Korea Medical Devices Industry Association
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</tbody>
</table>
Established in 1999, KMDIA is the largest trade association representing 839 member companies including domestic and international manufacturers, importers, exporters and consultants of medical devices. Our member companies supply more than 80% of the medical devices market in Korea.

Also, our association advocates the rights of the medical devices corporations and commits to promoting access to the latest technologies as well as high-quality and reasonable medical devices from overseas, in order to improve public health and boost growth of the medical devices industry.

KMDIA makes an effort to be a valuable partner of the medical devices industry and leads technological advances in the 21st century, helping the members to be strong in the global competition.

The Korea Medical Devices Industry Association (KMDIA) has been contributing to improving the quality of life and the public health by developing new technologies and high-quality medical devices since its foundation in 1999.

The government announced a long-term plan to become the world’s top seven medical device powers by 2020 and committed to strengthening the medical devices industry as the future growth source. The KMDIA has been actively leading to support these government’s efforts and represent our membership’s rights and interests as a representative organization.

The KMDIA makes efforts to propose various measures to improve membership’s global competitiveness and increase opportunities to show advanced medical devices including reasonable quality goods.

We will become a trustworthy partner with the government, industry and healthcare organizations by helping institutional improvement of medical devices market. And we will keep on trying our best to develop Korean medical device industry through various activities such as building global networks and promoting interchanges among members.

Chairman’s message

Chairman Lee Kyung Kook
Vision

Renowned Medical Devices Association with Leading Global Competitiveness

Mission

Development of MD Industry  Enhancement of Healthcare Technology  Growth of MD Market

Strategy

01. Establishing fundamental infrastructure for the growth of MD industry
02. Formulating regulator framework for the MD industry
03. Forming a cooperative network within MD industry
04. Facilitating high-valued MD industry and supporting export of MD
05. Establishing a fair trade environment in supply of MD
06. Promoting global cooperation and regulatory harmonization

*MD : Medical Device

History

2017.05.12
MoU Signing with JFMDA

2016.07.12
Establishing MD Industry Awards

2015.02.05
Designated as an execution organization for international medical devices exhibitions

2014.04.10
Designated as a partner organization of Consortium for Human Resources Development Ability Magnified Program(CHAMP)

2014.03.21
Launching KMDIA Newsline(online)

2009-2013

2009.11.17
MoU Signing with EucoMed

2009.10.14
MoU Signing with AdvaMed

2002.03.14
Commissioned as confirmation of import requirements

2002.03.26
Commissioned as an organization of Statistic reports of Korean MD market

2002.03.14
Co-hosting KIMES

2001.11.29
Changing the name to Korea Medical Devices Industry Association

1999-2003

1999.11.10
Commissioned as confirmation of import requirements

1999.07.08
Establishing Korea Medical Devices Association

1999.02.26
Designated as pre-review organization for MD advertisements

2005.01.01
Launching KMDIA newspaper

2005.07.18
Designated as GMP education center

2004-2008

2004.03.26
Commissioned as an organization of Statistic reports of Korean MD market

2002.03.14
Co-hosting KIMES

2001.11.29
Changing the name to Korea Medical Devices Industry Association

1999.11.10
Commissioned as confirmation of import requirements

1999.07.08
Establishing Korea Medical Devices association

2002-2008

2002.03.14
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1999.07.08
Establishing Korea Medical Devices association

1999.01.01
Commissioned as confirmation of import requirements

1999.07.08
Establishing Korea Medical Devices association

1999.01.01
Commissioned as confirmation of import requirements

1999.07.08
Establishing Korea Medical Devices association
Current state of KMDIA

Total 839

- Manufacturers: 346
- Special members: 2
- Others (Sale/Repair/Consulting): 146
- Importers: 345

Membership’s proportion in Korean Market

- The Amount of Production: USD 2,572 million (2,985 billion won)
- The Amount of Export: USD 1,598 million (1,855 billion won)
- The Amount of Import: USD 2,693 million (3,125 billion won)

