REGULATORY READINESS AUDIT · GAP REPORT

Gap Report
Sample Extract

Class IIb Active Device · EU MDR 2017/745 + FDA 510(k)

Multi-Market Engagement · For Illustration Purposes Only

DEVICE CLASSIFICATION **Class IIb Active Device**	TARGET MARKETS **EU MDR 2017/745 + FDA 510(k)**
AUDIT REFERENCE **VN-SAMPLE-2025-001**	REPORT DATE **April 2025**

8	4	3	1	12
FINDINGS IN EXTRACT	CRITICAL	HIGH	MEDIUM	FULL AUDIT TOTAL

IMPORTANT DISCLAIMER

This document is a sanitised sample extract for illustration purposes only. All device details, company names and specific findings are fictional. Full reports contain client-specific data.

What a Full VerityNodes Gap Report Includes

01	**All findings**	Every gap identified across 8 audit areas with specific article, annex, and
01	**Severity rating**	Each finding rated Critical / High / Medium with remediation priority guida
01	**Action items**	Specific, actionable remediation instruction for each finding — no generic
01	**Roadmap**	Prioritised remediation sequence with estimated effort and recommended orde
01	**Standards map**	Full list of applicable IEC, ISO, and EN standards for your device and clas

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Gap Findings

F-01 Critical CLINICAL EVIDENCE

Clinical Evaluation Report non-compliant with MEDDEV 2.7/1 Rev 4

The existing CER lacks a systematic literature search protocol, a documented state-of-the-art review, and a structured equivalence assessment per EU MDR Article 61(4). The document does not follow the MEDDEV 2.7/1 Rev 4 four-stage methodology required

REF: EU MDR Art. 61 · Annex XIV · MEDDEV 2.7/1 Rev 4

ACTION: Commission a full CER rebuild structured against MEDDEV 2.7/1 Rev 4 and Annex XIV. Priority: before any notified body submission.

F-02 Critical IEC STANDARDS

IEC 60601-1-2 EMC test report absent

No electromagnetic compatibility test report exists for this active device. IEC 60601-1-2 EMC compliance is a mandatory GSPR requirement under EU MDR Annex I Section 17 for devices that emit or are susceptible to electromagnetic disturbance.

REF: EU MDR Annex I §17 · IEC 60601-1-2:2014+AMD1:2020

ACTION: Commission IEC 60601-1-2 EMC testing at an accredited test laboratory. Obtain test report before technical file submission.

F-03 Critical POST-MARKET

Post-Market Clinical Follow-up (PMCF) Plan not established

No standalone PMCF Plan document exists. EU MDR Annex XIV Part B requires a PMCF Plan for Class IIa and IIb devices specifying objectives, methods, timelines and rationale. Absence of a PMCF Plan is a recurring major non-conformity identified by

REF: EU MDR Annex XIV Part B · MDCG 2020-7

ACTION: Draft PMCF Plan per MDCG 2020-7 structure covering proactive and reactive PMCF methods, ob...

F-04 Critical FDA PATHWAY

FDA 510(k) predicate device strategy undocumented

No predicate device comparison exists. For a 510(k) submission, substantial equivalence must be demonstrated against a legally marketed predicate through comparison of intended use, technological characteristics, and performance data.

REF: FDA 21 CFR 807.87(f) · FDA 510(k) Guidance 2019

ACTION: Identify and document predicate device strategy. Prepare substantial equivalence compariso...

Gap Findings (continued)

F-05 | High | USABILITY

Usability Engineering file incomplete — summative evaluation absent

The usability engineering file exists but contains only formative evaluation records. IEC 62366-1 requires a summative usability evaluation demonstrating that use-related risks have been adequately mitigated before the device is placed on the market.

REF: IEC 62366-1:2015 §5.9 · EU MDR Annex I §5
ACTION: Conduct and document summative usability evaluation per IEC 62366-1 Section 5.9. Ensure us...

F-06 | High | RISK MANAGEMENT

Risk management file not updated with post-market data

The risk management file was last comprehensively reviewed in 2021. ISO 14971:2019 Section 10 requires the risk management file to be updated as post-market surveillance data is gathered. Current PMS data is not reflected in the risk estimation.

REF: ISO 14971:2019 §10 · EU MDR Annex I §8
ACTION: Update risk management file to incorporate post-market surveillance data collected since 2...

F-07 | High | UDI / EUDAMED

UDI not assigned — EUDAMED registration incomplete

No Unique Device Identifier has been assigned via an accredited Issuing Entity (GS1, HIBCC, or ICCBBA). EUDAMED actor registration is incomplete. Both are required before placing the device on the EU market under EU MDR Articles 27 and 30.

REF: EU MDR Art. 27 · Art. 30 · Art. 31 · EUDAMED
ACTION: Register with GS1 or HIBCC and assign UDI-DI. Complete EUDAMED actor registration. Appoint...

F-08 | Medium | LABELLING

Device labels do not fully comply with EU MDR Annex I Section 23

Current labels were designed under MDD requirements. EU MDR Annex I Section 23 requires additional information including the UDI carrier, updated EN ISO 15223 symbols with legend, and language requirements for all EU member states of intended

REF: EU MDR Annex I §23 · EN ISO 15223-1:2021
ACTION: Review and update all labels and IFU against EU MDR Annex I Section 23 requirements. Engag...

Recommended Next Steps

1. **Priority** Address all Critical findings before any notified body pre-submission meeting
2. **Sequence** Begin CER rebuild and IEC 60601-1-2 testing in parallel — both are long-lead items
3. **Register** Initiate EUDAMED actor registration and UDI assignment immediately — no cost, just time
4. **Commission** Book a VerityNodes discovery call to scope your full remediation roadmap

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