



AI in Medical Devices: AI Act, ISO/IEC 42001 & EN 18286

What AI medical device software manufacturers need to know

NEW

NEW: EN 18286:2026 is now a harmonised standard

Cited in the EU Official Journal in October 2026. First harmonised AI Act standard: presumption of conformity with the Article 17 QMS requirements it covers.

EN 18286 at a glance



Art. 17

AI Act QMS
scope and
coverage



Jul 2026

Published by
CEN/CENELEC JTC
21



Oct 2026

Cited in the OJEU
(Decision (EU)
2026/2274)



Any sector

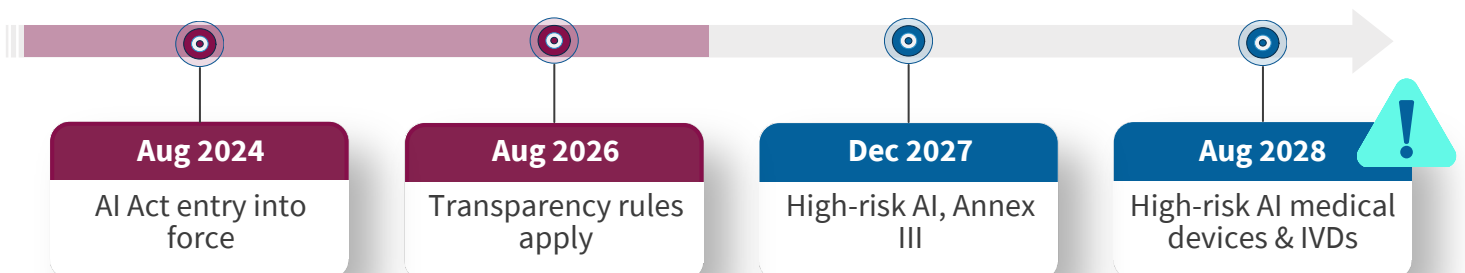
Written for
providers of high-
risk AI



Jan 2027

Deadline for
national adoption
(e.g. UNE)

