abimed

Associação Brasileira da Indústria
de Alta Tecnologia de Equipamentos,
Produtos e Suprimentos Médico-Hospitalares

MEDICAL DEVICES INDUSTRY VIEW

1st Brazil-Japan Seminar on Pharmaceuticals and Medical Devices Regulations

São Paulo, August 2nd 2014

Agenda

- Overview Healthcare structure in Brazil
- Healthcare and Medical Devices Market
- Industrial policies in Brazil
- Main aspects of regulation

abimed

Associação Brasileira da Indústria
de Alta Tecnologia de Equipamentos,
Produtos e Suprimentos Médico-Hospitalares

Healthcare Structure

- **Brazilian Constitution states:** *“Access to healthcare is a right of the citizen and a duty of the State”* (Art. 196). Additionally: *“Health assistance is open to private enterprise”* (Art. 199)

- **Ministry of Health is responsible for the execution of health policy. Under the Ministry of Health are, among others:**
  - ANVISA - National Health Surveillance Agency ➔ independent; power to regulate and control
  - SCTIE – Secretariat of Science, Technology and Strategic Materials
  - SAS – Secretariat of Healthcare Assistance
  - ANS – National Agency of Supplemental Healthcare - regulates the private sector – HMOs (Health Medical Organizations)
  - CONITEC – National Commission for implementing new technologies at SUS

Brazilian Healthcare Figures

- 6,831 hospitals (70 % private, 21% munic., 8% state, 1% fed.)
- 506,336 hospital beds
- 272,422 healthcare services
- 20,020 laboratories
- 421,384 physicians
- 2,58 million other healthcare professionals
- 220,000 dentists
- 70,000 drugstores

