Swann-Morton® LIMITED

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Declaration of Conformity

Manufacturer's Name:	Swann-Morton Limited
Manufacturer's Address:	Owlerton Green, Sheffield, S6 2BJ, England
Single Registration Number:	GB-MF-000001890
BUDI-DI	50339550STERILEEORETSCQ3
European Authorised Representative Name:	Emergo Europe
European Authorised Representative Address:	Westervoortsedijk 60 6827 AT Arnhem The Netherlands
Single Registration Number:	NL-AR-000000116

This Declaration of Conformity is issued under our sole responsibility as manufacturer of the devices covered by this declaration, Swann-Morton Limited, hereby ensure and declare that these devices meet the provisions of the medical devices regulations (EU) 2017/745.
The Notified Body used for our conformity assessment in accordance with Annex IV and Annex IX of the above Regulation is BSI NL (2797).
Certificates Issued:

MDR 721051 R001 in respect of: Sterile suture remover
For Class 1s devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintain sterile conditions.

FM73368: Operates a Quality Management System which complies with the requirements of ISO 13485 for the following scope: The design, manufacture, packaging and distribution of surgical blades, disposable scalpels, handles and blade removers.

MDSAP 674417 – The company listed on this certificate has been audited to and found to conform ISO 13485:2016 including the following country specific requirements:,
Australia – Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure;
Brazil – RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 – Good Manufacturing Practices, RDC ANVISA n. 551/2021;
Canada – Medical Device Regulations – Part 1 – SOR 98/282;
Japan – MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act;
USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D.
The design, manufacture, and distribution of surgical blades, disposable scalpels, handles and blade removers.

Country Registrations:
Canada Medical Device License: 5606
U.S.A Establishment Registration & Device Listing (FDA) Registration No. 9611194 Owner/Operator No. 9003320.
Australian Register of Therapeutic Goods Certificate: 238709
Brazilian RDC number: 10302860224
Japan MHLW registration number: BG20500131

VAT Reg No. GB 172 8625 45 Reg No. 696744 ENGLAND

Product Family:	STERILE EO RETRACTABLE STITCH CUTTERS
Intended Use:	CUTTING SUTURE THREAD IN ORDER TO REMOVE IT FROM A STITCHED INJURY SITE
Product Codes:	See Page 3
Classification:	Class I (Annex VIII, Rule 1) (EU) Class II (MDR Schedule 1, Part 1, Rule 4 (Health Canada) Class I (FDA CFR 878.4800) (U.S.A – FDA) Class I (TG(MD)R 2002) Schedule 2 Part 2 (2.1) (Australia) Class I (RDC Annex II, II, 1. Rule 1) (Brazil) Class I (JMDN: 35130001 Rule 6) (Japan)
Standards Used:	See Table Below
GMDN Code & Term	16224: Suture Cutter A dedicated hand held surgical instrument for cutting sutures. It will typically have a protected scalpel like blade which may be fixed or have a scissor like cutting action.
EMDN Code & Term	V0102 - Staple Remover Knives, Single-Use

Standards applied in relation to this Declaration are:

STANDARD NUMBER	TITLE
BS EN 556-1	Sterilization of medical devices – Requirements for medical devices to be designated "Sterile" – Part 1: Requirements for terminally sterilized medical devices
BS 2982	Specification for: Materials and packaging of surgical scalpels with detachable blades
BS EN ISO 20417	Medical devices - Information to be supplied by the manufacturer
BS EN ISO 11607-1	Packaging of terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems & packaging systems
BS EN ISO 11607-2	Packaging of terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing 7 assembly processes
BS EN ISO 10993-1	Biological evaluation of medical devices: Evaluation & Testing
BS EN ISO 10993-7	Biological evaluation of medical devices: Ethylene oxide sterilization residuals
BS EN ISO 11135	Sterilization of healthcare products – Ethylene Oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
BS EN ISO 7153-1	Surgical instruments – Metallic materials – Specification for stainless steel
BS EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling & information to be supplied
BS EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
BS EN ISO 14971	Medical devices – Application of risk management to medical devices
BS EN ISO 16061	Instrumentation for use in association with non-active surgical instruments – General requirements

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PRODUCT DESCRIPTION	PRODUCT CODE	UDI
Swann Morton Sterile Retractable Stitch Cutters	3926 (In 25's)	05033955039264
Swann Morton Sterile Retractable Stitch Cutters	4926 (In 10's)	05033955049263
Swann-Morton Sterile Disposable scalpel w/retracting guard stitch cutter	3626 (in 10's)	05033955036263
Paragon Sterile Disposable scalpel w/retracting guard stitch cutter	P626 (in 10's)	05033955106263

Signed for and on behalf of Swann-Morton Limited, Owlerton Green, Sheffield S6 2BJ.

SIGNATURE	
PRINT FULL NAME	Sally Shield
POSITION	QA/RA Assistant
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 9th January 2026

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