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	50339550STERILESCQA
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 R000 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 with the following criteria: ISO 13485:2016, Australia – Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure, Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3 Part 4 – Production Quality Assurance Procedure; Brazil – RDC ANVISA n.665/2022, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada Medical Device Regulations – Part 1 – SOR 98/282; Japan – MHLW Ministerial Ordinance 169, Article 4 to 68, PMD Act AND USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D. The design, manufacture, packaging 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: 114391
Brazilian RDC number: 10302860224
Japan MHLW registration number: BG20500131

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

Product Family:	STERILE 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 used for cutting sutures. It will typically have a protected scalpel like blade which may be fixed or have a scissor like cutting action.

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 EN ISO 20417	Medical devices - Information to be supplied by the manufacturer
BS 2982	Specification for: Materials and packaging of surgical scalpels with detachable blades
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 & assembly processes
BS EN ISO 10993-1	Biological evaluation of medical devices
BS EN ISO 11137-1	Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
BS EN ISO 11137-2	Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose
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 27740/ISO 7740 *(for 0326 Code Only)*	Instruments for surgery, scalpels with detachable blades
BS EN ISO 14971	Medical devices – Application of risk management to medical devices

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PRODUCT DESCRIPTION	PRODUCT CODE	UDI
Swann-Morton Sterile (Carbon) Stitch Cutter	0420	05033955004200
Swann-Morton Sterile Midi (Stainless Steel) Stitch Cutter	0422	05033955004224
Swann-Morton Sterile Long (Stainless Steel) Stitch Cutter	0421	05033955004217
Swann-Morton Sterile (No. 3 Fitment) (Stainless Steel) Stitch Cutter	0326	05033955003265
Swann-Morton Sterile Disposable Scalpel Stitch Cutter	0526	05033955005269
Swann-Morton Sterile Retractable Scalpel Stitch Cutter (Sold in 25's)	3926	05033955039264
Swann-Morton Sterile Retractable Scalpel Stitch Cutter (Sold in 10's)	4926	05033955049263
Paragon Sterile Midi (Stainless Steel) Stitch Cutter	P420	05033955104207
Lance Sterile Midi (Stainless Steel) Stitch Cutter	L420	05033955114206
Hartmann Stitch Cutter	0470	05033955004705

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

SIGNATURE	
PRINT FULL NAME	Darren Hall
POSITION	QA/RA Systems Manager
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 1st February 2023

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