HTCert
Health Technology Certification

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.

Certificate No: **C08 GB003881 2503 Rev.01**

Effective Date: 09/06/2025
Expiry Date: 23/03/2030
Assessment Report: FR_ GB003881_2506

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

HTCert
Health Technology Certification

EU Authorized Representative:

Advena Limited

Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013,
Malta

SRN: MT-AR-000000234

Devices covered by the certificate

Device / Device Group:	Ultravision2 Generator
Classification:	IIb
Intended purpose:	The Ultravision2 Generator is intended to interface directly with the electrosurgical generator and serve as a pass-through for HF energy to HF electrosurgical instruments, to manage surgical smoke produced by energy-based instruments, and is indicated for use in surgery including laparoscopic surgery.

Device / Device Group:	Ultravision2 Integrated Monopolar L Hook (H/S)
Classification:	IIb
Intended purpose:	The Ultravision2 Integrated Monopolar L Hook (H/S) is intended to be used to facilitate the cutting and coagulation of soft tissue, to manage surgical smoke during laparoscopic surgical procedures, and is indicated for use in laparoscopic surgery.

Device / Device Group:	Ultravision2 IonPencil
Classification:	IIb
Intended purpose:	The Ultravision2 IonPencil is intended to be used to facilitate the cutting and coagulation of soft tissue, to manage surgical smoke during general surgical procedures, and is indicated for use in surgery.

Device / Device Group:	Ultravision 5mm Trocar
Classification:	IIb
Intended purpose:	The Ultravision 5mm Trocar is intended to be used to establish a path of entry for instruments and includes an Ionwand to manage surgical smoke, and is indicated for laparoscopic surgery.

HTCert
Health Technology Certification

Device / Device Group:	Ionwand Sterile Pack
Classification:	IIb
Intended purpose:	The Ionwand Sterile Pack is intended to be used to manage surgical smoke and is indicated for use in surgery including laparoscopic surgery.

Conditions for / limitations to the validity of the certificate: -

Certificate history

Revision	Date	Description of changes
Rev. 00	24/03/2025	Initial issue
Rev. 01	09/06/2025	Addition of Ionwand Sterile Pack