EU Quality Management System Certificate GB25/00000226

The management system of

Eakin Surgical Ltd

Greypoint Cardiff Business Park CF14 5WF Cardiff United Kingdom
SRN Number: GB-MF-000018442

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 12 December 2025 until 12 December 2030 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 12 June 2030

Issue 1. Certified since 12 December 2025

Authorised by
Virginie Siloret
Head of Certification and Compliance
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

EU Quality Management System Certificate
GB25/00000226, continued

Eakin Surgical Ltd

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class Is devices

MDS1005

Sterile single-use Spackman Cannula (B-UDI: 5055299SpackmanTS)
Sterile single-use ENT Forceps (B-UDI: 5055299Forceps57)

Class IIa devices

MDN1208, MDS1005

Sterile single-use Kerrison punches (B-UDI: 5055299kerrisonF7)
Sterile single-use Myringotomy Knife (B-UDI: 5055299MyrinKnife6K)
Sterile single-use Myringotomy Kit (B-UDI: 5055299Myrinkit7J)
Sterile single-use Vein Hook (B-UDI: 5055299VhookK7)

MDN1202, MDS1005

Sterile and non-sterile single-use Suction Tubes (B-UDI: 5055299SuctionDB)
Sterile and non-sterile single-use Zoellner Tips (B-UDI: 5055299SuctionDB)
Sterile single-use Aspiration Needle (B-UDI: 5055299aspirationQU)
Sterile single-use Blunt Aspiration Tube (B-UDI: 5055299aspirationQU)
Sterile single-use Curved, Angled, Straight Cannula devices (B-UDI: 5055299cannulaEA)

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.

EU Quality Management System Certificate
GB25/00000226, continued

Eakin Surgical Ltd

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Certification is based on following reports: - GB/PC/02665 –
S2A 1.2 & TFR 1.3+1.5+2.2

Authorized representative name and address (if relevant): Eakin B.V ; Medelse Poort Biezenwei 23 4004 MB Tiel Netherlands
Previous certificate number: N/A
Change in between this certificate and previous one: N/A