Timeline

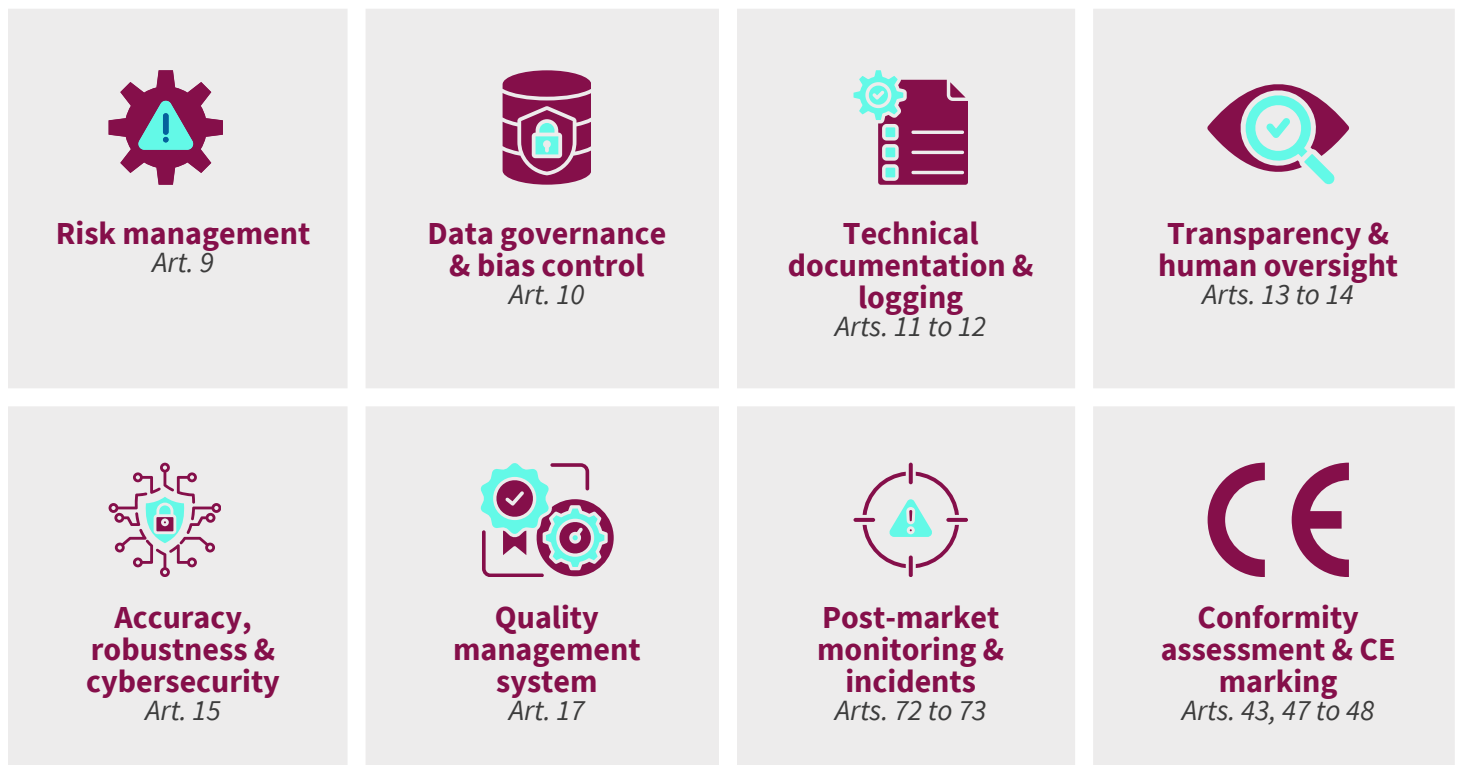


Dates as amended by Regulation (EU) 2026/1744 (Digital Omnibus on AI)

Is My AI MDSW Considered High-Risk Under the EU AI Act?



AI Act: What high-risk AI must meet



The two standards

ISO/IEC 42001

AI Management System (AIMS)

- **What:** international standard to govern AI across the organisation.
- **Who:** any organisation that develops, provides or uses AI.
- **Core:** AI policy, AI risk and impact assessment, 38 Annex A controls.
- **Certifiable:** yes.
- **AI Act value:** no presumption of conformity.