Organization

- General Assembly
- Chairman
- Vice Chairman
- Executive Director
- Advisor

- Legal committee
- Reimbursement committee
- Fair Trade Code committee
- Ethics Compliance committee
- Public Relations committee
- International affairs committee
- N/O committee
- Industry Development committee
- Education committee
- Membership committee
- Management Support Department
- Membership Support Department
- Legal & Healthcare Affairs Department
- Government Cooperation Department
- Industry Policy Research Department

- Industry Development Management Team
- Planning & Management Team
- Membership Management Team
- Regulatory System Management Team
- Corporate Complaints Report Center
- Reimbursement Policy Team
- Reimbursement Policy Team
- Advertisement Preview Team
- False AD Monitor
- Fair Trade Management Team
- Fair Trade Code Report Center
01 Membership Support

- Understanding on membership difficulties
  - Making support programs for member benefits
  - Working on appropriate countermeasures related to the current issues

- Training programs for MD human resources
  - Fostering professional MD manpower through practical education programs
  - Complimentary education by CHAMP (Government support business)
  - CHAMP: Consortium for Human Resources Development Ability Magnifies Program

- Networking with overseas MD associations
  - Holding domestic (KIMES) and international exhibitions (Korean Pavilion)
  - Mutual networks with GMITA, APACMED etc., and support for IMDRF activities

- Finding corporations’ complaints and proposing improvements to the government

02 Regulations & Reimbursement Policy Support

- Proposing improved regulations for membership
  - Supporting consultative groups to improve regulatory system
  - Finding corporations’ complaints and proposing improvements to the government

- Gathering industries’ opinions about legislative/administrative guidelines
  - Suggesting revised proposals by reflecting field opinions

- Gathering and distributing major MD-related issues and industrial support information
  - Holding policy forum, workshop and panel discussion
  - With government officials
  - Delivering opinions and proposing alternatives through CEO meeting

03 PR, Media support

- Introducing the activities of KMDIA and member companies
- Communicating industry’s perspectives on major healthcare issues to the news
- Publishing KMDIA newspaper and Newsline (online)

- Issuing press releases and on-offline newspapers
- Initiative activities (e.g., Press conference)
- Free distribution of 5,200 copies monthly
- Newsletter and mobile newspaper service

04 Industry Policy Research

- Strengthening competitiveness of MD industry
  - Data analysis on statistic reports of Korean MD market
  - Publication of an yearbook of MD industry’s statistics

- Proposing new policies throughout research and networking
  - Performing research project for the development of MD industry
  - Supporting for interconnected networks between domestic and global companies

- Supporting R&D of the cutting-edge MD
  - Operating the 4th Industrial Revolution Medical Devices Special Committee
  - Holding Medical Devices Industry Awards
  - Protecting the Intellectual Property Rights
### 05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review

**Statistic report of Korean MD market**
- Gathering the statistic data on production, exports, imports and repairs of Korean MD market

**Import approval of requirement exemption**
- Verifying import of MD exempt from requirements

**Medical Devices Advertisement pre-review**
- Preventing customers’ damages caused by false and exaggerated advertisements and providing the information for appropriate use

### 06 Ethics, Public Service Support

**Improving distribution environment of MD**
- Enacting and conducting the ‘Fair Trade Code’ of medical device

**Strengthening MD management ethics**
- Providing and institutional framework for the fair distribution environment
- Providing ‘Fair Pay Med’ system

**Promoting social contribution activities with membership**
- Free health examination service for the vulnerable

**Conducting a campaign for safe use of MD**
- Distributing the safety usage of life-friendly medical devices

### 07 General affairs, Budget, HRM

1. **Support and management of the overall operation**
   - General affairs, Accounting, Computerizing and Human Resources management

2. **Support of the board of directors and general meeting**
   - Holding the board of directors and general meeting
   - Follow-up on decisions

3. **Enactment and amendment of the articles of association**
   - Enactment and revision of internal guidance
Activities of Committee

**Legal Committee**
- Improving regulatory system of MD
- Proposing improved regulations for membership
- Promotion of MD industry environment

**Reimbursement Committee**
- Proposal of improved reimbursement regulations
- Development of health policy for industry
- Research and analysis of reimbursement policy

