Korea, Republic of

**Legal**

<table>
<thead>
<tr>
<th>Legal framework</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enforcement Regulations of the Medical Device Act, Ministerial Decree NO. 18 (1 Sept. 2010) <a href="http://www.mfds.go.kr/eng/eng/download.do?boardCode=16771&amp;boardSeq=66026&amp;fileSeq=5">link</a></td>
<td></td>
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<tr>
<td>Guidelines</td>
<td>N/A</td>
</tr>
</tbody>
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**National Regulatory Authority**

| National Regulatory Authority present | Yes |
| Name | Korean Food and Drug Administration (KFDA) [link](http://eng.kfda.go.kr/index.html) |
| Responsibilities of the NRA | Medical Device Safety Bureau  
- Management of Medical Devices Policies  
- Inspection for Import Approvals, Standards, Testing Methods, Safety and Efficacy [link](http://eng.kfda.go.kr/index.html) |

**Medical device definition**

| Medical device defined | Yes |
| Text | The term medical device means an instrument, machine, apparatus, material, or any other similar product specified in the following subparagraphs as one used, alone or in combination, for human beings or animals: provided, that drugs and quasi-drugs under the Pharmaceutical Affairs Act and the prosthetic limbs and aids among assistive devices for persons with disabilities under Article 65 of the Act on Welfare of Persons with Disabilities shall be excluded herefrom:  
1. A product used for the purpose of diagnosing, curing, alleviating, treating, or preventing a disease;  
2. A product used for the purpose of diagnosing, curing, alleviating, or correcting an injury or impairment;  
3. A product used for the purpose of testing, replacing, or transforming a structure or function;  
4. A product used for the control of conception.  
Medical Devices Act, Art. 2. |
| In vitro diagnostic medical device (IVD) defined | N/A |

**Medical device classification**

| Classification | Yes |
| Classification rules | N/A |
| Classification rules details | N/A |

**Essential principles**

| Essential principles | N/A |
| Details | N/A |

**Conformity assessment**

| Conformity assessment bodies | Yes |
| Details | The Minister of Food and Drug safety may examine facilities, and manufacturing and quality control systems.  
Medical Devices Act, Art. 28. |
| Pre-marketing / procedure | A person who intends to obtain manufacturing approval or manufacturing certification, or file a manufacturing notification, or a person who intends to conduct a clinical test may request the Minister of Food and Drug Safety to preliminarily examine materials necessary for the manufacturing approval, manufacturing certification, manufacturing notification, or approval of such test. Medical Devices Act, Art. 11 |

**Reliance**

| Reliance | N/A |
| Details | N/A |
| Jurisdictions | N/A |

**Clinical investigation**

| Clinical investigation controls | Yes |
| Details | A person who intends to conduct a clinical test using a medical device shall prepare a clinical test plan and obtain approval thereof from the Minister of Food and Drug Safety, and the same shall also apply to any revision to the clinical test plan. Medical Devices Act, Art. 10. |
Registration and listing
Registration of establishment: Yes
Details: A person who intends to engage in the business of manufacturing medical devices shall obtain a manufacturing business approval from the Minister of Food and Drug Safety. Medical Devices Act, Art. 6.
A person who intends to distribute and lease medical devices shall file a report on his/her business. Medical Devices Act, Art. 17.
Listing of medical devices: N/A
Details: N/A

Import controls
Import controls: Yes
Details: An importer must obtain an importer license as well as a product import license or a product import notification for each product. Medical Devices Act, Art. 15

Post market controls
Post Market Surveillance: Yes
Details: A manufacturer must maintain a QMS and must comply with Ministerial Decree on manufacturing, quality management and production control. Medical Devices Act, Art. 13.
Inspection (QMS): Yes
Details: The KFDA Commissioner may require medical device handlers to furnish records or may inspect the business or records, Medical Devices Act, Art. 28. If the Minister of Food and Drug Safety deems that a medical device is likely to cause harm to the public health, he/she may order a handler of the medical device to undergo an inspection by a medical device testing and inspection institution. Medical Devices Act, Art. 33.
Enforcement: Yes
Details: The Medical Devices Act provides penalties (imprisonment and/or fines) depending on the nature of the violation. Chp. VIII
Adverse event reporting: Yes
Details: If a medical device handler discovers any case or risk of death or occurrence of a serious adverse effect on human health while in use, he/she shall immediately report such discovery to the Minister of Food and Drug Safety and shall retain the records thereof. Medical Devices Act, Art. 31.
Field safety corrective action monitoring: Yes
Details: When a manufacturer, an importer, a repairer, a distributer, or a lessor of a medical device becomes aware that the medical device has caused, or is likely to cause, harm to human health due to its poor quality or other relevant factors, he/she shall recall such medical device or take measures necessary for recall without delay. Medical Devices Act, Art. 31.
Advertising: Yes
Details: A person who intends to advertise a medical device shall undergo a review in advance by the Minister of Food and Drug Safety in accordance with the guidelines, methods, and procedure of review determined by the Minister of Food and Drug Safety. Medical Devices Act, Art. 25 Ministerial Decree No. 18 provides additional advertisement rules in Art. 29.
Labelling: Yes
Details: A label must contain:
1. The trade name and address of the manufacturer or importer;
2. If imported, the origin of manufacture (the name of the country of manufacture and of the manufacturer);
3. The name of item, the name of model, and the approval (certification or notification) number;
4. The manufacturing number and the date of manufacturing (the use-by date may be stated in lieu of the date of manufacturing, if the use-by date exists);
5. Weight or packaging unit;
6. A label stating “medical device”;
7. A “single-use only” and “do not reuse” label for a single-use medical device.
Medical Devices Act, Art. 20 Labels shall be written at a position more noticeable than any other letter, article, picture, or symbol and shall be written accurately in Korean language with easily comprehensible terms. Medical Devices Act, Art. 23. Labelling must be written in Korean, and the Korean text must be larger than any other language’s text. Ministerial Decree No. 18, Art. 28.