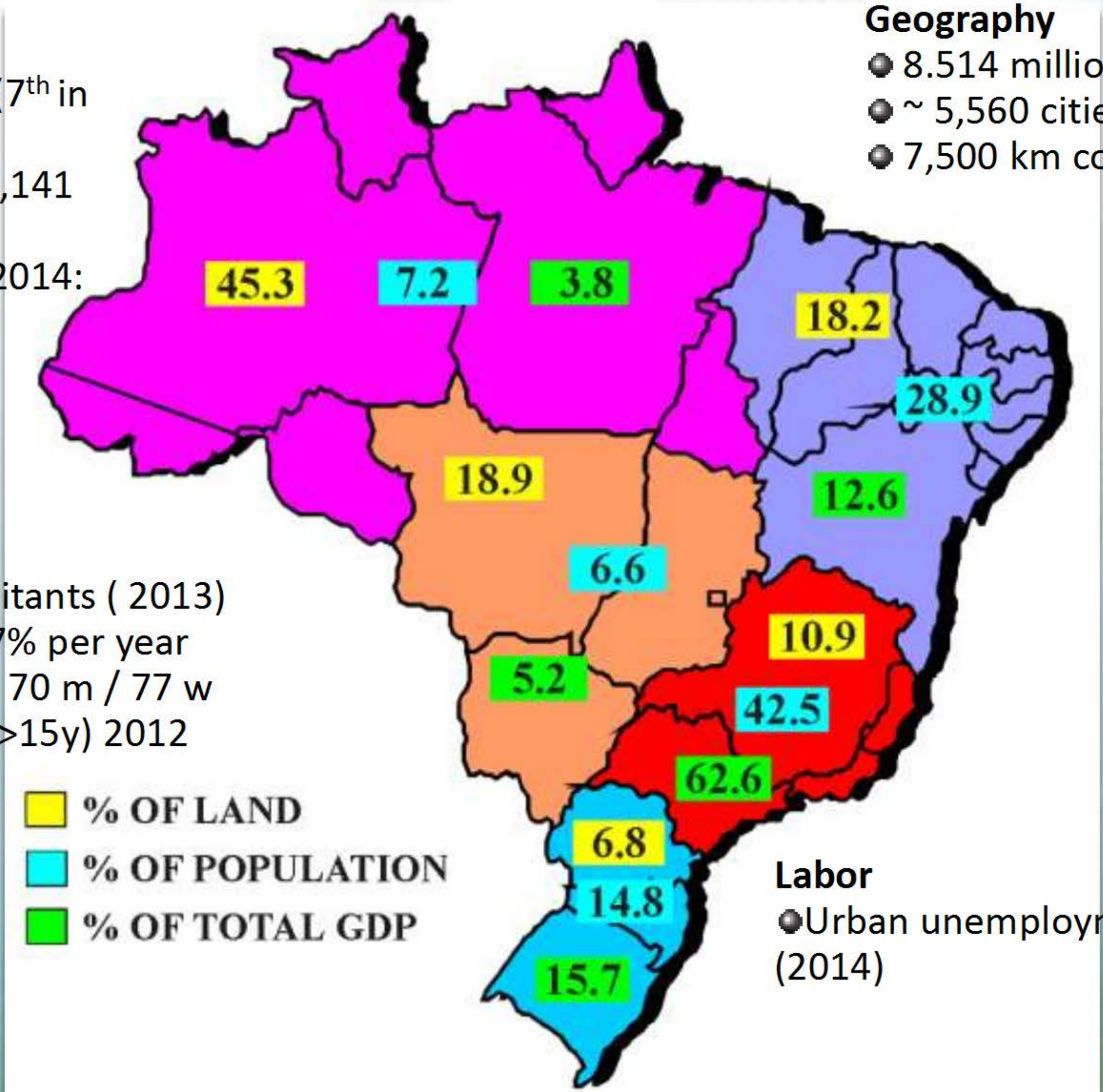
Sources: CNES, Jul 2014

A Country of Contrasts

Economy
- GDP 2013: US$ 2.240 Trillion (7th in the world)
- GDP per capita (2013): US$11,141
- Inflation rate (2013): 5.91%
- SELIC -Basic interest rate Jul. 2014: 11.00%
- GDP growth (2013): 2.3%
- GDP growth exp 2014: 1.8%

Geography
- 8.514 million km^2
- ~ 5,560 cities
- 7,500 km coastline

Population
- 201.3 mil. inhabitants (2013)
- Growth rate: 1,7% per year
- Life expectancy: 70 m / 77 w
- Illiteracy: 8.7% (>15y) 2012



Labor
- Urban unemployment: 7,1% (2014)

Sources: IBGE, BC, Copom

Healthcare and Medical Devices Market

abimed

Associação Brasileira da Indústria
de Alta Tecnologia de Equipamentos,
Produtos e Suprimentos Médico-Hospitalares

Healthcare Expenditures

Healthcare expenditures worldwide
10.4% of global GNP:US$ 7 tri. (2010)

- *59.2% covered by public services*
- *40.8%, covered by private services*

Brazilian Healthcare expenditures
9% of GNP : R$ 339 bi. (2010)
(8th largest in the world)