**Ethics Compliance Committee**
- Improving fair distribution environment
- Disputing over conflicts within industry
- Discussion over Fair Trade Code and specific standards

**In Vitro Diagnostics (IVD) Committee**
- Proposal of improved IVD regulations
- Research and analysis of reimbursement policy for IVD
- Improvement of new health technology assessment

**Industry Development Committee**
- Business support of venture and start-up
- Cooperation with competitive corporations for global market
- Commercialization of MD connected to technical R&D business
- DB building about domestic MD technologies

**Public Relations Committee**
- Introduction of new laws and regulations of MD
- Improvement of MD environment
- Introduction of the activities of KMDIA & member companies

**Education Committee**
- Fostering human resource through training programs
- Development and review for new education programs
- Consulting on improved educational programs

**Membership Committee**
- Making a plan to expand member companies
- Understanding on membership’s difficulties
- Developing new support programs for membership

**International Affairs Committee**
- Research & Analysis for overseas MD market
- MoU signing with international organizations
- Information sharing on global MD market
- Networking with foreign embassy

**4th Industrial Revolution Medical Device Special Committee**
- Building an environment for 4th Industrial Revolution in MD market
- Policy proposal for 4th industrial revolution
- Preparing regulations for industry 4.0
Key Activities

Standard Customs Clearance Schedule Report

- Accepting Standard Customs Clearance Schedule Report
- Reviewing Standard Customs Clearance Schedule Report
- Notifying Approval/Errors
- Approval Report
- Transmission to Korea Customs Service and Importers

1. Reviewing Import licensing / approval certificate
2. [Reinforcement standards] Below listed import items to be strictly reviewed (Ex)
   - BSE (bovine spongiform encephalopathy) related products
   - Breast pump
   - Mercury medical device (except for dental) or asbestos-contained products
   - Alloy, base metal

Fair Trade Code Review

- Academic society
  - Donation
  - Holding symposium

- Review Committee

- Businesses
  - Donation assistance
  - Support for symposium
  - Product presentation, education training
  - Advertising
  - Consultation

- Matters without Review
  - Charity donation
  - Product presentation (One day/No accommodation)
  - Advertising
  - Consultation
Our association has jointly owned and organized KIMES (Korea International Medical & Hospital Equipment Exhibition) with domestic agency. Our largest exhibition provides better opportunities to improve relationship among all related parties including researchers and industries. And it has been recognized as a global top exhibition (by the government) and risen as a representative one for stressing global competitiveness of Korean medical devices’ market.

Moreover, we are in charge of several overseas exhibitions affairs including U.S.A, Japan and Iran, supported by government funds. And we have made efforts to support Korean corporations successfully by holding various seminars and finding new exhibitions from all over the world.
Key Statistics

Overview of Korean Medical Devices Market

<table>
<thead>
<tr>
<th>Classification</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market scale</td>
<td>4,229</td>
<td>4,766</td>
<td>4,653</td>
<td>5,060</td>
<td>5,481</td>
</tr>
<tr>
<td>Production</td>
<td>3,857</td>
<td>4,372</td>
<td>4,420</td>
<td>4,828</td>
<td>5,149</td>
</tr>
<tr>
<td>Export</td>
<td>2,357</td>
<td>2,577</td>
<td>2,711</td>
<td>2,918</td>
<td>3,164</td>
</tr>
<tr>
<td>Import</td>
<td>2,729</td>
<td>2,971</td>
<td>2,944</td>
<td>3,151</td>
<td>3,495</td>
</tr>
</tbody>
</table>

Source: Medical Devices Production, Export and Import Annual Report, KMDIA
World Medical Market Forecasts for 2020, BMI Episcom

