

## Declaration of Conformity

<b>Manufacturer's Name:</b>	Swann-Morton Limited
<b>Manufacturer's Address:</b>	Owlerton Green, Sheffield, S6 2BJ, England
<b>Single Registration Number:</b>	Not yet issued
<b>BUDI-DI</b>	50339550STERILEDISPS89
<b>European Authorised Representative Name:</b>	Emergo Europe
<b>European Authorised Representative Address:</b>	Prinsessegracht 20 2514 AP The Hague The Netherlands
<b>Single Registration Number:</b>	Not yet issued

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.16/2013, 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

<b>Product Family:</b>	STERILE DISPOSABLE SCALPELS
<b>Intended Use:</b>	SKIN AND TISSUE CUTTING
<b>Product Codes:</b>	See Pages 3, 4, 5 & 6
<b>Classification:</b>	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)
<b>Standards Used:</b>	See Table Below
<b>GMDN Code &amp; Term</b>	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 1041	Information supplied by the manufacturer of medical devices
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	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile Disposable Scalpels	6	0516	5033955005160
Swann-Morton Sterile Disposable Scalpels	9	0517	5033955005177
Swann-Morton Sterile Disposable Scalpels	10	0501	5033955005016
Swann-Morton Sterile Disposable Scalpels	10A	0502	5033955005023
Swann-Morton Sterile Disposable Scalpels	11	0503	5033955005030
Swann-Morton Sterile Disposable Scalpels	E11	0525	5033955005252
Swann-Morton Sterile Disposable Scalpels	12	0504	5033955005047
Swann-Morton Sterile Disposable Scalpels	12D	0518	5033955005184
Swann-Morton Sterile Disposable Scalpels	13	0539	5033955005399
Swann-Morton Sterile Disposable Scalpels	14	0519	5033955005191
Swann-Morton Sterile Disposable Scalpels	15	0505	5033955005054
Swann-Morton Sterile Disposable Scalpels	15A	0520	5033955005207
Swann-Morton Sterile Disposable Scalpels	15C	0521	5033955005214
Swann-Morton Sterile Disposable Scalpels	16	0522	5033955005221
Swann-Morton Sterile Disposable Scalpels	18	0523	5033955005238
Swann-Morton Sterile Disposable Scalpels	19	0524	5033955005245
Swann-Morton Sterile Disposable Scalpels	20	0506	5033955005061
Swann-Morton Sterile Disposable Scalpels	21	0507	5033955005078
Swann-Morton Sterile Disposable Scalpels	22	0508	5033955005085
Swann-Morton Sterile Disposable Scalpels	22A	0509	5033955005092
Swann-Morton Sterile Disposable Scalpels	23	0510	5033955005108
Swann-Morton Sterile Disposable Scalpels	24	0511	5033955005115
Swann-Morton Sterile Disposable Scalpels	25	0512	5033955005122
Swann-Morton Sterile Disposable Scalpels	25A	0515	5033955005153
Swann-Morton Sterile Disposable Scalpels	26	0513	5033955005139
Swann-Morton Sterile Disposable Scalpels	27	0514	5033955005146
Swann-Morton Sterile Disposable Scalpels	SGD	0527	5033955005276
Swann-Morton Sterile Disposable Scalpels	Sabre E11	0563	5033955005634
Swann-Morton Sterile Disposable Scalpels	Sabre D15	0565	5033955005658



PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile Disposable Scalpels	Sabre B23	0570	5033955005702
Swann-Morton Sterile Disposable Scalpels	11P	0591	5033955005917
Swann-Morton Sterile Disposable Scalpels	15T	0592	5033955005924

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile Disposable Scalpels with Guard	10	6601	5033955066017
Swann-Morton Sterile Disposable Scalpels with Guard	10A	6602	5033955066024
Swann-Morton Sterile Disposable Scalpels with Guard	11	6603	5033955066031
Swann-Morton Sterile Disposable Scalpels with Guard	12	6604	5033955066048
Swann-Morton Sterile Disposable Scalpels with Guard	15	6605	5033955066055
Swann-Morton Sterile Disposable Scalpels with Guard	20	6606	5033955066062
Swann-Morton Sterile Disposable Scalpels with Guard	21	6607	5033955066079
Swann-Morton Sterile Disposable Scalpels with Guard	22	6608	5033955066086
Swann-Morton Sterile Disposable Scalpels with Guard	23	6610	5033955066109
Swann-Morton Sterile Disposable Scalpels with Guard	24	6611	5033955066116

