratislava, Slovakia)

Novelties from the field of equipment related to the dental industry

[*Slovmedica*](#) (Bratislava, Slovakia)

Latest medical techniques, technologies, and equipment

[*Vitalis*](#) (Gothenburg, Sweden)

The largest eHealth event in Scandinavia

RESOURCES

➤ [The U.S. Commercial Service Global Healthcare Team](#)

The CS Healthcare Technologies Team works to address issues and trade opportunities specific to the strong and growing healthcare sector, and to ensure you have the information you need to grow your business. This resource guide is just one of the ways we can provide the information you need to set priorities and plan for business growth. To learn more about how we can help you, visit [export.gov/industry/health](https://www.export.gov/industry/health).

For more information on how CS can help your business increase its international sales, please contact your local CS office. A list of offices appears at the back of this guide and at export.gov/usoffices.

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- [2014 Healthcare Resource Guide](#): a reference for U.S. exporters, covering healthcare industries worldwide
- Commercial Service [Medical & Pharmaceutical Contacts](#) by country
- [Eucomed](#): Represents the medical technology industry in Europe. Any company with at least one manufacturing facility in Europe can become a Eucomed member.
 - Eucomed [Newsletters](#) can be a valuable source for industry events, facts & figures, and news.
- [International Medical Device Regulators Forum](#): promotes discussion about further medical device regulatory harmonization. Conceived in 2011, the forum is a voluntary group of regulatory authorities including the United States and Europe, among others.