EU Quality Management System Certificate GB24/00000131

The management system of

Medasil Surgical Ltd

Medasil House Hunslet Road Leeds LS10 1AU United Kingdom

SRN Number: GB-MF 000009549

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 10 September 2024 until 13 June 2029 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 December 2028

Issue 2. Certified since 13 June 2024

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

Medasil Surgical Ltd

MDR EU Quality Management System certificate (Annex IX QMS)

class Is devices:
MDN1214, MDS1005

Sterile Single Use Silicone Boyle Davis Gag Covers (Adult & Child) (506046556140-11BB)
Sterile Single Use Silicone Bite Guards (with & without tape) (506046556101-11A6)
Sterile Silicone Tubing (506046556261-11CM)
Sterile Laser bite guard (506046556520-11C9)
Sterile Laserguard Ocular shields (506046556510-11BW)

class IIa devices:
MDN1208, MDS1005

Sterile Zoellner suction tip to provide fine suction at the aural cavity (506046556112-31AW)
Sterile Silicone Nerve Vessel Loops for slinging, retraction and identification of blood vessels, nerves and tendons during a surgical procedure (506046556420-11BU)

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - GB/PC/240818 - S2A 5.0 & TFR 1.1+1.5, 1.6+1.9
Authorized representative name and address (if relevant): European Healthcare & Device Solutions Ltd. (EHDSL) Stratton House, Bishopstown Road, T12 Y9TC Cork, Ireland

Previous certificate number: N/A
Change in between this certificate and previous one: to include class IIa devices Sterile Zoellner suction tip and Sterile Silicone Nerve Vessel Loops to the scope of certification