Top 10 Production Items in 2017

<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>amount</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Implant Fixture (endosseous)</td>
<td>569.7</td>
<td>11.07</td>
</tr>
<tr>
<td>2</td>
<td>Ultrasound Imaging System</td>
<td>437.8</td>
<td>8.5</td>
</tr>
<tr>
<td>3</td>
<td>Implant Superstructure</td>
<td>216.2</td>
<td>4.2</td>
</tr>
<tr>
<td>4</td>
<td>Biomaterial graft /prosthesis</td>
<td>182.6</td>
<td>3.5</td>
</tr>
<tr>
<td>5</td>
<td>Soft Contact Lens (daily-wear)</td>
<td>168.5</td>
<td>3.2</td>
</tr>
<tr>
<td>6</td>
<td>Medical Image (digital transform)</td>
<td>119.8</td>
<td>2.3</td>
</tr>
<tr>
<td>7</td>
<td>Implant Hand Instrument</td>
<td>101.2</td>
<td>1.97</td>
</tr>
<tr>
<td>8</td>
<td>Sight Corrective Ophthalmics</td>
<td>79.5</td>
<td>1.5</td>
</tr>
<tr>
<td>9</td>
<td>IVD Reagents for self testing II</td>
<td>73.5</td>
<td>1.4</td>
</tr>
<tr>
<td>10</td>
<td>Heating Pad System</td>
<td>70.3</td>
<td>1.3</td>
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</table>

Top 10 Export Items in 2017

<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>amount</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ultrasound Imaging System</td>
<td>551.4</td>
<td>17.4</td>
</tr>
<tr>
<td>2</td>
<td>Biomaterial graft /prosthesis</td>
<td>188.1</td>
<td>5.9</td>
</tr>
<tr>
<td>3</td>
<td>Soft Contact Lens (daily-wear)</td>
<td>152.6</td>
<td>4.8</td>
</tr>
<tr>
<td>4</td>
<td>Implant Fixture (endosseous)</td>
<td>140.1</td>
<td>4.4</td>
</tr>
<tr>
<td>5</td>
<td>IVD Reagents for self testing II</td>
<td>132.8</td>
<td>4.2</td>
</tr>
<tr>
<td>6</td>
<td>Medical Image (digital transform)</td>
<td>97.5</td>
<td>3.1</td>
</tr>
<tr>
<td>7</td>
<td>IVD Reagents for infectious disease marker</td>
<td>85.9</td>
<td>2.7</td>
</tr>
<tr>
<td>8</td>
<td>Dental X-ray system</td>
<td>75.0</td>
<td>2.4</td>
</tr>
<tr>
<td>9</td>
<td>Heating Pad System</td>
<td>71.3</td>
<td>2.2</td>
</tr>
<tr>
<td>10</td>
<td>Implant Superstructure</td>
<td>62.5</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Top 10 Import Items in 2017

<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>amount</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Soft Contact Lens (daily-wear)</td>
<td>120.3</td>
<td>3.4</td>
</tr>
<tr>
<td>2</td>
<td>Coronary Artery Stent</td>
<td>95.5</td>
<td>2.7</td>
</tr>
<tr>
<td>3</td>
<td>Disposable Dialyser</td>
<td>85.4</td>
<td>2.4</td>
</tr>
<tr>
<td>4</td>
<td>IVD Reagents for clinical Immunochemistry</td>
<td>66.9</td>
<td>1.9</td>
</tr>
<tr>
<td>5</td>
<td>Knee Prosthesis</td>
<td>65.0</td>
<td>1.8</td>
</tr>
<tr>
<td>6</td>
<td>MRI system</td>
<td>63.6</td>
<td>1.8</td>
</tr>
<tr>
<td>7</td>
<td>CT system</td>
<td>55.3</td>
<td>1.5</td>
</tr>
<tr>
<td>8</td>
<td>Sight Corrective ophthalmics</td>
<td>49.9</td>
<td>1.4</td>
</tr>
<tr>
<td>9</td>
<td>Heating Pad System</td>
<td>40.0</td>
<td>1.1</td>
</tr>
<tr>
<td>10</td>
<td>Implant Superstructure</td>
<td>35.8</td>
<td>1.0</td>
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</tbody>
</table>
## Top 10 Export Countries