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile Retractable Scalpels	10	3901	5033955039011
Swann-Morton Sterile Retractable Scalpels	15	3905	5033955039059
Swann-Morton Sterile Retractable Scalpels	11P	3991	5033955039912
Swann-Morton Sterile Retractable Scalpels	20	3906	5033955039066
Swann-Morton Sterile Retractable Scalpels	21	3907	5033955039073
Swann-Morton Sterile Retractable Scalpels	22	3908	5033955039080
Swann-Morton Sterile Retractable Scalpels	23	3910	5033955039103
Swann-Morton Sterile Retractable Scalpels	24	3911	5033955039110
Swann-Morton Sterile Retractable Scalpels	25A	3915	5033955039158

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile Retractable Scalpels	10	4901	5033955049010
Swann-Morton Sterile Retractable Scalpels	10A	4902	5033955049027
Swann-Morton Sterile Retractable Scalpels	12	4904	5033955049041

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Sterile Retractable Scalpels	15	4905	5033955049058
Swann-Morton Sterile Retractable Scalpels	20	4906	5033955049065
Swann-Morton Sterile Retractable Scalpels	21	4907	5033955049072
Swann-Morton Sterile Retractable Scalpels	22	4908	5033955049089
Swann-Morton Sterile Retractable Scalpels	23	4910	5033955049102
Swann-Morton Sterile Retractable Scalpels	24	4911	5033955049119
Swann-Morton Sterile Retractable Scalpels	25A	4915	5033955049157
Swann-Morton Sterile Retractable Scalpels	14	4919	5033955049195
Swann-Morton Sterile Retractable Scalpels	15C	4921	5033955049218
Swann-Morton Sterile Retractable Scalpels	10R	4990	5033955049904
Swann-Morton Sterile Retractable Scalpels	11P	4991	5033955049911

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Lance Sterile Disposable Scalpels	10	L501	5033955115012
Lance Sterile Disposable Scalpels	11	L503	5033955115036
Lance Sterile Disposable Scalpels	12	L504	5033955115043
Lance Sterile Disposable Scalpels	15	L505	5033955115050
Lance Sterile Disposable Scalpels	20	L506	5033955115067
Lance Sterile Disposable Scalpels	21	L507	5033955115074
Lance Sterile Disposable Scalpels	22	L508	5033955115081
Lance Sterile Disposable Scalpels	23	L510	5033955115104
Lance Sterile Disposable Scalpels	24	L511	5033955115111
Lance Sterile Disposable Scalpels	15T	L592	5033955115920

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Paragon Sterile Disposable Scalpel	10	P501	5033955105013
Paragon Sterile Disposable Scalpel	11	P503	5033955105037
Paragon Sterile Disposable Scalpel	12	P504	5033955105044
Paragon Sterile Disposable Scalpel	15	P505	5033955105051
Paragon Sterile Disposable Scalpel	20	P506	5033955105068
Paragon Sterile Disposable Scalpel	21	P507	5033955105075

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Paragon Sterile Disposable Scalpel	22	P508	5033955105082
Paragon Sterile Disposable Scalpel	23	P510	5033955105105
Paragon Sterile Disposable Scalpel	24	P511	5033955105112
Paragon Sterile Disposable Scalpel	15T	P592	5033955105921

Signed for and on behalf of Swann-Morton Limited, Owlerton Green, Sheffield S6 2BJ

<b>SIGNATURE</b>	
<b>PRINT FULL NAME</b>	Darren Hall
<b>POSITION</b>	Quality Assurance/Regulatory Affairs Systems Manager
<b>PLACE &amp; DATE</b>	Swann-Morton Ltd, Sheffield S6 2BJ, England 1st January 2021