IMDRF International Medical Device Regulators Forum

Japan Update

IMDRF Open Stakeholder Forum

March 15, 2017

厚生労働省
Ministry of Health, Labour and Welfare

PMDA

IMDRF International Medical Device Regulators Forum

- Regulatory Authorities in Japan -

MHLW

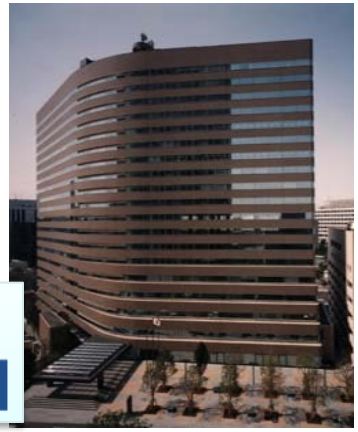
Ministry of Health, Labor and Welfare

- **Final Authorization of applications**
- **Publishing Guidelines**
- **Advisory committee**
- **Supervising PMDA Activities**

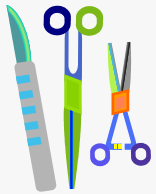
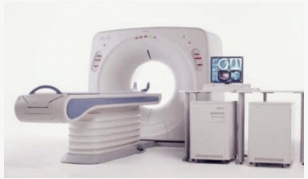
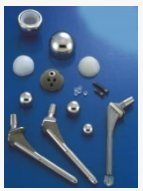
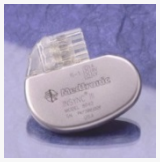
PMDA

Pharmaceuticals and Medical Devices Agency

- **Scientific Review for Drugs & MD**
- **GCP, GMP Inspection**
- **Consultation on Clinical Trials etc.**



Medical Device Regulations in Japan

Classification	Class I	Class II	Class III	Class IV
Category	General MDs	Controlled MDs	Specially controlled MDs	
Review regulation	Self-declaration	Third party certification	PMDA review (MHLW approval)	
Example		 	 	  
Post market safety (vigilance/surveillance)	PMDA and MHLW			

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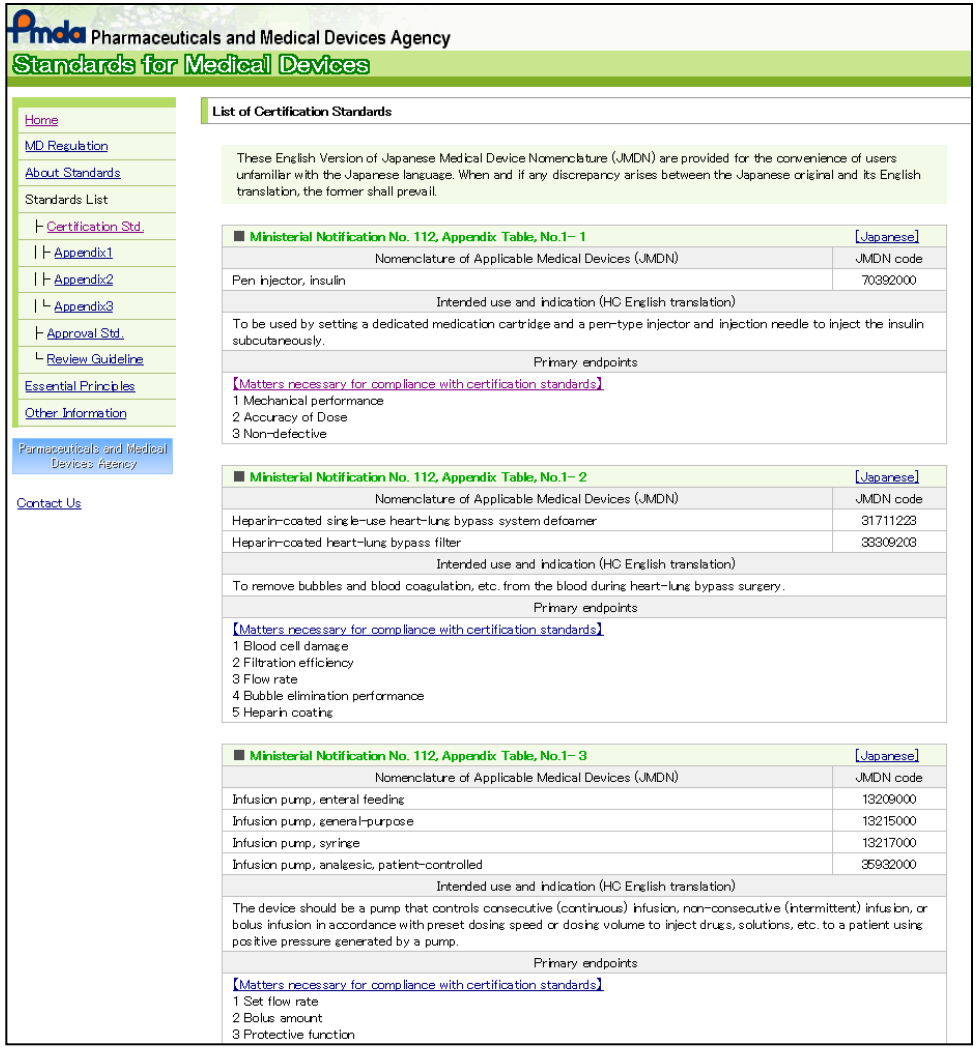
(Reference) List of Certification Standards for Third Party Certification



