EU

Latest Updates

- Note added in AI act.

Software	
Embedded Software	Per EU MDR, embedded software is treated differently based on its intended purpose. If the software has a medical purpose on its own, it is usually classified independently. If it is driving or influencing the use of a hardware medical device, it is classified with the hardware. In either case, if multiple classification rules apply, the higher risk classification rule shall be used to classify the whole device. Source: MDCG 2019-11: Guidance on qualification and classification of software
Software as Medical Device (SaMD)	Per EUMDR, standalone software is classified either according to EU MDR classification rule 11 or using the IMDRF risk-based classification framework. Source: MDCG 2019-11: Guidance on qualification and classification of software
Clinical Decision Support Software (CDS)	Per EUMDR, standalone software is classified either according to EU MDR classification rule 11 or using the IMDRF risk-based classification framework. Source: MDCG 2019-11: Guidance on qualification and classification of software
Change Management Requirements for Software/SaMD	MCDCG 2020-3 provides guidance on the types of changes to devices subject to EU MDR may be considered "significant", requiring a re-evaluation of conformity assessment. This guidance includes changes to software and SaMD as a separate section. https://ec.europa.eu/docsroom/documents/40301
Quality Management System (QMS)	The IMDRF guidance on QMS for SaMD addresses application of EN ISO 13485 to SaMD. EN ISO 13485 is a harmonized standard with EU - which indicates compliance to EN ISO 13485 presumes compliance with the MDD / EU MDR.
Post-Market Management	No updates at present.

Real World Data/Evidence

EU MDR contains requirements for Post Market Surveillance. An MDCG working group has been established to develop guidance around Post Market Surveillance and Vigilance. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20170505

Artificial Intelligence (SiMD & SaMD)	
Machine Learning	No specific regulations for AiML. SaMD with AIML may be classified according the the MDCG guidance on qualification and classification of Software. MDCG 2019-11: Guidance on qualification and classification of software Note: Medical Device AI systems are in scope of the AI Act - which introduces requirements for AI risk management (in trilogue at the moment)
Deep Learning	No specific regulations for AiML. SaMD with AIML may be classified according the the MDCG guidance on qualification and classification of Software. MDCG 2019-11: Guidance on qualification and classification of software Note: Medical Device AI systems are in scope of the AI Act - which introduces requirements for AI risk management
Best Ethical Practices	No updates at present.
Generative AI	No specific regulations for AiML. SaMD with AIML may be classified according the the MDCG guidance on qualification and classification of Software. MDCG 2019-11: Guidance on qualification and classification of software Note: Medical Device AI systems are in scope of the AI Act - which introduces requirements for AI risk management

Cybersecurity
MDCG 2019-16 rev 1: Guidance on cybersecurity for medical devices.

Data Privacy
EU GDPR: https://gdpr-info.eu/

Labelling	
UDI	EU MDR contains requirements for establishing a UDI system for medical devices. The EU Commission is working on creating a holistic database for medical devices in EU, (EUDAMED) that will have actor registration, UDI / Certificate, Vigilance, Clinical Investigation and Market Surveillance modules. EUDAMED is under development and expected to be completed in 2029.
Specific Market Requirements	No updates at present.