

Declaration of Conformity

Manufacturer's Name: Swann-Morton Limited

Manufacturer's Address: Penn Works, Owlerton Green, Sheffield S6 2BJ, England

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 EC Directive 93/42/EEC and the amending Directive 2007/47/EC.

The Notified Body used for our conformity assessment in accordance with Annex V of the above Directive is BSI (0086). Certificates Issued:

CE 59550 in respect of: Those aspects of Annex V related to securing and maintaining the sterility in the manufacture of stitch cutters.

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 AND CANADA – Medical Devices Regulations – Part 1 - SOR 92/282: USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A-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.


Product Family:	STERILE STITCH CUTTERS
Intended Use:	CUTTING SUTURE THREAD IN ORDER TO REMOVE IT FROM A STITCHED INJURY SITE
Product Codes:	See Pages 2
Classification:	Class I (Annex IX Rule 6)(EU) Class II (MDR Schedule 1, Part 1, Rule 4 (Health Canada) Class 1 (FDA CFR 878.4800) (U.S.A – FDA)
Harmonised Standards Used:	See Page 2
GMDN Term & Definition	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.

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

Harmonized standards used 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 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

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

SIGNATURE	
PRINT FULL NAME	Darren Hall
POSITION	QA/RA Systems Manager
PLACE & DATE	Swann-Morton Ltd, Sheffield S5 2BJ, England 26 th April 2019

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