- *47% covered by public services*
- *53% covered by private services*

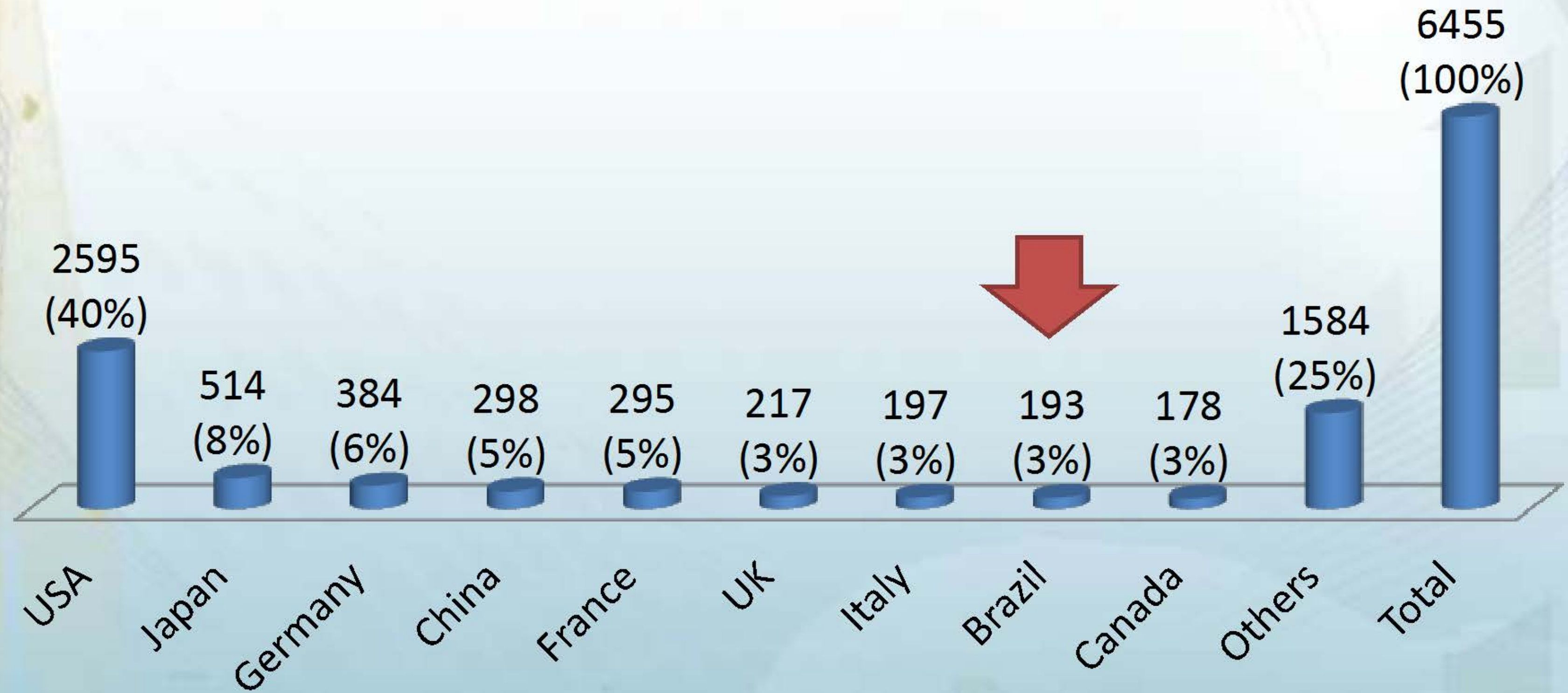
Source: WHO

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Healthcare Expenses (2010)

Billions of USD



Source: WHO

Healthcare expenditures distribution

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

- **Total Expenditure on Health (9% of GDP)[1]**
  R$ 396.7 bi
  - **Public Health (47%)[1]**
    R$ 186.5 bi
    R$ 961 per capita
    - **Federal (47,8%)[2]**
      R$ 89.2 bi
    - **State (21,4%)[2]**
      R$ 39.9 bi
    - **Municipal (30,8%)[2]**
      R$ 57.4 bi
  - **Private Health (53%)[1]**
    R$ 210.2 bi
    R$ 1,083 per capita
    - **Supplementary Healthcare (Income)[3]**
      R$ 90.5 bi
    - **Out-of-Pocket Expenditures with Healthcare and Drugs**
      R$ 119.7 bi

[1] World Health Organization
[2] IBGE (2009)
[3] ANS (Oct/2011 to Sep/2012)

Medical Devices Market

Total market: US$ 1 tri

- ***US$ 670 bi - Pharma***
- ***US$ 9 bi - Vaccines***
- ***US$ 25 bi - IVD – Invitro Diagnosis***
- ***US$ 300 bi – MD - Medical Devices (Brazil: U$ 11bi)***

Source:WHO

Opportunities & Challenges

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

- Opportunities
  - Dynamic and growing internal market
  - Demography bonus
  - Rise of a new middle class
  - Pursuit of healthcare and life quality
- Challenges
  - High tax burden
  - Deficient infrastructure and logistics
  - Lack of qualified labor
  - Increase of health costs

Brazilian MD market
(2013)

- 13 K companies (majority small companies)
- 130 K employees
- Market: US$ 11 bill.
- Taxes generated by MD: US$2,4 bi
- Import: US$ 4.5 bi
- Export: US$ 700 mil
- Local production: US$2.4bi

Source: WebSetorial

abimed
Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Medical Devices Export

- **Main products**
  - Odonthology: chairs, dental implants, consummables
  - Neonatal incubators
  - Catheters, suture needles
  - Orthopaedic implants and articles
  - Radiology
- **Main destinations**
  - USA
  - Argentina
  - Mexico
  - Colombia
  - Venezuela
  - Chile
  - Belgium
  - Germany
  - Spain
  - Paraguay