Pharmaceuticals and Medical Devices Agency

Standards for Medical Devices

Home
MD Regulation
About Standards
Standards List
- Certification Std.
  - Appendix1
  - Appendix2
  - Appendix3
- Approval Std.
- Review Guideline

Essential Principles
Other Information

Pharmaceuticals and Medical Devices Agency

Contact Us

List of Certification Standards

These English Version of Japanese Medical Device Nomenclature (JMDN) are provided for the convenience of users unfamiliar with the Japanese language. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

Ministerial Notification No. 112, Appendix Table, No.1- 1 [Japanese]

Nomenclature of Applicable Medical Devices (JMDN)	JMDN code
Pen injector, insulin	70392000

Intended use and indication (HC English translation)

To be used by setting a dedicated medication cartridge and a pen-type injector and injection needle to inject the insulin subcutaneously.

Primary endpoints

【Matters necessary for compliance with certification standards】
1 Mechanical performance
2 Accuracy of Dose
3 Non-defective

Ministerial Notification No. 112, Appendix Table, No.1- 2 [Japanese]

Nomenclature of Applicable Medical Devices (JMDN)	JMDN code
Heparin-coated single-use heart-lung bypass system defoamer	31711223
Heparin-coated heart-lung bypass filter	33309203

Intended use and indication (HC English translation)

To remove bubbles and blood coagulation, etc. from the blood during heart-lung bypass surgery.

Primary endpoints

【Matters necessary for compliance with certification standards】
1 Blood cell damage
2 Filtration efficiency
3 Flow rate
4 Bubble elimination performance
5 Heparin coating

Ministerial Notification No. 112, Appendix Table, No.1- 3 [Japanese]

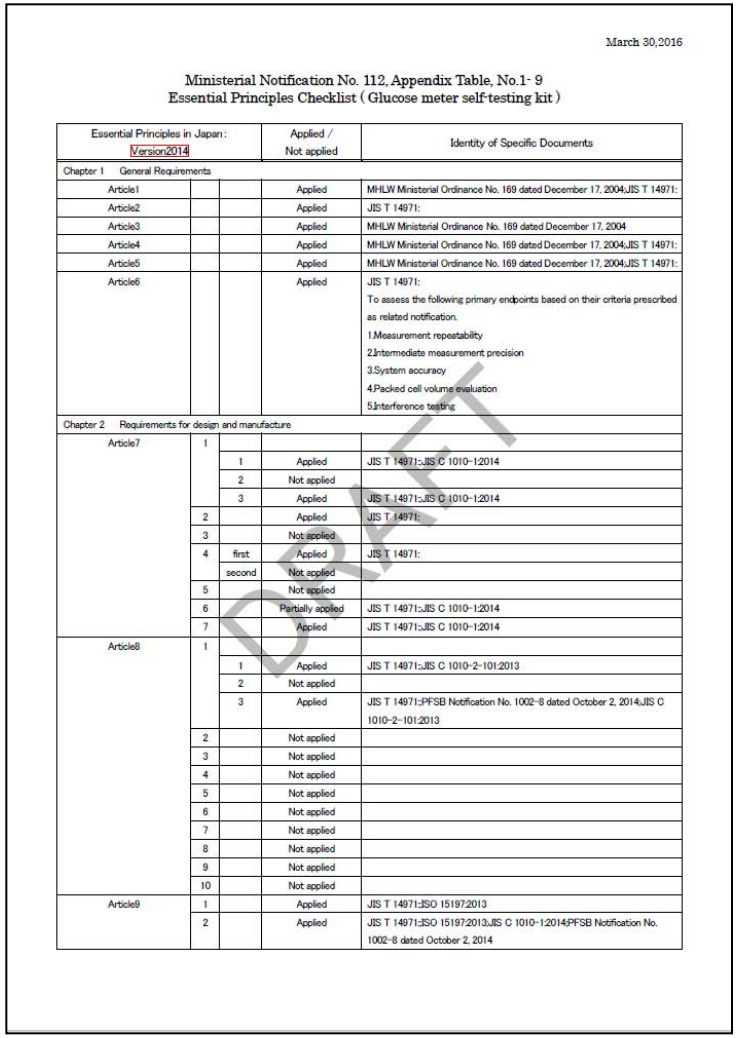
Nomenclature of Applicable Medical Devices (JMDN)	JMDN code
Infusion pump, enteral feeding	13209000
Infusion pump, general-purpose	13215000
Infusion pump, syringe	13217000
Infusion pump, analgesic, patient-controlled	35932000

Intended use and indication (HC English translation)

The device should be a pump that controls consecutive (continuous) infusion, non-consecutive (intermittent) infusion, or bolus infusion in accordance with preset dosing speed or dosing volume to inject drugs, solutions, etc. to a patient using positive pressure generated by a pump.

