

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 50339550STERILEDISPS89

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 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: Single use surgical scalpels and blades

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: 114372

Brazilian RDC number: 10302860224

Japan MHLW registration number: BG20500131

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|-----------------------------|--|
| Product Family: | STERILE DISPOSABLE SCALPELS |
| Intended Use: | SKIN AND TISSUE CUTTING |
| Product Codes: | See Pages 3, 4, 5 & 6 |
| Classification: | Class IIa (Annex VIII, Rule 6) (EU) Class II (MDR Schedule 1, Part 1, Rule 1(1) (Health Canada) Class I (FDA CFR 878.4800) (U.S.A – FDA) Class IIa (TG(MD)R 2002) Schedule 3 Part 3.2(2) (Australia) Class II (RDC Annex II, II, 2. Rule 6) (Brazil) Class II (JMDN: 35130002 Rule 6) (Japan) |
| Standards Used: | See Table Below |
| GMDN Code & Term | 47569: Scalpel, Single Use A sterile, hand held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single use device. |

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 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 |
| BS EN ISO 16061 | Instrumentation for use in association with non-active surgical instruments – General requirements |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|--|-------------|--------------|----------------|
| Swann-Morton Sterile Disposable Scalpels | 6 | 0516 | 05033955005160 |
| Swann-Morton Sterile Disposable Scalpels | 9 | 0517 | 05033955005177 |
| Swann-Morton Sterile Disposable Scalpels | 10 | 0501 | 05033955005016 |
| Swann-Morton Sterile Disposable Scalpels | 10A | 0502 | 05033955005023 |
| Swann-Morton Sterile Disposable Scalpels | 11 | 0503 | 05033955005030 |
| Swann-Morton Sterile Disposable Scalpels | E11 | 0525 | 05033955005252 |
| Swann-Morton Sterile Disposable Scalpels | 12 | 0504 | 05033955005047 |
| Swann-Morton Sterile Disposable Scalpels | 12D | 0518 | 05033955005184 |
| Swann-Morton Sterile Disposable Scalpels | 13 | 0539 | 05033955005399 |
| Swann-Morton Sterile Disposable Scalpels | 14 | 0519 | 05033955005191 |
| Swann-Morton Sterile Disposable Scalpels | 15 | 0505 | 05033955005054 |
| Swann-Morton Sterile Disposable Scalpels | 15A | 0520 | 05033955005207 |
| Swann-Morton Sterile Disposable Scalpels | 15C | 0521 | 05033955005214 |
| Swann-Morton Sterile Disposable Scalpels | 16 | 0522 | 05033955005221 |
| Swann-Morton Sterile Disposable Scalpels | 18 | 0523 | 05033955005238 |
| Swann-Morton Sterile Disposable Scalpels | 19 | 0524 | 05033955005245 |
| Swann-Morton Sterile Disposable Scalpels | 20 | 0506 | 05033955005061 |
| Swann-Morton Sterile Disposable Scalpels | 21 | 0507 | 05033955005078 |
| Swann-Morton Sterile Disposable Scalpels | 22 | 0508 | 05033955005085 |
| Swann-Morton Sterile Disposable Scalpels | 22A | 0509 | 05033955005092 |
| Swann-Morton Sterile Disposable Scalpels | 23 | 0510 | 05033955005108 |
| Swann-Morton Sterile Disposable Scalpels | 24 | 0511 | 05033955005115 |
| Swann-Morton Sterile Disposable Scalpels | 25 | 0512 | 05033955005122 |
| Swann-Morton Sterile Disposable Scalpels | 25A | 0515 | 05033955005153 |
| Swann-Morton Sterile Disposable Scalpels | 26 | 0513 | 05033955005139 |
| Swann-Morton Sterile Disposable Scalpels | 27 | 0514 | 05033955005146 |
| Swann-Morton Sterile Disposable Scalpels | SGD | 0527 | 05033955005276 |
| Swann-Morton Sterile Disposable Scalpels | Sabre E11 | 0563 | 05033955005634 |
| Swann-Morton Sterile Disposable Scalpels | Sabre D15 | 0565 | 05033955005658 |
| Swann-Morton Sterile Disposable Scalpels | Sabre B23 | 0570 | 05033955005702 |
| Swann-Morton Sterile Disposable Scalpels | 11P | 0591 | 05033955005917 |
| Swann-Morton Sterile Disposable Scalpels | 15T | 0592 | 05033955005924 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|---|-------------|--------------|----------------|
| Swann-Morton Sterile Disposable Scalpels with Guard | 10 | 6601 | 05033955066017 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 10A | 6602 | 05033955066024 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 11 | 6603 | 05033955066031 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 15 | 6605 | 05033955066055 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 20 | 6606 | 05033955066062 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 21 | 6607 | 05033955066079 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 22 | 6608 | 05033955066086 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 23 | 6610 | 05033955066109 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 24 | 6611 | 05033955066116 |
| Swann-Morton Sterile Disposable Scalpels with Guard | 10R | 6690 | 05033955066901 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|---|-------------|--------------|----------------|
| Swann-Morton Sterile Retractable Scalpels | 10 | 3901 | 05033955039011 |
| Swann-Morton Sterile Retractable Scalpels | 10A | 3902 | 05033955039028 |
| Swann-Morton Sterile Retractable Scalpels | 12 | 3904 | 05033955039042 |
| Swann-Morton Sterile Retractable Scalpels | 15 | 3905 | 05033955039059 |
| Swann-Morton Sterile Retractable Scalpels | 14 | 3919 | 05033955039196 |
| Swann-Morton Sterile Retractable Scalpels | 11P | 3991 | 05033955039912 |
| Swann-Morton Sterile Retractable Scalpels | 20 | 3906 | 05033955039066 |
| Swann-Morton Sterile Retractable Scalpels | 21 | 3907 | 05033955039073 |
| Swann-Morton Sterile Retractable Scalpels | 22 | 3908 | 05033955039080 |
| Swann-Morton Sterile Retractable Scalpels | 23 | 3910 | 05033955039103 |
| Swann-Morton Sterile Retractable Scalpels | 24 | 3911 | 05033955039110 |
| Swann-Morton Sterile Retractable Scalpels | 25A | 3915 | 05033955039158 |
| Swann-Morton Sterile Retractable Scalpels | 15C | 3921 | 05033955039219 |


| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|---|-------------|--------------|----------------|
| Swann-Morton Sterile Retractable Scalpels | 10 | 4901 | 05033955049010 |
| Swann-Morton Sterile Retractable Scalpels | 10A | 4902 | 05033955049027 |
| Swann-Morton Sterile Retractable Scalpels | 12 | 4904 | 05033955049041 |
| Swann-Morton Sterile Retractable Scalpels | 15 | 4905 | 05033955049058 |
| Swann-Morton Sterile Retractable Scalpels | 20 | 4906 | 05033955049065 |
| Swann-Morton Sterile Retractable Scalpels | 21 | 4907 | 05033955049072 |
| Swann-Morton Sterile Retractable Scalpels | 22 | 4908 | 05033955049089 |
| Swann-Morton Sterile Retractable Scalpels | 23 | 4910 | 05033955049102 |
| Swann-Morton Sterile Retractable Scalpels | 24 | 4911 | 05033955049119 |
| Swann-Morton Sterile Retractable Scalpels | 25A | 4915 | 05033955049157 |
| Swann-Morton Sterile Retractable Scalpels | 14 | 4919 | 05033955049195 |
| Swann-Morton Sterile Retractable Scalpels | 15C | 4921 | 05033955049218 |
| Swann-Morton Sterile Retractable Scalpels | 10R | 4990 | 05033955049904 |
| Swann-Morton Sterile Retractable Scalpels | 11P | 4991 | 05033955049911 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|-----------------------------------|-------------|--------------|----------------|
| Lance Sterile Disposable Scalpels | 10 | L501 | 05033955115012 |
| Lance Sterile Disposable Scalpels | 11 | L503 | 05033955115036 |
| Lance Sterile Disposable Scalpels | 12 | L504 | 05033955115043 |
| Lance Sterile Disposable Scalpels | 15 | L505 | 05033955115050 |
| Lance Sterile Disposable Scalpels | 20 | L506 | 05033955115067 |
| Lance Sterile Disposable Scalpels | 21 | L507 | 05033955115074 |
| Lance Sterile Disposable Scalpels | 22 | L508 | 05033955115081 |
| Lance Sterile Disposable Scalpels | 23 | L510 | 05033955115104 |
| Lance Sterile Disposable Scalpels | 24 | L511 | 05033955115111 |
| Lance Sterile Disposable Scalpels | 15T | L592 | 05033955115920 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|------------------------------------|-------------|--------------|----------------|
| Paragon Sterile Disposable Scalpel | 10 | P501 | 05033955105013 |
| Paragon Sterile Disposable Scalpel | 11 | P503 | 05033955105037 |
| Paragon Sterile Disposable Scalpel | 12 | P504 | 05033955105044 |
| Paragon Sterile Disposable Scalpel | 15 | P505 | 05033955105051 |
| Paragon Sterile Disposable Scalpel | 20 | P506 | 05033955105068 |
| Paragon Sterile Disposable Scalpel | 21 | P507 | 05033955105075 |
| Paragon Sterile Disposable Scalpel | 22 | P508 | 05033955105082 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|------------------------------------|-------------|--------------|----------------|
| Paragon Sterile Disposable Scalpel | 23 | P510 | 05033955105105 |
| Paragon Sterile Disposable Scalpel | 24 | P511 | 05033955105112 |
| Paragon Sterile Disposable Scalpel | 15T | P592 | 05033955105921 |

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 1 st February 2023 |