Industrial Policies in Brazil

Brazilian Industrial Policies

"Brasil Maior" Plan

Innovate to compete . Compete to grow

- Foster local innovation and technological development
- Create and strengthen critical competences of Brazilian economy
- Increase internal and external markets for Brazilian companies
- Assure a socially-including and environmental sustainable growth

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Brazilian Policies

- Foster local production and reduce the external dependence on Medical Devices
- Prioritize the clinical and pre-clinical research in the country
- Promote international cooperation for technology transfer
- Strengthen structure for R&D and innovation
- Use the purchasing power of government for strategic products for NHS
- Preference for domestic products and services in federal public tenders

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Brazilian Industrial Policies

Fostering the industrial policy

- Ministerial policies
  - PPB – Basic Productive Process
  - PDP – Partnership for Productive Development (Ord. 837/2012) – technology transfer x governmental procurement 5 years
  - Offset model – e.g.: Linear accelerators for radiotherapy
- Interface management among "Brasil Maior" Pan, GECIS and Sanitary Surveillance
  - Agreement 13/2013: ANVISA / MoH / MDIC –
- INOVA Saúde Plan – Focus on innovation
  - Funding by FINEP, BNDES & MoH
- Preference to locally manufactured products and services
  - Law 12.349/2010 – Decree 7767/2012 for MD

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Health Technology Assessment & Policy Reimbursement Criteria

- Law 12.401/2011
  - Changes rules for therapeutical assistance and technology incorporation at SUS
  - Defines CONITEC as responsible for evaluating the technologies
  - Establishes 180 days as max. period for evaluation
  - Regulated by decree 7724/2012 and Ordinance 748/2012
- Alignment with government policies
  - Prioritizes strategic products


Main aspects of
regulation

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Medical Devices Industry

- Medical technologies will continue to evolve rapidly
- Top 20 companies invest (average) 8% in R&D
- Rapid product obsolescence (differently from drugs)
- Short product lifecycle
- Importance of having well trained professionals
- Importance of having a competitive environment, enabling the access of population to new technologies

abimed
Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Medical Devices Lifecycle

Conception and development → Manufacture → Packaging

← MANUFACTURER →

PRE-MARKET CONTROL

Close cooperation is needed with the manufacturer/importer of the product.

Important activities include:

- Collaboration on acceptance criteria;
- Collaboration on international quality systems and product-specific standards;
- Agreement on systems for conformity assessments;
- Clinical trials/testing;
- Appropriate and effective customs control system on imported medical devices.

Advertising → Sale

← VENDOR →

SALES MONITORING

A national database on vendors and products is essential for effective control of medical devices.

Important activities include:

- Vendor registration;
- Product registration;
- Prohibition of fraudulent/misleading advertising;
- After sales obligations, including:
  - ✓ distribution records;
  - ✓ complaint handling;
  - ✓ problem reporting;
  - ✓ recall procedures.

Use → Disposal

← USER →

POST-MARKET SURVEILLANCE

Correct use is the ultimate determinant of safety and effectiveness.

Important activities include:

- Training of user before use;
- Regular maintenance of devices in accordance with operation and service manuals;
- User networks and medical device vigilance systems to facilitate alert notification;
- Adequate management and disposal of discarded devices.

Source: WHO *(40)*.

