Japan

Latest Updates

Software	
Embedded Software	Embedded software is not registered separately, but as part of the system. Classification is depending on the main system's classification. Medical Device is classified by risk based concept. https://www.std.pmda.go.jp/scripts/stdDB/refetc/stdDB_refetc_sum_absbttm.cgi?absdisp=1 (G1)
Software as Medical Device (SaMD)	Base of a registration requirement for SaMD is the same as that of medical devices. Specific requirements on Medical Software; clarification of algorithm, system requirements for OS, desirable to have a lifecycle process. No guidance in English. http://www.jaame.or.jp/mdsi/program-files/280331guidance.pdf https://www.pmda.go.jp/files/000220691.pdf https://www.mhlw.go.jp/content/11120000/000764274.pdf (G3) For definition and classification on SaMD, see next deck from page 4 to page 11. https://www.pmda.go.jp/files/000215558.pdf (G4) Review Index for behavioural change SaMD: https://dmd.nihs.go.jp/jisedai/tsuuchi/%E8%96%AC%E7%94%9F%E6%A9%9F%E5%AF%A9%E7%99%BA0609%E7%AC%AC%EF%BC%91%E5%8F%B7.pdf September 2 2022: new pilot program for software as a medical device (SaMD) has been issued -> SAKIGAKE PROGRAM (PSEHB/MDED No. 0902/2: Trial Implementation of Priority Review for Programmed Medical Devices)
Clinical Decision Support Software (CDS)	Regulations are same to SaMD. However, because classification of Medical Device Software is based on 'contribution to diagnosis' and 'impact/risk of misdiagnosis', CDS tends to be classified into upper category.
Change Management Requirements for Software/SaMD	No updates at present.

Quality Management System (QMS)	Same as general Medical Devices.
Post-Market Management	No specific requirements or regulations for software.

Real World Data/Evidence

"RWD is available for HA submission. Several products are approved with a use of registry outcomes,

English slide deck (RWE/RWD on page 13-17)
https://www.mhlw.go.jp/content/11123000/000335171.pdf

For RWD/RWE utilization for HA submission, guidance was published in 2021.

As for the utilization of RWE/RWD for post marketing surveillance has been working and the following guidance are available. Basic Policy on the Use of Medical Information Databases for post marketing surveillance: https://www.pmda.go.jp/files/000218531.pdf (G7)

Key considerations for ensuring data reliability in post-marketing surveillance for drug:
https://www.pmda.go.jp/files/000223003.pdf (G8)

Key considerations for ensuring data reliability in post-marketing surveillance for medical device:
https://www.pmda.go.jp/files/000229088.pdf (G9)"

Artificial Intelligence (SiMD & SaMD)

Machine Learning	"The guidance of performance test with clinical data was published in 2021. https://www.pmda.go.jp/files/000243109.pdf"
Deep Learning	No updates at present.
Best Ethical Practices	No updates at present.
Generative AI	No updates at present.

Cybersecurity

"3 documents were published from MLHW for Cybersecurity.

Guidance for Ensuring Cybersecurity of Medical Devices. It is a cybersecurity requirement based on IMDRF cybersecurity guidance. Marketing Authorization Holders (including manufacturer etc) need to establish a system to ensure these requirements. It will be enforced in summer 2023.

1)Basic concept for Cybersecurity of medical device: https://www.mhlw.go.jp/file/05-Shingikai-11121000-Iyakushokuhinkyoku-Soumuka/0000090664.pdf(G10)

2) Guidance on Ensuring Cybersecurity of Medical Devices:
https://www.mhlw.go.jp/content/11121000/000346114.pdf (G11)

3)Announcement for publication of "Principle and practice for medical device Cybersecurity" from IMDRF (G12)

Q&A document for basic concept and guidance was published from MD Industry association
http://www.jfmda.gr.jp/wp-content/uploads/2019/03/1d24d95a1fee8b20fed8c7d3c103f4ef.pdf
(G13)

English version is not available."

Data Privacy

Ethical Guidelines for Medical and Health Research Involving Human Subjects (in Chapter 6):
https://www.mhlw.go.jp/content/000946358.pdf (G14)

Amended Act on the Protection of Personal Information
https://www.ppc.go.jp/files/pdf/APPI_english.pdf (G15)

Labelling

UDI	No updates at present.
Specific Market Requirements	No updates at present.