Primary endpoints

【Matters necessary for compliance with certification standards】
1 Set flow rate
2 Bolus amount
3 Protective function



March 30,2016

Ministerial Notification No. 112, Appendix Table, No.1- 9
Essential Principles Checklist (Glucose meter self-testing kit)

Essential Principles in Japan: Version2014			Applied / Not applied	Identity of Specific Documents
Chapter 1 General Requirements				
Article1			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIS T 14971:
Article2			Applied	JIS T 14971:
Article3			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004
Article4			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIS T 14971:
Article5			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIS T 14971:
Article6			Applied	JIS T 14971: To assess the following primary endpoints based on their criteria prescribed as related notification. 1.Measurement repeatability 2.Intermediate measurement precision 3.System accuracy 4.Packed cell volume evaluation 5.Interference testing
Chapter 2 Requirements for design and manufacture				
Article7	1			
		1	Applied	JIS T 14971:;JIS C 1010-1:2014
		2	Not applied	
		3	Applied	JIS T 14971:;JIS C 1010-1:2014
	2		Applied	JIS T 14971:
	3		Not applied	
	4	first	Applied	JIS T 14971:
		second	Not applied	
	5		Not applied	
	6		Partially applied	JIS T 14971:;JIS C 1010-1:2014
	7		Applied	JIS T 14971:;JIS C 1010-1:2014
Article8	1			
		1	Applied	JIS T 14971:;JIS C 1010-2-101:2013
		2	Not applied	
		3	Applied	JIS T 14971:PFSB Notification No. 1002-8 dated October 2, 2014;JIS C 1010-2-101:2013
	2		Not applied	
	3		Not applied	
	4		Not applied	
	5		Not applied	
	6		Not applied	
	7		Not applied	
	8		Not applied	
	9		Not applied	
	10		Not applied	
Article9	1		Applied	JIS T 14971:;ISO 15197:2013
	2		Applied	JIS T 14971:;ISO 15197:2013;JIS C 1010-1:2014;PFSB Notification No. 1002-8 dated October 2, 2014

Science Board Subcommittees for 3rd Stage

(Apr. 2016-)

Science Board

The Science Board was established in May 2012 to discuss how PMDA can better cope with products with advanced science & technology, in each developmental stage such as basic research, development support, product review, and post market safety measures.

Board members

Academia

- ✓ Artificial Intelligence (AI) subcommittee
- ✓ Orphan cancer subcommittee
- ✓ Drug development subcommittee

IMDRF International Medical Device Regulators Forum

”PMDA-ATC Medical Devices Seminar 2016” for regulators in other jurisdictions

7 – 11 November, 2016 at PMDA (Tokyo, Japan)

- Topics such as pre-market review, QMS, PMS, training facility visit and group works for review were provided in the 2016 seminar.
- 28 officials from the following jurisdictions participated:

- ✓ Australia
- ✓ Brazil
- ✓ Chinese Taipei
- ✓ Hong Kong SAR
- ✓ India
- ✓ Indonesia
- ✓ Malaysia
- ✓ Myanmar
- ✓ Singapore
- ✓ South Africa
- ✓ Sri Lanka
- ✓ Thailand
- ✓ Zambia

Fast Break Scheme for Innovative MD (Draft)

<Support for accelerated approval for innovative Medical device ~Importance of approval system encouraging medical venture~>

Innovative MDs created by medical venture enterprises are expected to have extremely effective and safe profile, however, these MDs tend to target extremely few patients. In that case, the development might be stagnated because of difficulties in collecting cases for clinical trial.

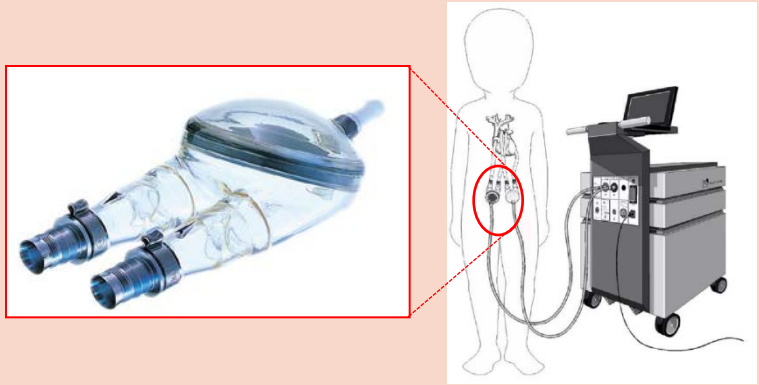
Considering such a situation and our mission to introduce innovative MDs to the public the government should construct the scheme which accelerate the approval the innovative MDs by minimizing the burden regarding clinical trials and enhancing the post-market surveillance.

