



# EU Quality Management System Certificate

## Regulation (EU) 2017/745, Annex IX, Chapters I and III

HTCert Notified body (identification number 2803) certifies that

### Alesi Surgical Ltd

Cardiff Medicentre,  
Cardiff, CF14 4UJ,  
United Kingdom

SRN: GB-MF-000003881

has established, documented and implemented a quality management system in accordance with Regulation (EU) 2017/745. The conformity assessment has been carried out according to Annex IX Chapter I and III of the Regulation and it was found that the quality management system conforms to the relevant provisions.

The scope of certification, as well as further information and conditions, are described on the following page(s).

The quality management system is subject to periodical surveillance in accordance with Annex IX, Chapter 1, Section 3 of Regulation (EU) 2017/745.

The results of the assessment and information on all examinations and tests carried out are summarized in the report referred to below.

For the placing on the market of Class III devices or Class IIb implantable devices referred to in Article 52(4) subparagraph 2 covered by this certificate, an additional EU Technical Documentation Assessment certificate is required.

For Class I sterile devices, sterilized systems or procedure packs, the certificate covers only the aspects relating to establishing, securing, and maintaining sterile conditions. For Class I devices with a measuring function, the certificate covers only the aspects relating to the conformity of the devices with the metrological requirements. For Class I reusable surgical instruments, the certificate covers only the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

Further information may be requested from [certification@htcert.com](mailto:certification@htcert.com).

**Certificate No:** C08 GB003881 2503 Rev.00

Effective Date: 24/03/2025

Expiry Date: 23/03/2030

Assessment Report: FR\_GB003881\_2503

For and on behalf of HTCert

GEORGE PAPPOUS  
Managing Director

FILIPPOS KOTTIS  
Certification Director