Activities of the regulated sector

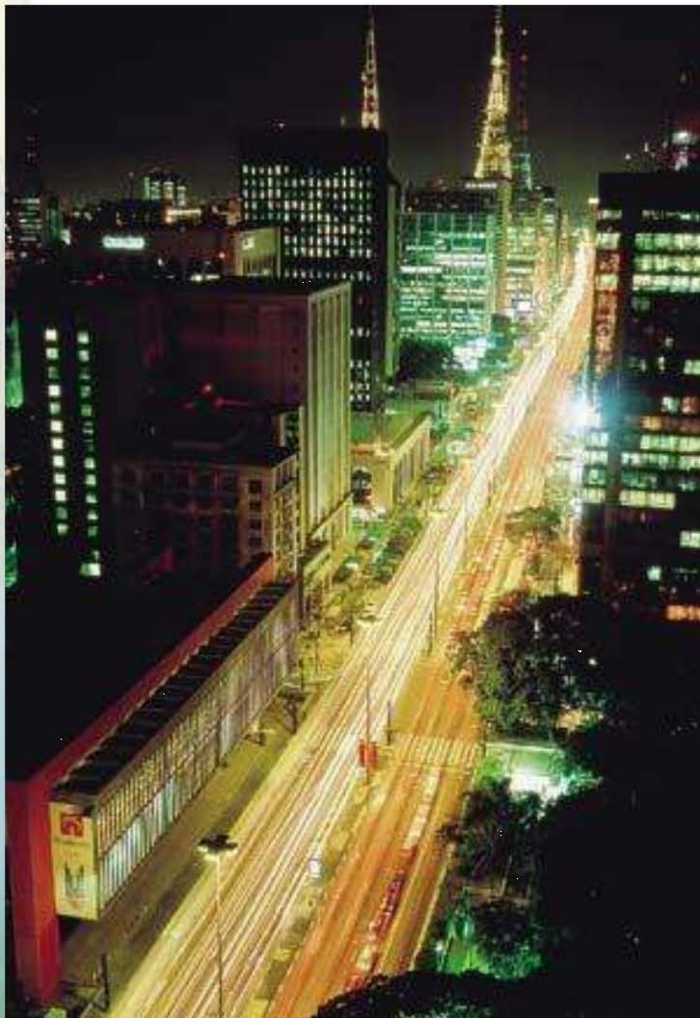
- **Contribute at political level**
  - Show the value our industry brings to the country
  - Enable universal access to new technologies
  - Alignment with government policies
- **Strengthen relationship with Ministries**
  - Participate in industrial policies discussions (Health Industry Complex)
  - Cooperation with Conitec (rational incorporation of technologies)
- **Close collaboration with Anvisa**
  - E.g.: Agenda, IMDRF, Regulatory impact analysis
- **Increase market intelligence**
- **Importance of predictability and legal security**
- **Promote Ethics and foster compliance implementation**
- **Articulate actions along healthcare chain**
- **Promote and expand training**


Abimed

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Brazilian Association of High Technology Industry for Medical Equipment, Products and Supplies



- Founded on June 18th, 1996
- Non-profit, non-governmental organization
- 170 active members
- Member of GMTA, DITTA, ALDIMED
- Focus on innovation as a tool for access to healthcare and economic development of the Country
- Support to create an ethical environment to foster competitiveness and industry growth
- Close cooperation with Regulators and Government to support Brazilian industrial policies
- Cooperation with medical societies and peer associations as well
- Training and fostering the education in the sector

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

THANK YOU

Carlos Alberto P. Goulart

carlos.goulart@abimed.org.br

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

- BACKUP

Abimed's Regular Activities

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

- **Internal Chambers** (e.g. Audiology, Imaging, Cardiovascular, Orthopaedics, Ophthalmology, Surgery)
- **Main Permanent Groups** (Legal, Regulatory Intelligence, HTA, Ethics, Advocacy, Solid Waste)
- **Ad Hoc Groups** (dependent on Anvisa's agenda)
- **Outsourced services and consultants** (Market Data:Websetorial, Official:Stahl, Press:Duplo Z, Legal: CSA,)
- **Interaction with international Associations** (e.g.:Advamed, GMTA, DITTA, Aldimed)
- **Periodical Meetings with Government/Regulatory Authorities**
- **Training and seminars to members**
- **Participation at Hospitalar & others**

abimed

Associação Brasileira da Indústria de Alta Tecnologia de Equipamentos, Produtos e Suprimentos Médico-Hospitalares

Global Market of MD

WW Medtech Sales by EvaluateMedTech™ Device Area (2012/18): Top 15 Categories & Total Market

