

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 | 50339550STERILEBLADES8D |
| 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 (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: 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: 10302860222 & 10302860224

Japan MHLW registration number: BG20500131

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| Product Family: | STERILE SURGICAL BLADES |
| Intended Use: | SKIN AND TISSUE CUTTING |
| Product Codes: | See Pages 3, 4, 5 and 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 | 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 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 27740/ISO 7740 | Instruments for surgery, scalpels with detachable blades |
| BS 2982 | Materials and packaging of surgical scalpels with detachable blades |
| BS EN ISO 15223-1 | Medical devices – Symbols to be used with medical device labels, labelling & information to be supplied |
| 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 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 Carbon Steel Surgical Blade | 10 | 0201 | 05033955002015 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 10A | 0202 | 05033955002022 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 11 | 0203 | 05033955002039 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 12 | 0204 | 05033955002046 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 15 | 0205 | 05033955002053 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 20 | 0206 | 05033955002060 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 21 | 0207 | 05033955002077 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 22 | 0208 | 05033955002084 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 22A | 0209 | 05033955002091 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 23 | 0210 | 05033955002107 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 24 | 0211 | 05033955002114 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 25 | 0212 | 05033955002121 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 26 | 0213 | 05033955002138 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 27 | 0214 | 05033955002145 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 25A | 0215 | 05033955002152 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 6 | 0216 | 05033955002169 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 9 | 0217 | 05033955002176 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 12D | 0218 | 05033955002183 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 14 | 0219 | 05033955002190 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 15A | 0220 | 05033955002206 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 15C | 0221 | 05033955002213 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 16 | 0222 | 05033955002220 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 18 | 0223 | 05033955002237 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 19 | 0224 | 05033955002244 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | E11 | 0225 | 05033955002251 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 36 | 0236 | 05033955002367 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 13 | 0239 | 05033955002398 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 40 | 0240 | 05033955002404 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | E11 (Sabre) | 0263 | 05033955002633 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | D15 (Sabre) | 0265 | 05033955002657 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 11P | 0291 | 05033955002916 |
| Swann-Morton Sterile Carbon Steel Surgical Blade | 15T | 0292 | 05033955002923 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|---|-------------|--------------|----------------|
| Swann-Morton Sterile Stainless Steel Surgical Blade | 10 | 0301 | 05033955003012 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 10A | 0302 | 05033955003029 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 11 | 0303 | 05033955003036 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 12 | 0304 | 05033955003043 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 15 | 0305 | 05033955003050 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 20 | 0306 | 05033955003067 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 21 | 0307 | 05033955003074 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 22 | 0308 | 05033955003081 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 22A | 0309 | 05033955003098 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 23 | 0310 | 05033955003104 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 24 | 0311 | 05033955003111 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 25 | 0312 | 05033955003128 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 26 | 0313 | 05033955003135 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 27 | 0314 | 05033955003142 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 25A | 0315 | 05033955003159 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 6 | 0316 | 05033955003166 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 9 | 0317 | 05033955003173 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 12D | 0318 | 05033955003180 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 14 | 0319 | 05033955003197 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 15A | 0320 | 05033955003203 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 15C | 0321 | 05033955003210 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 16 | 0322 | 05033955003227 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 18 | 0323 | 05033955003234 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 19 | 0324 | 05033955003241 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | E11 | 0325 | 05033955003258 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 13 | 0339 | 05033955003395 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 10R | 0390 | 05033955003906 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 11P | 0391 | 05033955003913 |
| Swann-Morton Sterile Stainless Steel Surgical Blade | 15T | 0392 | 05033955003920 |


| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|---|-------------|--------------|----------------|
| Lance Sterile Carbon Steel Surgical Blade | 10 | L201 | 05033955112011 |
| Lance Sterile Carbon Steel Surgical Blade | 11 | L203 | 05033955112035 |
| Lance Sterile Carbon Steel Surgical Blade | 12 | L204 | 05033955112042 |
| Lance Sterile Carbon Steel Surgical Blade | 15 | L205 | 05033955112059 |
| Lance Sterile Carbon Steel Surgical Blade | 20 | L206 | 05033955112066 |
| Lance Sterile Carbon Steel Surgical Blade | 21 | L207 | 05033955112073 |
| Lance Sterile Carbon Steel Surgical Blade | 22 | L208 | 05033955112080 |
| Lance Sterile Carbon Steel Surgical Blade | 23 | L210 | 05033955112103 |
| Lance Sterile Carbon Steel Surgical Blade | 15T | L292 | 05033955112929 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|--|-------------|--------------|----------------|
| Lance Sterile Stainless Steel Surgical Blade | 10 | L301 | 05033955113018 |
| Lance Sterile Stainless Steel Surgical Blade | 11 | L303 | 05033955113032 |
| Lance Sterile Stainless Steel Surgical Blade | 12 | L304 | 05033955113049 |
| Lance Sterile Stainless Steel Surgical Blade | 15 | L305 | 05033955113056 |
| Lance Sterile Stainless Steel Surgical Blade | 20 | L306 | 05033955113063 |
| Lance Sterile Stainless Steel Surgical Blade | 21 | L307 | 05033955113070 |
| Lance Sterile Stainless Steel Surgical Blade | 22 | L308 | 05033955113087 |
| Lance Sterile Stainless Steel Surgical Blade | 23 | L310 | 05033955113100 |
| Lance Sterile Stainless Steel Surgical Blade | 24 | L311 | 05033955113117 |
| Lance Sterile Stainless Steel Surgical Blade | 25A | L315 | 05033955113155 |
| Lance Sterile Stainless Steel Surgical Blade | 15T | L392 | 05033955113926 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|---|-------------|--------------|----------------|
| Paragon Sterile Carbon Steel Surgical Blade | 10 | P201 | 05033955102012 |
| Paragon Sterile Carbon Steel Surgical Blade | 11 | P203 | 05033955102036 |
| Paragon Sterile Carbon Steel Surgical Blade | 12 | P204 | 05033955102043 |
| Paragon Sterile Carbon Steel Surgical Blade | 15 | P205 | 05033955102050 |
| Paragon Sterile Carbon Steel Surgical Blade | 20 | P206 | 05033955102067 |
| Paragon Sterile Carbon Steel Surgical Blade | 21 | P207 | 05033955102074 |
| Paragon Sterile Carbon Steel Surgical Blade | 22 | P208 | 05033955102081 |
| Paragon Sterile Carbon Steel Surgical Blade | 23 | P210 | 05033955102104 |
| Paragon Sterile Carbon Steel Surgical Blade | 24 | P211 | 05033955102111 |
| Paragon Sterile Carbon Steel Surgical Blade | 15T | P292 | 05033955102920 |

| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|--|-------------|--------------|----------------|
| Paragon Sterile Stainless Steel Surgical Blade | 10 | P301 | 05033955103019 |
| Paragon Sterile Stainless Steel Surgical Blade | 10A | P302 | 05033955103026 |
| Paragon Sterile Stainless Steel Surgical Blade | 11 | P303 | 05033955103033 |
| Paragon Sterile Stainless Steel Surgical Blade | 12 | P304 | 05033955103040 |
| Paragon Sterile Stainless Steel Surgical Blade | 15 | P305 | 05033955103057 |
| Paragon Sterile Stainless Steel Surgical Blade | 20 | P306 | 05033955103064 |
| Paragon Sterile Stainless Steel Surgical Blade | 21 | P307 | 05033955103071 |
| Paragon Sterile Stainless Steel Surgical Blade | 22 | P308 | 05033955103088 |
| Paragon Sterile Stainless Steel Surgical Blade | 23 | P310 | 05033955103101 |
| Paragon Sterile Stainless Steel Surgical Blade | 24 | P311 | 05033955103118 |
| Paragon Sterile Stainless Steel Surgical Blade | 25 | P312 | 05033955103125 |
| Paragon Sterile Stainless Steel Surgical Blade | 25A | P315 | 05033955103156 |
| Paragon Sterile Stainless Steel Surgical Blade | 6 | P316 | 05033955103163 |
| Paragon Sterile Stainless Steel Surgical Blade | 15T | P392 | 05033955103927 |

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 |