Swann-Morton® LIMITED

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# 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** | 50339550NONSTCYGHANDLEUZ |
| **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: Reusable Instruments
For Class 1r devices (class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

**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: 72
U.S.A Establishment Registration & Device Listing (FDA) Registration No. 9611194 Owner/Operator No. 9003320.
Australian Register of Therapeutic Goods Certificate: N/A
Brazilian RDC number: N/A
Japan MHLW registration number: BG20500131



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

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| **Product Family:** | NON-STERILE CYGNETIC HANDLES |
| **Intended Use:** | TO HOLD A CYGNETIC SURGICAL BLADE |
| **Product Codes:** | See Table Below |
| **Classification:** | Class I (Reusable) (Annex VIII, Rule 6) (EU)<br>Class I (MDR Schedule 1, Part 1, Rule 3 (Health Canada)<br>Class I (FDA CFR 878.4800) (U.S.A – FDA)<br>Class I (TG(MD)R 2002) Schedule 2 Part 3.2(4) (Australia)<br>Class I (RDC Annex II, II, 1. Rule 1) (Brazil)<br>Class I (JMDN: 12235000 Rule 6) (Japan) |
| **Standards Used:** | See Table Below |
| **GMDN Code & Term** | 12235 Knife/Blade Handle<br>A metal surgical instrument, e.g. stainless steel or brass, designed to mount a compatible blade used for cutting or dissecting tissue. |

Standards applied in relation to this Declaration are:

| STANDARD NUMBER | TITLE |
|---|---|
| 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 17664 – 1 | Processing of healthcare products, information to be provided by the medical device manufacturer for the processing of medical devices |
| BS EN ISO 20417 | Medical Devices – Information to be supplied by the manufacturer |

| PRODUCT DESCRIPTION | PATTERN | PRODUCT CODE | UDI |
|---|---|---|---|
| Swann-Morton Non-Sterile Cygnetic Handle | N/A | 5398 | 05033955053987 |

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>11th May 2023 |



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