

Scorecard of Japan

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Review of Classifications and Safety Measures Concerning Medical Devices

International Classification	Current status and Proposed revision
	Classification of medical devices according to risk
Class A	Medical devices that are believed to pose extremely low risk to the human body even if they fail Examples: In vitro diagnostic devices, steel supplies, x-ray film, dental prosthetic supplies
Class B	Medical devices that are believed to pose low risk to the human body even if they fail Examples: MRI, electromanometers, electronic endoscopes, digestive catheters, ultrasonic diagnostic equipment, and dental alloys
Class C	Medical devices that are believed to pose medium risk to the human body if they fail Examples: dialyzers, artificial bones, respirators, and balloon catheters
Class D	Medical devices that are highly invasive upon the patient and may directly endanger the patient's life (high risk) if they fail Examples: pacemakers, artificial heart valves, and stents

EU system outline	FDA system outline
Notified Body's audit is not required	PMA or 510k is not required
Notified Body's audit is required	PMA or 510k is required
Document review is required	
On-site inspection only	

Current Pharmaceutical Affairs Law
Regulations
Manufacturing regulations
Pre-wholesale, Pre-retail Notification is not required
Approval of manufacturing is not necessary
Pre-wholesale, Pre-retail notification is required
Minister's approval for manufacturing



Proposed Revision		
Classification name	Risk	Marketing regulations
General Medical Device	Extremely low	Pre-wholesale, Pre-retail Notification is not required Approval for marketing authorization is not required
Controlled Medical Device	Low	Pre-wholesale, Pre-retail notification is required* Introduction of third-party certification system
Specialty Controlled Medical Device	Middle	Introduction of license system for wholesale or retail
	High	Minister's approval for marketing authorization

Note: The products shown as examples will be classified, in principle, based on GHTF recommendations. Minister of Health, Labour and Welfare to classify products according to recommendation of the Pharmaceutical Affairs and Food Sanitation Council. Although some medical devices are rented, and since rentals are handled in the same way as sales under the Pharmaceutical Affairs Law's regulations, they are omitted from this table. Specially Designated Maintenance Required Medical Device, even those that are classified as low risk, require a license for distribution as do high-risk medical devices.

Currently Implemented

- Labelling for Medical Devices (SG1 N9)
- Global Medical Device Competent Authority Report (SG2 N9)
- Minimum Data Set for Manufacturer Reports to C.A. (SG2 N7)
- Guidance on How to handle Information Concerning Vigilance Reporting Related to Medical Devices (SG2 N8)
- Medical Devices: Post Market Surveillance:
National Competent Authority Report Exchange Criteria (SG2 N20)

After PAL Reform

PAL: Pharmaceutical Affairs Law

Following guidances are planed for implementation.

- . Essential Principles of Safety & Performance of Medical Devices (SG1 N20)
- . Role of Standards in the Assessment of Medical Devices (SG1 N12)
- . Summary Technical Documentation (STED) (SG1 N11)
- . Global Medical Devices Nomenclature (GMDN)
- . ISO 13485 : 200X (SG3)