		WW Sales ($bn)		CAGR	WW Market Share			Rank
	Device Area	2012	2018	% Growth	2012	2018	Chg. (+/-)	Chg. (+/-)
1	In Vitro Diagnostics (IVD)	43.6	58.8	+5.1%	12.5%	12.9%	+0.4pp	-
2	Cardiology	38.1	48.7	+4.2%	10.9%	10.7%	-0.2pp	-
3	Diagnostic Imaging	36.1	45.1	+3.8%	10.3%	9.9%	-0.4pp	-
4	Orthopedics	32.7	40.0	+3.4%	9.4%	8.8%	-0.6pp	-
5	Ophthalmics	23.6	32.9	+5.7%	6.8%	7.2%	+0.5pp	-
6	Endoscopy	17.7	24.2	+5.3%	5.1%	5.3%	+0.2pp	-
7	Drug Delivery	17.7	22.0	+3.7%	5.1%	4.8%	-0.2pp	-
8	General & Plastic Surgery	13.4	18.4	+5.4%	3.8%	4.0%	+0.2pp	-
9	Dental	12.6	16.5	+4.6%	3.6%	3.6%	+0.0pp	-
10	Wound Management	11.9	14.7	+3.5%	3.4%	3.2%	-0.2pp	-
11	Diabetic Care	11.8	14.4	+3.4%	3.4%	3.2%	-0.2pp	-
12	Nephrology	10.9	13.9	+4.1%	3.1%	3.0%	-0.1pp	-
13	Ear, Nose & Throat (ENT)	6.6	9.5	+6.2%	1.9%	2.1%	+0.2pp	-
14	Anesthesia & Respiratory	6.1	8.5	+5.6%	1.7%	1.9%	+0.1pp	+1
15	Neurology	5.3	8.0	+6.9%	1.5%	1.8%	+0.2pp	+2
	Top 15	288.2	375.6	+4.5%	82.6%	82.6%	+0.0pp	
	Other	60.8	79.1	+4.5%	17.4%	17.4%	-0.0pp	
	Total WW MedTech Sales	349.0	454.6	+4.5%	100.0%	100.0%		

Source: EvaluateMedTech™ (23 SEP 2013)

abimed

Associação Brasileira da Indústria
de Alta Tecnologia de Equipamentos,
Produtos e Suprimentos Médico-Hospitalares

Global Market of MD

WW Medtech Sales by EvaluateMedTech™ Device Area (2012/18): Top 15 Categories & Total Market

	Device Area	WW Sales ($bn) 2012	WW Sales ($bn) 2018	CAGR % Growth	WW Market Share 2012	WW Market Share 2018	Chg. (+/-)	Rank Chg. (+/-)
1	In Vitro Diagnostics (IVD)	43.6	58.8	+5.1%	12.5%	12.9%	+0.4pp	-
2	Cardiology	38.1	48.7	+4.2%	10.9%	10.7%	-0.2pp	-
3	Diagnostic Imaging	36.1	45.1	+3.8%	10.3%	9.9%	-0.4pp	-
4	Orthopedics	32.7	40.0	+3.4%	9.4%	8.8%	-0.6pp	-
5	Ophthalmics	23.6	32.9	+5.7%	6.8%	7.2%	+0.5pp	-
6	Endoscopy	17.7	24.2	+5.3%	5.1%	5.3%	+0.2pp	-
7	Drug Delivery	17.7	22.0	+3.7%	5.1%	4.8%	-0.2pp	-
8	General & Plastic Surgery	13.4	18.4	+5.4%	3.8%	4.0%	+0.2pp	-
9	Dental	12.6	16.5	+4.6%	3.6%	3.6%	+0.0pp	-
10	Wound Management	11.9	14.7	+3.5%	3.4%	3.2%	-0.2pp	-
11	Diabetic Care	11.8	14.4	+3.4%	3.4%	3.2%	-0.2pp	-
12	Nephrology	10.9	13.9	+4.1%	3.1%	3.0%	-0.1pp	-
13	Ear, Nose & Throat (ENT)	6.6	9.5	+6.2%	1.9%	2.1%	+0.2pp	-
14	Anesthesia & Respiratory	6.1	8.5	+5.6%	1.7%	1.9%	+0.1pp	+1
15	Neurology	5.3	8.0	+6.9%	1.5%	1.8%	+0.2pp	+2
	Top 15	288.2	375.6	+4.5%	82.6%	82.6%	+0.0pp	
	Other	60.8	79.1	+4.5%	17.4%	17.4%	-0.0pp	
	Total WW MedTech Sales	349.0	454.6	+4.5%	100.0%	100.0%		

Source: EvaluateMedTech™ (23 SEP 2013)