Certifications

Certifications & Quality Standards

ISO 13485:2016

Medical devices QMS. Certified since 2009. Annual surveillance by UKAS-accredited body. Scope: design, manufacture and export of metallic orthopedic implants and instruments.

CE Mark — EU MDR

Full conformity assessment under EU MDR 2017/745 for Class IIb and III devices. SSCP published for all Class III products. NB certificate available on request.

FDA Establishment Registration

Manufacturing facility registered with FDA. Selected lines hold 510(k) clearance. Device Listing current and annually renewed.

ISO 10993 Biocompatibility

All implant materials evaluated to ISO 10993 series. Cytotoxicity, sensitisation and implantation studies documented in biological evaluation reports.

Testing Standards

Standard	Applies To
ASTM F136 / ISO 5832-3	Ti-6Al-4V ELI for surgical implants
ASTM F138 / ISO 5832-1	316L stainless steel for surgical implants
ASTM F543	Metallic medical bone screws
ISO 7206-4	Hip joint prostheses fatigue testing
ASTM F2083	Knee replacement performance requirements
ISO 11135 / ISO 11607	ETO sterilisation and sterile packaging

Contact

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