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Tandem
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Application of the EU AI Act to Tandem's Medical Device Software

The Tandem Product and Its Medical Device Modules

The Tandem product is a software platform made up of several functional modules. Consistent with MDCG 2019-11 Rev.1 (Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745), which recognises that a software product may consist of multiple modules (some qualifying as medical devices and some not), Tandem has identified the boundaries and interfaces of each module and determined which modules qualify as medical device software (MDSW).

On this basis, the Tandem product contains three distinct medical device modules. Each has been independently qualified as medical device software and certified as a **Class IIa** medical device under Rule 11 of Annex VIII of the **EU MDR**.

- **Tandem AI Medical Scribe:** a clinical document generation module that drafts structured clinical documents from patient consultations for review and verification by the healthcare professional.
- **Tandem AI Medical Coder (Coding Module):** a clinical coding module that suggests relevant clinical codes from the content of consultation notes for review and selection by the healthcare professional.
- **Tandem AI Medical Guide (CDS):** a clinical decision support module that processes clinical queries and presents referenced clinical information, guidelines and treatment options to inform clinical management.

Because each of the three modules is a Class IIa AI-enabled medical device that undergoes notified body conformity assessment, each is a **high-risk AI system** under the EU AI Act. The classification and compliance analysis set out in this statement applies to all three modules.

Overview of the EU AI Act

The EU Artificial Intelligence Act (Regulation (EU) 2024/1689, the "AIA") is the first comprehensive regulatory framework for AI in the world. It introduces obligations based on risk classification, with the most extensive requirements applying to "high-risk" AI systems.

For medical devices, the AIA works alongside existing frameworks such as the EU MDR. The European Commission's Medical Device Coordination Group has published dedicated guidance on this interplay (MDCG 2025-6), which clarifies how the two regulations apply together to AI-enabled medical device software.

Classification of the Tandem Modules under the AI Act

Under Article 6(1) of the AIA, an AI system is high-risk where it is a product - or a safety component of a product - covered by EU harmonisation legislation listed in Annex I of the AIA (which includes the EU MDR) and is subject to third-party conformity assessment. In line with MDCG 2025-6, AI-enabled medical devices classified as Class IIa or higher under the EU MDR, which undergo notified body

assessment, are therefore automatically deemed high-risk AI systems. This means the full set of requirements for high-risk AI systems (Articles 8–15 AIA) applies to each module, covering risk management, data and data governance, technical documentation, record-keeping, transparency, human oversight, and accuracy, robustness and cybersecurity.

Interplay between the EU MDR and the AI Act (MDCG 2025-6)

MDCG 2025-6 confirms that the AIA does not operate in isolation from the EU MDR; the two frameworks are designed to be applied in an integrated manner and to avoid duplication of effort. In practice, this means:

- A single, integrated set of technical documentation may cover both MDR and AIA requirements.
- AIA requirements can be embedded into the existing medical device quality management system (ISO 13485), rather than run as a parallel system (Article 17 AIA).
- Risk management, post-market surveillance, and incident reporting processes under the MDR are extended to address AI-specific risks and AIA obligations, rather than duplicated.

Tandem follows this integrated approach: AI Act requirements are implemented within our certified medical device quality management system.

What We Have Done to Comply

We have taken the following measures to meet the high-risk AI system requirements across the Tandem AI Medical Scribe, Coder and Guide modules:

- **Integrated QMS and gap assessment.** We have conducted a gap assessment of Articles 8–15 AIA against our existing MDR documentation and integrated the AIA requirements into our quality management system.
- **Risk management.** Our ISO 14971 risk management process has been extended to cover AI-specific risks across the system’s lifecycle
- **Technical documentation and logging.** Our MDR technical documentation has been expanded to cover the AIA requirements, and the system automatically logs events to ensure traceability of its functioning
- **Transparency and human oversight.** Instructions for use and system information enable healthcare professionals to understand the system’s capabilities, limitations and expected performance. Outputs are designed for effective oversight: guidance is referenced to its underlying sources, and the healthcare professional reviews and validates all outputs before acting on them.
- **Post-market monitoring.** Our post-market surveillance system captures both MDR vigilance and AIA post-market monitoring and serious incident reporting obligations in one unified process.

ISO/IEC 42001 Certification

Tandem Health is certified against ISO/IEC 42001, the international standard for Artificial Intelligence Management Systems (AIMS). This certification provides independent, third-party assurance that we govern the development, deployment and monitoring of AI responsibly and systematically - including accountability structures, AI risk and impact assessments, data quality management, and continuous improvement. Our ISO/IEC 42001 management system underpins our AI Act compliance and operates in an integrated manner with our ISO 13485 quality management system and ISO 27001 information security management system.

Timeline and Our Commitment

The AI Act's requirements for high-risk AI systems embedded in medical devices apply from 2 August 2027; under the EU's recently agreed "Digital Omnibus" amendments, this deadline is expected to be extended to 2 August 2028 to allow harmonised standards to mature.

Tandem is not waiting for these deadlines: we are implementing the high-risk requirements now, as part of our ongoing MDR conformity efforts, so that each of the Tandem modules is placed on the market as a fully compliant AI-enabled medical device.

Dr. Yan Peng Zhao,
Head of Medical Compliance