

MEDICAL DEVICES & AI SAMD APPROVALS

MDR Article 120 Transition Framework Governs Legacy SaMD as AI Omnibus Aligns Embedded Systems to August 2028

Timestamp: 2026-10-10_1402 UTC
Risk Posture: HIGH

Telemetry Hash: 9ad6909732ebdf5480ceb0e4...
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PRIMARY LIABILITY DRIVER: Operating legacy SaMD under MDR Article 120 requires adherence to statutory transition conditions—including valid 2024 Notified Body agreements, compliant QMS, and avoiding significant changes in design or intended purpose—while AI SaMD must prepare for dual conformity under amended AI Act Article 113.

EXECUTIVE SUMMARY

As of 10 October 2026, manufacturers of Software as a Medical Device (SaMD) operating in the EU navigate the transitional architecture of Regulation (EU) 2017/745 (MDR), as extended by Regulation (EU) 2023/607 and amended by Regulation (EU) 2024/1860. Statutory extensions defer Directive certificate validity to 31 December 2027 for Class III and Class IIb implantable non-WET devices, and 31 December 2028 for other Class IIb devices, Class IIa devices, well-established-technology implantables, and Class I devices requiring notified body involvement. These extensions remain strictly contingent upon statutory conditions: formal Notified Body application by 26 May 2024, signed written agreement by 26 September 2024, maintaining a compliant QMS, and implementing no significant change in design or intended purpose under Article 120(3c). Ongoing Post-Market Clinical Follow-up (PMCF) under Annex XIV Part B is an active surveillance duty; deficiencies can lead to Notified Body audit suspension, but do not operate as an automatic statutory forfeiture of legacy status.

Concurrently, Regulation (EU) 2026/1744 (Digital Omnibus on AI) amended Article 113 of the AI Act, aligning the application date for AI systems that are safety components of products subject to Union harmonisation legislation listed in Annex I Section A (specifically Regulation (EU) 2017/745 on Medical Devices) to 2 August 2028. In the US, the FDA governs machine-learning modifications through Predetermined Change Control Plans (PCCPs) authorized under Section 515C of the FD&C; Act (21 U.S.C. § 360e-4). While authorized PCCPs allow pre-specified model updates without supplemental submissions, modifications exceeding authorized boundaries require standard regulatory filings. Furthermore, manufacturers must comply with MDR Article 10a, which mandates at least 6 months advance notice to competent authorities, health institutions, and distributors prior to an anticipated disruption or discontinuation in supply that could reasonably foreseeably cause serious harm or a risk of serious harm to patients or public health.

1. AUDITED STATUTORY MILESTONES & PRIMARY SOURCE VERIFICATION

Statutory Instrument / Citation	Gate	Legal & Operational Impact
Regulation (EU) 2017/745, Article 120(3a)-(3c) (as amended by Reg (EU) 2023/607) Status: ENACTED / TRANSITIONAL EXTENSION	2027-12-31	Transitional validity extension for legacy Class III and Class IIb implantable devices, contingent upon maintaining a certified QMS, Notified Body agreement, and implementing no significant design or intended-purpose changes.
Regulation (EU) 2017/745, Article 120(3b)-(3c) (as amended by Reg (EU) 2023/607) Status: ENACTED / TRANSITIONAL EXTENSION	2028-12-31	Transitional validity extension for Class IIa, non-implantable Class IIb devices, WET implantables, and Class I sterile/measuring devices subject to ongoing QMS surveillance and significant change restrictions.
Regulation (EU) 2024/1689, Article 113(c) & Annex I Section A (MDR) Status: ADOPTED (COMMENCING 2028-08-02)	2028-08-02	Codifies unified application date for AI systems embedded as safety components in medical devices covered by MDR, aligning technical documentation and conformity assessment workflows.

Regulation (EU) 2017/745, Article 10a (as inserted by Reg (EU) 2024/1860) Status: ENACTED / IN FORCE	2025-01-10	Statutory duty requiring manufacturers to provide at least 6 months advance notice to competent authorities, health institutions, and distributors prior to an anticipated disruption in supply posing serious harm risks.
US FD&C; Act Section 515C [21 U.S.C. § 360e-4] & FDA PCCP Framework Status: ENACTED / IN FORCE	2024-12-18	Authorizes pre-cleared iterative machine learning modifications without supplemental 510(k)/PMA filings, provided changes remain strictly within authorized PCCP boundaries and verification protocols.

2. GENERAL COUNSEL ACTION MATRIX & WORKSTREAMS

Priority & Classification	Required Operational Action	Owner	Gate
[CRITICAL] LEGAL REQUIREMENT	Audit PMCF data streams and clinical evaluation reports against Notified Body audit schedules to sustain MDR QMS compliance and legacy certificate surveillance. Anchor: Regulation (EU) 2017/745, Article 120(3c) & Annex XIV Part B	Chief Regulatory Officer	2026-12-15
[CRITICAL] RECOMMENDED CONTROL	Establish algorithmic change control procedures to verify that ML software updates do not constitute significant design changes under MDCG 2020-3 guidance. Anchor: Regulation (EU) 2017/745, Article 120(3c)	VP of Quality Assurance	2026-11-30
[MEDIUM] LEGAL REQUIREMENT	Implement supply monitoring procedures to ensure mandatory 6-month advance notice is submitted under Article 10a prior to any anticipated device shortage posing serious risk. Anchor: Regulation (EU) 2017/745, Article 10a	General Counsel	2027-01-15
[HIGH] REGULATORY EXPECTATION	Construct a synchronized technical documentation plan aligning SaMD clinical evaluation with AI Act Article 113 dual conformity requirements ahead of August 2028. Anchor: Regulation (EU) 2024/1689, Article 113(c)	Chief Compliance Officer	2027-03-31

3. 90-DAY EXPOSURE & CAPITAL ALLOCATION PROFILE

Modeled 90-Day Budget Range: €420,000 - €780,000 (Model Total: €650,000) Estimation Basis: Illustrative enterprise scenario: assumes 3 commercial SaMD applications undergoing MDR technical file transition, external notified body clinical surveillance fees, and FDA PCCP monitoring tooling. • Notified Body clinical evaluation review & surveillance retainers: €195,000 • Algorithmic change control & PCCP drift monitoring systems: €160,000 • MDR / AI Act dual conformity alignment legal counsel: €130,000 • PMCF clinical registry data extraction and statistical validation: €115,000 • Article 10a supply continuity governance buffer: €50,000 Primary Liability Vector: Suspension or withdrawal of CE certificate by Notified Bodies for QMS or clinical deficiencies; loss of Article 120 transitional eligibility if significant unapproved design changes are introduced; FDA Warning Letters under 21 CFR 807.81(a)(3) for algorithmic modifications exceeding authorized PCCP specifications. Affected Population: Manufacturers of Class IIa, IIb, and III legacy Software as a Medical Device (SaMD) operating under MDR Article 120, AI diagnostic software developers, and medical device manufacturers marketing products with authorized PCCPs in the US.

4. DECISIONS REQUIRED THIS QUARTER (BOARD AUDIT COMMITTEE)

1. DECISION: Confirm active Notified Body written agreements remain in force across all legacy SaMD certificates, closed upon notified body contract review memo.
2. DECISION: Authorize algorithmic drift monitoring implementation (modeled at €160,000) to maintain FDA compliance boundaries, closed upon validation of drift alert thresholds.
3. DECISION: Approve Article 10a early-warning escalation protocol for manufacturing and cloud infrastructure dependencies, closed upon SOP distribution.