QUALITY EXCELLENCE SERVICES

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STANDARDS & GUIDANCE BRIEF · EUROPEAN UNION · EU REGULATION

EU MDR Annex I

Regulation (EU) 2017/745, Annex I — General Safety and Performance Requirements

DOCUMENT	QES-WP-111, Rev B	DATE	November 7, 2026
ISSUED BY	European Parliament and Council	PREPARED BY	Conner Davidson
EDITION	Regulation (EU) 2017/745, applicable since May 26, 2021; transition for legacy devices extended by Regulation (EU) 2023/607	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-mdr-annex-i.html

IN FORCE Regulation (EU) 2023/607 extended the transition for qualifying legacy devices to December 31, 2027 (class III and implantable class IIb) and December 31, 2028 (other classes), subject to conditions.

What It Covers

The essential safety and performance requirements every device placed on the EU market must meet, in three chapters: general requirements, design and manufacture, and the information supplied with the device.

Who It Applies To

Every manufacturer placing medical devices on the EU market, whatever the class.

Key Requirements

- General requirements 1 to 9: safety, performance, and risk management across the life cycle.
- Design and manufacture requirements 10 to 22, including chemical, biological, software, electrical, and usability aspects.
- Requirements 23 on labels and instructions for use.
- Conformity shown through a GSPR checklist in the technical documentation (Annex II), using harmonized standards or common specifications where they exist.

What an Auditor Asks to See

- The GSPR checklist, with each requirement marked applicable or not, and why.
- For each applicable requirement, the evidence and the standards applied, by edition.
- Evidence that the checklist was revisited after design changes.

Where Systems Fall Short

- "Not applicable" entered without a justification.
- Standards cited without an edition, or by a withdrawn edition.

How QES helps. GSPR checklists rebuilt with edition-specific standards and real evidence references. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. EUR-Lex — Regulation (EU) 2017/745 on medical devices — eur-lex.europa.eu/eli/reg/2017/745/oj; EUR-Lex — Regulation (EU) 2023/607 (transition extension) — eur-lex.europa.eu/eli/reg/2023/607/oj.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.