

THE OFFICIAL JOURNAL DROPPED TWO BIG MDR MOVES ON 17 JUNE 2026

1) EN 60601-1 IS FINALLY ON THE LIST - ENTRY 65

- Cite: EN 60601-1:2006 / A13:2024. A13 carries Annex ZZ (the GSPR mapping); technical content = IEC 60601-1 Ed. 3.2.
- First time EN 60601-1 has ever carried a presumption of conformity under the MDR. Live now (effective 17 June 2026).
- Presumption applies only when you comply with the harmonised standard AND its Annex ZZ.

2) WHAT TO CITE NOW vs. WHAT IS ON THE CLOCK

Full standard-by-standard list in Commission Implementing Decision (EU) 2026/1231: [open Decision](#)

Cite this now	Domain	Status	Old ref. withdrawn
EN 60601-1:2006 + A13:2024 (entry 65)	Medical electrical (general)	New - 1st under MDR	No transition date (live 17 Jun 2026)
EN ISO 15223-1:2021 + A1:2025	Symbols (EU REP)	Replaces 2021 (EC REP)	15 Jun 2031 (MDR); 17 Jun 2031 (MDCG/IVDR)
EN IEC 60601-2-83:2020 + A1:2025	ME - home light therapy	Replaces prior	15 Dec 2027
EN ISO 10993-23 / -12 / -17 + A1:2025	Biological evaluation	Replace prior	15 Dec 2027
New additions across categories: transfusion, biological evaluation, ophthalmic optics, non-active implants, washer-disinfectors, prosthetics, sharps protection	Various	New listings	No transition date (live 17 Jun 2026)

3) EU REP ESSENTIALS (EN ISO 15223-1:2021/A1:2025, MDR + IVDR)

- **Source for all of the below:** [MDCG 2021-5 Rev. 1 Appendix \(June 2026\)](#)
- Purely editorial on its own, so this single change needs no prior notified body approval (p.4). BUT labelling changes are costly - most manufacturers batch them, and any other change you bundle in can trigger NB involvement. Do not assume touching the label is 'free.'
- Generic symbol is 'XX REP' (ISO 3166-1 code); for the Union, XX = EU, so 'EU REP' (pp.3-4).
- 5-year coexistence to 17 June 2031: EC REP and EU REP are both valid in the meantime (p.5).
- Acceptable to use one or both symbols 'EC REP' and 'EU REP' on different levels of packaging (though mixing is not recommended), incl. re-labelling/over-labelling, provided the authorised representative info remains clear and intelligible (pp.5-6).
- Devices bearing 'EC REP' placed on the market before 17 June 2031 may continue to be made available (p.6).

4) WHAT TO DO NOW

- Cite EN 60601-1:2006/A13:2024 (with Annex ZZ) in your DoC and standards list.
- Confirm your GSPR mapping actually uses Annex ZZ.
- Update DoC / technical documentation for the other replaced standards; assess retest needs before 15 Dec 2027.
- Plan the EC REP to EU REP switch into your next labelling cycle (to mid-2031) and bundle changes deliberately.