CE Marking Under EU MDR 2017/745: A Guide for Implant Importers

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Since full application of EU MDR 2017/745, CE marking requirements for Class III orthopedic implants have become substantially more demanding. This guide summarises the key obligations for importers and distributors.

Classification

Most active orthopedic implants remaining in situ for more than 30 days are Class III under Annex VIII Rule 8. Passive implants (simple bone screws) may qualify as Class IIb, reducing conformity assessment requirements slightly.

Conformity Assessment

Class III devices require full quality assurance via a Notified Body (NB). Route A audits the manufacturer’s complete QMS against MDR requirements. Route B performs type-examination followed by production quality assurance. Both routes now require explicit clinical evaluation — equivalence claims alone no longer suffice.

Clinical Evaluation

Manufacturers must demonstrate clinical performance through systematic literature review and Post-Market Clinical Follow-Up (PMCF) plans. A publicly accessible Summary of Safety and Clinical Performance (SSCP) is mandatory for all Class III devices.

Importer Obligations

Non-EEA manufacturers must appoint an Authorised Representative established in the EEA who shares legal responsibility for MDR compliance. The AR’s name and address must appear on the EU

Declaration of Conformity and device labelling.

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