

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.


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|-----------------------------------|---|
| 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 1(1) (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

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|-------------------------|--|
| 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 |