

Declaration of Conformity

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| Manufacturer's Name: | Swann-Morton Limited |
| Manufacturer's Address: | Owlerton Green, Sheffield, S6 2BJ, England |
| Single Registration Number: | GB-MF-000001890 |
| BUDI-DI | 50339550STERILEFINE6U |
| 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: 114374

Brazilian RDC number: 10302860224

Japan MHLW registration number: BG20500131

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| Product Family: | STERILE FINE SURGICAL BLADES |
| Intended Use: | SKIN AND TISSUE CUTTING |
| Product Codes: | See Page 3 |
| 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 | 37445 Blade, Scalpel, Single Use A component of a surgical instrument (scalpel) that is designed to be attached to a handle. It is capable of cutting through tissue when moved with downward pressure. |

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 Fine Surgical Blade | SM61 | 5901 | 05033955059019 |
| Swann Morton Sterile Fine Surgical Blade | SM62 | 5902 | 05033955059026 |
| Swann Morton Sterile Fine Surgical Blade | SM63 | 5903 | 05033955059033 |
| Swann Morton Sterile Fine Surgical Blade | SM64 | 5904 | 05033955059040 |
| Swann Morton Sterile Fine Surgical Blade | SM65 | 5905 | 05033955059057 |
| Swann Morton Sterile Fine Surgical Blade | SM65A | 5906 | 05033955059064 |
| Swann Morton Sterile Fine Surgical Blade | SM67 | 5907 | 05033955059071 |
| Swann Morton Sterile Fine Surgical Blade | SM68 | 5908 | 05033955059088 |
| Swann Morton Sterile Fine Surgical Blade | SM69 | 5909 | 05033955059095 |
| Swann Morton Sterile Fine Surgical Blade | Single Bevel Fine SM61 | 5911 | 05033955059118 |
| Swann Morton Sterile Fine Surgical Blade | Single Bevel Fine SM62 | 5912 | 05033955059125 |
| Swann Morton Sterile Fine Surgical Blade | Fine 90 (SP) | 5921 | 05033955059217 |
| Swann Morton Sterile Fine Surgical Blade | Fine 91 (SP) | 5922 | 05033955059224 |

Signed for and on behalf of Swann-Morton Limited, 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 S6 2BJ, England 1 st February 2023 |