<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>Amount</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>U. S. A</td>
<td>512.0</td>
<td>16.18</td>
</tr>
<tr>
<td>2</td>
<td>China</td>
<td>508.5</td>
<td>16.07</td>
</tr>
<tr>
<td>3</td>
<td>Germany</td>
<td>237.7</td>
<td>7.52</td>
</tr>
<tr>
<td>4</td>
<td>Japan</td>
<td>197.9</td>
<td>6.25</td>
</tr>
<tr>
<td>5</td>
<td>India</td>
<td>127.1</td>
<td>4.02</td>
</tr>
<tr>
<td>6</td>
<td>Russia</td>
<td>124.0</td>
<td>3.92</td>
</tr>
<tr>
<td>7</td>
<td>Vietnam</td>
<td>71.7</td>
<td>2.27</td>
</tr>
<tr>
<td>8</td>
<td>Brazil</td>
<td>71.0</td>
<td>2.25</td>
</tr>
<tr>
<td>9</td>
<td>Italy</td>
<td>64.2</td>
<td>2.03</td>
</tr>
<tr>
<td>10</td>
<td>Thailand</td>
<td>62.2</td>
<td>1.97</td>
</tr>
</tbody>
</table>

## Top 10 Import Countries

<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>Amount</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>U. S. A</td>
<td>1,641.1</td>
<td>46.95</td>
</tr>
<tr>
<td>2</td>
<td>Germany</td>
<td>548.6</td>
<td>15.69</td>
</tr>
<tr>
<td>3</td>
<td>Japan</td>
<td>348.9</td>
<td>9.98</td>
</tr>
<tr>
<td>4</td>
<td>Switzerland</td>
<td>159.0</td>
<td>4.55</td>
</tr>
<tr>
<td>5</td>
<td>China</td>
<td>155.3</td>
<td>4.44</td>
</tr>
<tr>
<td>6</td>
<td>France</td>
<td>64.3</td>
<td>1.84</td>
</tr>
<tr>
<td>7</td>
<td>U.K.</td>
<td>62.5</td>
<td>1.79</td>
</tr>
<tr>
<td>8</td>
<td>Netherlands</td>
<td>49.5</td>
<td>1.42</td>
</tr>
<tr>
<td>9</td>
<td>Sweden</td>
<td>45.1</td>
<td>1.29</td>
</tr>
<tr>
<td>10</td>
<td>Italy</td>
<td>42.0</td>
<td>1.29</td>
</tr>
</tbody>
</table>

## Export Items by Continent
- **America**
  1. Ultrasound Imaging System
  2. Diagnostic Probe
  3. Medical Image(digital transform)
- **Europe**
  1. Ultrasound Imaging System
  2. Biomaterial Graft/Prosthesis
  3. Soft Contact Lens(daily-wear)
- **Africa**
  1. IVD reagents for Infectious Disease Marker
  2. IVD reagents for Diagnosis of HIV, HBV, HCV, HTLV
  3. Ultrasound Imaging System
- **Middle East**
  1. Ultrasound Imaging System
  2. Implant Fixture(endosseous)
  3. ND:YAG Surgical Laser
- **Asia-Pacific**
  1. Ultrasound Imaging System
  2. Biomaterial Graft/Prosthesis
  3. Soft Contact Lens(daily-wear)

## Import Items by Continent
- **America**
  1. Soft Contact Lens(daily-wear)
  2. Coronary Artery Stent
  3. Knee Prosthesis
- **Europe**
  1. Disposable Dialyser
  2. MRI System
  3. IVD reagents for Clinical Immunochemistry
- **Africa**
  1. Occlusive Hydrogel Dressing
  2. Class 2 Combination Stimulator
  3. Balloon Dilatation Angioplasty Catheter
- **Middle East**
  1. Visible light irradiator
  2. Medical gas system
  3. Laser surgical apparatus
- **Asia-Pacific**
  1. Sight Corrective Ophthalmic lens
  2. MRI System
  3. Stimulator, Electrical, Auditory Cochlear
Location

8, 9F Yeosam Bldg., 123 Teheran-ro, Yeoksam-dong, Gangnam-gu, Seoul, Korea (06133)
TEL: +82-2-596-7404 FAX: +82-2-596-7401
E-mail: kmdia@kmdia.or.kr

- 5 minutes from Gangnam station line No.2, Exit 12
- 5 minutes from Yeoksam station line No.2, Exit 4