South Korea 

Latest Updates

- Embedded software is not registered separately, but as part of the system.
  - Classification is depending on the main system's class.
- Registration is according to the following regulation;
  - http://www.law.go.kr/행정규칙/의료기기허가·신고·심사등에관한규정/-2023-80호
- Classification is according to the following regulation;
  - http://www.law.go.kr/행정규칙/의료기기품목및품목별등급에관한규정/2023-41호
- Guidances:
  - (a) Korea Guideline for Evaluation of Artificial Intelligence (AI)-based Medical Device (D12)
  - (b) Guidance on the Review and Approval of Artificial Intelligence (AI)-based Medical Devices- 2023 July
  - (c) Guidance on the Review and Approval of Medical Device Software (Handbook 0612-04) - 2023 July+G15:G16

Software	
Embedded Software	Embedded software is not registered separately, but as part of the system. Classification is depending on the main system's class. Registration is according to the following regulation; http://www.law.go.kr/행정규칙/의료기기허가·신고·심사등에관한규정/-2023-80호 Classification is according to the following regulation; http://www.law.go.kr/행정규칙/의료기기품목및품목별등급에관한규정/2023-41호 Guidances: (a) Korea Guideline for Evaluation of Artificial Intelligence (AI)-based Medical Device (D12) (b) Guidance on the Review and Approval of Artificial Intelligence (AI)-based Medical Devices- 2023 July (c) Guidance on the Review and Approval of Medical Device Software (Handbook 0612-04) - 2023 July
Software as Medical Device (SaMD)	Registration is according to the following regulation; http://www.law.go.kr/행정규칙/의료기기허가·신고·심사등에관한규정/ 2023-80호 Classification is according to the following regulation; http://www.law.go.kr/행정규칙/의료기기품목및품목별등급에관한규정/ 2023-41호 Guidances: (a) Guidance on the Review and Approval of Medical Device Software (Handbook 0612-04) - 2023 July
Clinical Decision Support Software (CDS)	There're 4 specific types of CDSS clinical evaluation guideline (D5) released. Refer to the attached(Zip file : CDSS Guideline). Only Korean available. - Coronary stenosis - Breast cancer - Lung cancer / Solitary pulmonary nodule - Ischemic stroke

Change Management Requirements for Software/SaMD	Registration is according to the following regulation; http://www.law.go.kr/행정규칙/의료기기허가·신고·심사등에관한규정/2023-80호
Quality Management System (QMS)	Software/SaMD is managed under the equivalent regulations to medical devices(MDs). Standards of Medical Device Good Manufacturing Practices/2023-79 Guidances: (a) Guidance on Software Medical device Good Manufacturing Practices Operation (Handbook 1185-01) - 2021 Dec
Post-Market Management	Software/SaMD is managed under the equivalent regulations to medical devices(MDs).

Real World Data/Evidence

Guidelines: Application of Real World Evidence for Medical Device(0934-02) / July 2023

Artificial Intelligence (SiMD & SaMD)

Machine Learning	Guideline: (a) Guidance on the Review and Approval of Artificial Intelligence (AI)-based Medical Devices (0804-03) / May 2022 (b) Guidance on Clinical Trials Design of Artificial Intelligence(AI)-based Medical Devices (0801-03) / July 2022
Deep Learning	No updates at present.
Best Ethical Practices	Not published
Generative AI	Not published

Cybersecurity

Medical Device Cybersecurity requirements are equivalent to the IMDRF guidance.

Guideline:
(a) Guideline on Review and Approval for Cybersecurity of Medical Devices (For industry)
(b) Principles and practices of software material specification for cybersecurity of medical devices
(c) Principles and Practice for Cybersecurity of Legacy Medical Devices
(d) Principles and Practices for Medical Device Cybersecurity

Data Privacy

Personal Information Protection Act http://www.law.go.kr/법령/개인정보보호법 (D11)

Labelling	
UDI	SaMD is managed under the equivalent regulations to medical devices (MDs). Guidelines: (a) Medical device barcode marking guidelines (b) Instructions on Labelling and Management of Unique Device Identifiers
Specific Market Requirements	SaMD is managed under the equivalent regulations to medical devices (MDs). Regulations on Labelling and Description of Medical Devices (MFDS notification no. 20-71) Guidelines: (a) Instructions on Labelling and Management of Unique Device Identifiers