Swann-Morton® LIMITED

Owlerton Green
Sheffield, S6 2BJ
Telephone: (0114) 234 4231
Email: info@swann-morton.com
Web: www.swann-morton.com

# Declaration of Conformity

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| **Manufacturer's Name:** | Swann-Morton Limited |
| **Manufacturer's Address:** | Owlerton Green,<br>Sheffield, S6 2BJ, England |
| **Single Registration Number:** | GB-MF-000001890 |
| **BUDI-DI** | 50339550STERILESKGRAFTRT |
| **European Authorised Representative Name:** | Emergo Europe |
| **European Authorised Representative Address:** | Westervoortsedijk 60<br>6827 AT Arnhem<br>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: 297237
Brazilian RDC number: 10302860262
Japan MHLW registration number: BG20500131



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

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| **Product Family:** | STERILE SKIN GRAFT BLADES |
| **Intended Use:** | SKIN AND TISSUE CUTTING SKIN AND TISSUE SLICING/LIFTING PORTIONS OF DERMIS FOR SKIN GRAFTING OPERATIONS |
| **Product Codes:** | See Page 3 |
| **Classification:** | Class IIa (Annex VIII, Rule 6) (EU)<br>Class II (MDR Schedule 1, Part 1, Rule 1(1)) (Health Canada)<br>Class I (FDA CFR 878.4800) (U.S.A – FDA)<br>Class IIa (TG(MD)R 2002 Schedule 3 Part 3.2(2)) (Australia)<br>Class II (RDC Annex II, II, 2. Rule 6) (Brazil)<br>Class II (JMDN: 35130002 Rule 6) (Japan) |
| **Standards Used:** | See Below |
| **GMDN Code & Term** | 35134 Blade, Dermatome, Single Use. To fit a dermatome.<br>A surgical instrument used for harvesting skin for grafting purposes. |

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.<br>Part 1: Requirements for materials, sterile barrier systems & packaging systems |
| BS EN ISO 11607-2 | Packaging of terminally sterilized medical devices.<br>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 |



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| PRODUCT DESCRIPTION | BLADE SHAPE | PRODUCT CODE | UDI |
|---|---|---|---|
| Swann-Morton Sterile Skin Graft Blades | SG3 | 2201 | 05033955022013 |
| Swann-Morton Sterile Skin Graft Blades | SGD | 2203 | 05033955022037 |
| Swann-Morton Sterile Skin Graft Blades (158mm) | N/A | 9940 | 05033955099404 |
| Swann-Morton Sterile Skin Graft Blades (Silvers) | N/A | 9942 | 05033955099428 |
| Swann-Morton Sterile Skin Graft Blade DER 001 | N/A | 9943 | 05033955099435 |
| Swann-Morton Sterile Skin Graft Blades DER 002 | N/A | 9944 | 05033955099442 |
| Swann-Morton Sterile Skin Graft Blades DER 003 | N/A | 9945 | 05033955099459 |
| Paragon Sterile Skin Graft Blades (158mm) | N/A | PS50 | 05033955120504 |
| Swann-Morton Sterile Skin Graft Blades + Non-Sterile Braithwaite Handle | N/A | 9904 | 05033955099046 |
| Swann-Morton Sterile Skin Graft Blades + Non-Sterile Cobbett Handle | N/A | 9905 | 05033955099053 |
| Swann-Morton Sterile Skin Graft Blades + Non-Sterile Watson Handle | N/A | 9906 | 05033955099060 |

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<br>1st February 2023 |



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