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:	Not yet issued
BUDI-DI	50339550STERILESCQA
European Authorised Representative Name:	Emergo Europe
European Authorised Representative Address:	Prinsessegracht 20 2514 AP The Hague The Netherlands
Single Registration Number:	Not yet issued

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.16/2013, 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 6) (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 1041	Information supplied by the manufacturer of medical devices
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 ISO 14971	Medical devices – Application of risk management to medical devices

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PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile (Carbon) Stitch Cutter	N/A	0420	5033955004200
Swann-Morton Sterile Midi (Stainless Steel) Stitch Cutter	N/A	0422	5033955004224
Swann-Morton Sterile Long (Stainless Steel) Stitch Cutter	N/A	0421	5033955004217
Swann-Morton Sterile (No. 3 Fitment) (Stainless Steel) Stitch Cutter	N/A	0326	5033955003265
Swann-Morton Sterile Disposable Scalpel Stitch Cutter	N/A	0526	5033955005269
Swann-Morton Sterile Retractable Scalpel Stitch Cutter (Sold in 25's)	N/A	3926	5033955039264
Swann-Morton Sterile Retractable Scalpel Stitch Cutter (Sold in 10's)	N/A	4926	5033955049263
Paragon Sterile Midi (Stainless Steel) Stitch Cutter	N/A	P420	5033955104207
Lance Sterile Midi (Stainless Steel) Stitch Cutter	N/A	L420	5033955114206
Hartmann Stitch Cutter	N/A	0470	5033955004705

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

SIGNATURE	
PRINT FULL NAME	Darren Hall
POSITION	Quality Assurance/Regulatory Affairs Systems Manager
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 1st January 2021

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