EN 18286

QMS for EU AI Act purposes

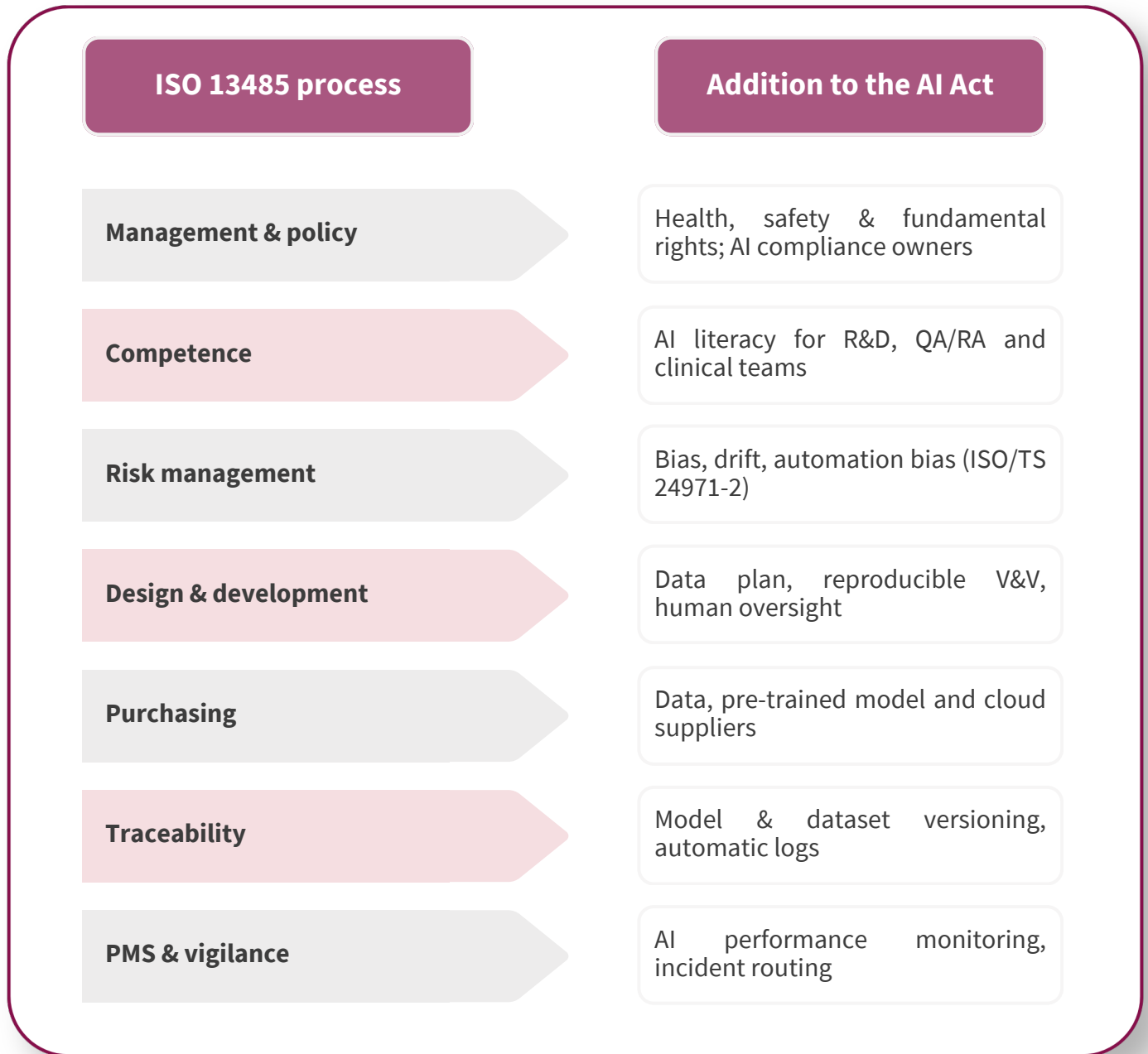
- **What:** European standard that turns AI Act Art. 17 into an auditable QMS.
- **Who:** providers of high-risk AI systems.
- **Core:** compliance strategy, AI lifecycle control, data, V&V, PMS, incidents.
- **Integrates:** into ISO 13485, cited as its own example.
- **AI Act value:** presumption of conformity (Art. 17).

Inside EN 18286: A clause-by-clause review

Clause	What it requires
4. Quality management	Identify applicable regulatory requirements, define which AI systems are in scope and keep a documented strategy for regulatory compliance (conformity route, standards used and gaps, changes, PMS, incidents).
5. Leadership	Quality policy on health, safety and fundamental rights. Named roles for regulatory compliance, AI risk management and state-of-the-art review.
6. Planning	Measurable quality objectives linked to regulatory requirements, plus actions on risks to the QMS itself.
7. Support	Resources, competence, accessible communication and staff awareness of their regulatory duties.
8. AI system realization	Lifecycle processes, AI risk management, verifiable requirements, separate verification and validation under reproducible conditions (versions, seeds, datasets), data management, continuous learning with predetermined changes, retirement.
9. Operations & control	Traceability, supplier control, change control (a substantial modification means a new conformity assessment), post-market monitoring, serious incident reporting, recalls and withdrawals.
10. Performance evaluation	Management review with measurable criteria, and planned changes to the QMS when new AI systems enter scope.
Annexes	A: consultation with affected persons. B and C: mapping to ISO 9001 and ISO/IEC 42001. ZA: link to the AI Act.

Companion AI Act standards referenced: EN 18228 (AI risk management), EN 18284 (dataset quality), EN 18229 (logging, accuracy and robustness).

Adapt your ISO 13485 QMS



Need help?

Asphalion helps AI medical device manufacturers get AI Act ready: gap analysis, QMS integration and technical documentation.



www.asphalion.com



info@asphalion.com