From the Report by Conference for promotion of Venture companies driving clinical innovations

Subjects to be solves

- The scope of the scheme
- The way of pre-market review with limited number of clinical cases, overseas data and literature
- Post-market safety monitoring system which enables accelerated approval
  …etc.

【example image of target MD】



EXCOR Pediatric (Ventricular assist device for pediatric)

Single-use Medical Device (SUD) Reprocessing

- Backed by the high interest in SUD reprocessing, currently carried out in an orderly manner in such countries like the US and Germany etc., Japan is now studying its appropriate implementation, since it could give great benefits of saving materials, reducing wastes and suppressing medical costs.
- After organizing a Study Group in FY 2015, the following investigations have been conducted, in order to identify the issues and to develop implementation guidelines.
  1) **Actual regulatory situations (US, Germany, UK)**
  2) **Domestic needs for reprocessed SUD**

- Relevant regulations will be streamlined in FY 2017 for the proper implementation of SUD reprocessing, and studies are on-going to establish criteria for the quality of reprocessed SUD, and for the reprocessing quality control.

Designation of Sakigake products

As of 28 February 2017, 7 more products (3 medical devices, 1 IVD and 3 regenerative medicines) have been designated as Sakigake products.

No.	Product name	Expected performance/effectiveness
MD3	**Artificial tracheal** (made of polypropylene mesh and collagen sponge)	Aiding reconstruction of tracheal while maintaining intratracheal structure after partial removal.
MD4	**Boron neutron capture therapy (BNCT) system** (Neutron irradiation system for BNCT)	Selective destruction of tumor cells marked by boron agents, without damaging normal cells.
MD5	**UT-Heart** (Software program to aid prediction of effectiveness of cardiac resynchronization therapy)	Higher accuracy of prediction of effectiveness of cardiac resynchronization therapy for patients with serious heart failure.
IVD1	**Cancer-related gene panel examination system** (Diagnostic system for DNA sequencer)	Collective examination of cancer-related genes to aid decisions on cancer treatment strategies

No.	Product name	Expected performance/effectiveness
RP4	**CLS2702C/D** (Oral mucosa-derived esophageal cell sheet)	Shorter re-epithelialization period after extensive endoscopic submucosa dissection (ESD) in esophageal cancer.
RP5	**Dopamine neural precursor cell derived from non-autologous iPS cell** (Therapeutic stem cell for Parkinson's disease)	Novel therapy by inducing dopamine discharge to mitigate neural symptoms of patients with Parkinson's disease.
RP6	**Pluripotent progenitor cell derived form human (allogeneic) adult bone marrow** (Stem cell suspension derived from adult marrow)	Novel therapy for improving functional impairment caused by acute brain infarction.

- Meanwhile, the absorbing barrier for adhesion prevention (MD2) which was designated last year will be withdrawn, due to the termination of development by the manufacturer.

(Reference) Implementation of Strategy of Sakigake

An ***innovative MD/IVD for patients in urgent need of innovative therapy*** may be designated as a Sakigake Product if;
1)its premarket application will be filed in Japan firstly or simultaneously in some countries including Japan, ***AND***
2)prominent effectiveness can be expected.

Once an MD/IVD is designated, its developer can enjoy such benefits as:

A) Prioritized Consultation by PMDA

B) Pre-application substantive review

C) Prioritized Review
(12 months → 6 months [MD])

D) Review Concierge assigned by PMDA

(Reference) Designation of Sakigake products in 2016

The following 5 products under development have been designated as Sakigake products since 10 February 2016.
If a pre-market application for the products is filed, a priority review is applied.

No.	Product name	Expected performance/effectiveness
MD1	**Titanium Bridge** (Hinge-type plate with titanium)	Adduction-type spasmodic dysphonia
MD2	**Absorbing barrier for adhesion prevention** (Trehalose solution)	Reduction of postoperative adhesion prevention by Intraperitoneal injection
RP1	**STR01** (Autologous bone marrow-derived stem cells)	Improvement of neurological symptoms and functional impairment due to spinal cord injury
RP2	**G47Δ** (Recombinant herpes virus)	Glioma
RP3	**Autologous intracardiac stem cells**	Improvement of heart function in children with congenital heart disease

Thank you!