Industry Focus: Medical Devices

Top 15 Medical Device Export Countries 2015 (USD 000s)		% Total
Netherlands	$ 5,250,225	11,9 %
Japan	$ 4,676,534	10,6%
Belgium	$ 4,152,375	9,4 %
Canada	$ 3,654,161	8,3 %
China	$ 3,404,533	7,7 %
Germany	$ 3,395,546	7,7 %
Mexico	$ 3,018,698	6,8 %
Australia	$ 1,486,486	3,4 %
Singapore	$ 1,321,051	3,0 %
Brazil	$ 1,142,621	2,6 %
Switzerland	$ 1,125,528	2,5 %
United Kingdom	$ 1,034,534	2,3 %
France	$ 935,503	2,1 %
South Korea	$ 790,185	1,8 %
Ireland	$ 715,001	1,6 %

Trade Flows for Medical Devices Sector		
Description	2014 Exports (USD Billions)	2015 Exports (USD Billions)
In Vitro Diagnostic Substance	$ 6,0	$ 6,1
Electro-Medical Apparatus	$ 8,3	$ 7,5
Irradiation Apparatus	$ 3,4	$ 3,6
Surgical and Medical Instruments	$ 12,6	$ 12,4
Surgical Appliances and Supplies	$ 9,3	$ 9,6
Dental Equipment and Supplies	$ 1,2	$ 1,2
Ophthalmic Goods	$ 2,7	$ 2,7
Total	$ 43,5	43,2

Global Drivers

- High value placed on innovation and new technologies
- Growing elderly population and the increasing number of patients with chronic and life-style diseases

- Increased access to medical services especially in urban areas of developing countries
- Continued pressure to reduce costs and inventory resulting in mergers and acquisitions

Current Trends

- Due to aging of population and the increasing number of patients with chronic and life-style diseases, medical devices that alleviate pain, complement lost functions, and improve the quality of life should show steady growth in demand.
- Focus towards miniaturization of medical devices allowing more minimally-invasive and non-invasive procedures
- Medical software, telemedicine and e-health are also sectors with a strong market potential
- 3D medical printing is gaining importance in several areas of medicine
- In order to save resources, recently many public and private hospitals are hiring companies that offer "integral surgery services" and provide service "per event," offering all the necessary products required to perform a surgery. In this way, hospitals avoid making large investments in materials, pharmaceuticals, and instruments, and also reduce the costs involved in keeping and controlling inventories, and maintaining instruments for specialized surgeries.
- Also, the market for in-home care devices, technologies, and health IT related products is expected to grow as the number of people in out-patient care increases.
- Due to stronger consumer health concerns, other promising growth areas include self-care and preventive care medical devices and products; increasing demand for medical services; shifts from institutional towards out-patient care; a move from curative towards preventative care.

Concerning Issues

- **Globalization – emerging markets: Brazil, India and China**
  - Companies are focusing on increasing market share in emerging countries
  - Doing business in these places is more challenging than most expect
  - Regulatory requirements in developing countries are often above those of developed countries. Determining and satisfying the requirements is often costly and time consuming
  - State-owned companies have strong ties to the government
  - Reimbursement rates in emerging markets can be a challenging

- It can be difficult to ensure that international firms have access to all the resources available to domestic companies

- Domestic U.S. industry must become increasingly cost-efficient as device makers in Europe and Asia gain market share

- **Ensuring patient safety**

  - Protecting devices from threats that have been demonstrated by ethical hackers

  - Protecting the integrity of patient and customer data

  - Meeting patient privacy and security needs while also complying with regulations

For more country-specific information, visit the Healthcare Technologies Resource Guide.

Medical Device Regulatory & Compliance Factors

The information below is intended to be a starting point, but please note medical device regulations are complex, and vary depending on device, country of origin, destination country, and many other factors. Please contact your local U.S. Commercial Service trade specialist to discuss your specific medical device, and international regulatory factors.

