Your Vision, Our Future
Korean Medical Device
With a 5% average annual growth rate, the Korean medical device market was valued at approximately US$ 5.8 billion in 2016, making it the 9th largest market in the world.

### Major Exports of Korean Medical Devices in 2016

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Top 10 Exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ultrasound Imaging System</td>
</tr>
<tr>
<td>2</td>
<td>Dental Implant</td>
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<tr>
<td>3</td>
<td>Soft Contact Lens</td>
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<tr>
<td>4</td>
<td>Biomaterial Graft/Prosthesis</td>
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<tr>
<td>5</td>
<td>Medical Image Processing System</td>
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<tr>
<td>6</td>
<td>IVD Reagents for Testing of the Immune System</td>
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<tr>
<td>7</td>
<td>Probe for Medical Use</td>
</tr>
<tr>
<td>8</td>
<td>IVD Reagents for Infectious Disease</td>
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<tr>
<td>9</td>
<td>Laser Surgical Unit</td>
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<tr>
<td>10</td>
<td>X-ray System</td>
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</tbody>
</table>
Based on ISO 14155 and due to expedited processing for clinical trials, diverse clinical researches are conducted in Korea.

There are a total of 153 clinical trial centers designated by Ministry of Food Drug Safety (MFDS), ensuring good clinical trial environments.
Korea comprehensively regulates medical devices with a well-organized legal system and clearly defined regulations.

MFDS has an efficient and well-balanced system to manage the total lifecycle of medical devices.
Strategic Operation based on Expertise & Efficacy

With a systematic organizational structure, MFDS is strategically operated for an effective medical device management.

MFDS works cooperatively with other third party organizations to increase efficiency and expertise.

Affiliated Organization

A legal entity established in 2012
- Supports and provides with information regarding clinical trials, standards, safety, training, etc.
- Issues Notification of Class I devices & Certification of Class II devices

Related Organizations designated by MFDS

- Test medical devices (16 Labs)
- Conduct QMS audit and issue certificates with MFDS (4 Institutions)
- Review technical documents on class II devices (7 Agencies)
- Hospitals designated by MFDS (153 Centers)
- Conduct clinical trials for medical devices
Predictable Approval System with Scientific Approach

Based on risk classification of medical devices, each classes of devices have different pathways for a marketing authorization.

For an easy access and better compliance of regulations, MFDS provides consultations and various guidelines for applicants.

MFDS also gains additional scientific understanding from a pool of external experts as needed, and invests on various R&D projects to increase expertise in review and approval processes.
Emphasis on Quality: QMS

- Korean QMS is harmonized with the international standard, ISO 13485.

QMS Audit Procedures for Medical Device

1. Application of QMS audit
2. Preparation of QMS audit
3. Receipt of application
   - Pre-review
   - Confirmation of third-party auditor and audit date
   - Notice for QMS audit schedule
4. Notifying to MFDS auditor about audit schedule
5. MFDS auditor
6. Audit
   - Conformity
   - Major-Nonconformity
   - Minor-Nonconformity
   - Correction
   - Incorrection
7. Issuing QMS certification
8. Correction request for identified deficiency
9. Notice to applicant for prohibition of distribution
Adverse Event Reporting

Medical device manufacturers, importers and distributors are required to report any adverse events and keep those records.

- Life-threatening adverse events should be reported within 7 days, with additional report to be submitted within 8 days after the initial report.
- Other non-life-threatening adverse events should be reported within 30 days.

Medical Device Adverse Event Reporting and Management System

- All of collected information regarding adverse event reports are being reviewed and analyzed to be used for field safety corrective actions.
MFDS has designated 52 implantable and life-supporting medical devices, which are subject to tracking for patient safety.

MFDS collects information about devices and patients from manufacturers and importers to regulate the safe use of those devices and prevent medical incidents.
Types of Recall

- **(Firm-initiated Recall)** Recall made voluntarily by the firm after the discovery of safety issues or product defects that may have potential health risk to patients.

- **(Government-initiated Recall)** Recall order made by Minister of MFDS when the product is determined to be defective or potentially harmful.

Procedure for Government-initiated Recall

<table>
<thead>
<tr>
<th>MFDS</th>
<th>Manufacturers/Importers</th>
<th>Distributors/User facility</th>
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</thead>
<tbody>
<tr>
<td>Product that is in violation of laws</td>
<td>Discontinuation of market distributions</td>
<td>Notification: temporary discontinuation of market distributions</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
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<tr>
<td>Assessment of the product</td>
<td></td>
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<tr>
<td>Order of recall</td>
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<tr>
<td>Public warning about the product</td>
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<tr>
<td></td>
<td>No</td>
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<tr>
<td></td>
<td>Review of submission</td>
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<tr>
<td></td>
<td>Submission of a recall strategy</td>
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<tr>
<td></td>
<td>Public notification about the Recall</td>
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<tr>
<td></td>
<td>Recall of product as planned</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>Approval of a proposed recall strategy</td>
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<td></td>
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<tr>
<td></td>
<td>Effectiveness Checks</td>
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<tr>
<td></td>
<td>Approval of termination of a recall</td>
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<td></td>
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<tr>
<td></td>
<td>Submission of final report</td>
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<tr>
<td></td>
<td>Termination of a recall</td>
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Sustainable Effort & Commitment for International Cooperation

Asian Harmonization Working Party (AHWP)

- MFDS, as a chair of AHWP, takes a leading role among 30 member economies from Asia, Middle East, South America and Africa.
- Publishes various AHWP guidelines for implementation in pre- and post-market management of medical devices.
- Provides Capacity Building workshops for low and middle income countries.

International Medical Device Regulators Forum (IMDRF)

- MFDS actively participates and cooperates with IMDRF working groups and the committee members.
- Member countries: EU, US, Canada, Japan, Australia, China, Russia, Brazil and Singapore

International Cooperation Activities

Collaboration with International Organizations

- ANVISA (Brazil)
- CFDA (China)
- DHMA (Denmark)
- MHLW (Japan)
- MoH (Equador)
- NADFC (Indonesia)
- NAMHP (France)
- MHRA (England)
- NDA (Uganda)
- MHLW (Japan)
- COFEPRIS (Mexico)
- HSA (Singapore)
- URPLW/MPB (Poland)

Bilateral Cooperation