- **U.S. Food and Drug Administration** (U.S. FDA) approval of a medical device is often, but not always, required to meet regulatory and compliance requirements of other countries. Even if U.S. FDA approval is not required, similar information will often by requested by the given country's regulatory agency.
- U.S. FDA's **Center for Devices and Radiological Health (CDRH)** Export Certification Application and Tracking System (CECATS) is CDRH's web-based application for requesting export certificates, simple notifications, and export permit letters.
  - **Exporting Medical Devices FAQs** from U.S. FDA
  - "Device Advice: Comprehensive Regulatory Assistance" Portal from U.S. FDA
- U.S. Regulations
  - Compliance with U.S. FDA requirements is mandatory – U.S. FDA is a law enforcement agency.
  - For questions:
    Division of Industry and Consumer Education
    1.800.638.2041
    1.301.796.7100
    DICE@fda.hhs.gov
- **ISO** is an independent, non-governmental international organization with a membership of 163 national standards bodies.
  - "ISO" is derived from the Greek *isos*, meaning equal.
  - Compliance with ISO requirements is voluntary – but certification may be required to register medical devices by a given country.
    - ISO develops International Standards, but is not involved in a company's certification, and does not issue certificates – This is performed by an external certification body.
  - ISO 13485 "Medical devices - Quality management systems - Requirements for regulatory purposes" published in March 2016
    - Overview of ISO 13485:2016
    - According to EmeISO 13485 is the most commonly chosen path to meet the Quality Management System (QMS) medical device requirements in Europe, Canada, and Australia, and serves as the basis for QMS compliance in other countries such as Japan, Korea, and Brazil.

- **European Union**
  - Medical Devices Directive (MDD) 93/42/EEC
  - New Medical Device Regulation (MDR) just released – compliance required within the next 3-5 years depending on product
    - European Commission Announcement shows transitional periods as:
      - Spring 2020: Medical devices
      - Spring 2022: In vitro diagnostic medical devices
- **Canada**
  - Canadian Medical Device Regulation (CMDR) - SOR 98/282
  - New Medical Device Single Audit Program (MDSAP) will be implemented by 2019
    - Please see Health Canada's Transition Plan to MDSAP.
  - ISO 13485:2016: Health Canada has set **March 1st 2019**, as the transition date to ISO 13485:2016.
    - All manufacturers of class II, III, and IV medical devices holding licenses or applying for new or amended licenses must complete the transition to ISO 13485:2016 by March 1st, 2019.

Domestic Trade Shows		
BIO	6/19/2017 - 6/22/2017	San Diego, CA
AACC Clinical Lab Expo	7/30/2017 - 8/3/2017	San Diego, CA
Florida International Medical Expo (FIME)	8/1/2017 - 8/3/2017	Miami, FL
Regulatory Affairs Professionals Society (RAPS)	9/11/2017 - 9/12/2017	Baltimore, MD
AdvaMed 2017	9/25/2017 - 9/27/2017	San Jose, CA
Health 2.0	10/1/2017 - 10/4/2017	Santa Clara, CA
World Medical Tourism and Global Healthcare Congress	10/2/2017 - 10/4/2017	Los Angeles, CA
Supply Side West	10/5/2017 - 10/6/2017	Las Vegas, NV
Greater New York Dental Meeting 2017	11/24/2017 - 11/29/2017	New York, NY
MD&M West	2/6/2018 – 2/8/2018	Anaheim, CA
Advanced Design & Manufacturing Cleveland	3/7/2018- 3/8/2018	Cleveland, OH
AORN-Surgical Conference & Expo	3/24/2018 – 3/28/2018	New Orleans, LA

International Trade Shows		
BIO Japan	10/11/2017 -10/13/2017	Yokohama, Japan
Healthcare Trade Mission to South Africa and Kenya	10/22/2017 - 10/27/2017	South Africa, Kenya, Ethiopia, Ghana, Mozambique
Medica 2017 Corporate Executive Office (CEO) program, B2B Matchmaking	11/13/2017 - 11/16/2017	Dusseldorf, Germany
Arab Health	1/29/2018 – 2/1/2018	Dubai, UAE
Medlab	2/5/2018 – 2/8/2018	Dubai, UAE
SALMED-International Trade Fair of Medical Equipment and Instruments	3/15/2018 – 3/17/2018	Poznan, Poland
Medtec Europe	4/24/2018 -4/26/2018	Stuttgart, Germany
TOS+H Expo-Turkish Occupational Safety + Health Exhibition	5/6/2018 – 5/9/2018	Istanbul, Turkey

***www.expodatabase.com**
***EMERGO Medical Device Industry Outlook 2016** from http://www.emergogroup.com/resources/research/outlook-medical-device-industry
***2016 Top Markets Report: Medical Devices** http://www.trade.gov/topmarkets/medical-devices.asp
***BMI Research: Industry Forecast – Annual Medical Device Exports – US – Q2 2017**
https://bmo.bmiresearch.com/article/view?article=1251872&advanced_search=1&matches=10000+&page=1&position=4&keyword=medical%20device%20%20US

Koreen Grube is the Medical Device Industry Focus Group leader for the U.S. Commercial Service Global Healthcare Team.

More information on the medical device market can also be found in our Top Market Report

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