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

Manufacturer's Name:	Swann-Morton Limited
Manufacturer's Address:	Owlerton Green, Sheffield, S6 2BJ, England
Single Registration Number:	GB-MF-000001890
BUDI-DI	50339550STERILEDISPS89
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 ISO 13485:2016 including the following country specific requirements:,
Australia – Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure;
Brazil – RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 – Good Manufacturing Practices, RDC ANVISA n. 551/2021;
Canada – Medical Device Regulations – Part 1 – SOR 98/282;
Japan – MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act;
USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D.
The design, manufacture, 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

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

Product Family:	STERILE DISPOSABLE SCALPELS
Intended Use:	SKIN AND TISSUE CUTTING
Product Codes:	See Pages 3, 4, 5 & 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	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 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

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PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Sterile Disposable Scalpels	10	0501	05033955005016
Swann-Morton Sterile Disposable Scalpels	10A	0502	05033955005023
Swann-Morton Sterile Disposable Scalpels	11	0503	05033955005030
Swann-Morton Sterile Disposable Scalpels	12	0504	05033955005047
Swann-Morton Sterile Disposable Scalpels	15	0505	05033955005054
Swann-Morton Sterile Disposable Scalpels	20	0506	05033955005061
Swann-Morton Sterile Disposable Scalpels	21	0507	05033955005078
Swann-Morton Sterile Disposable Scalpels	22	0508	05033955005085
Swann-Morton Sterile Disposable Scalpels	22A	0509	05033955005092
Swann-Morton Sterile Disposable Scalpels	23	0510	05033955005108
Swann-Morton Sterile Disposable Scalpels	24	0511	05033955005115
Swann-Morton Sterile Disposable Scalpels	25	0512	05033955005122
Swann-Morton Sterile Disposable Scalpels	26	0513	05033955005139
Swann-Morton Sterile Disposable Scalpels	27	0514	05033955005146
Swann-Morton Sterile Disposable Scalpels	25A	0515	05033955005153
Swann-Morton Sterile Disposable Scalpels	6	0516	05033955005160
Swann-Morton Sterile Disposable Scalpels	9	0517	05033955005177
Swann-Morton Sterile Disposable Scalpels	12D	0518	05033955005184
Swann-Morton Sterile Disposable Scalpels	14	0519	05033955005191
Swann-Morton Sterile Disposable Scalpels	15A	0520	05033955005207
Swann-Morton Sterile Disposable Scalpels	15C	0521	05033955005214
Swann-Morton Sterile Disposable Scalpels	16	0522	05033955005221
Swann-Morton Sterile Disposable Scalpels	18	0523	05033955005238
Swann-Morton Sterile Disposable Scalpels	19	0524	05033955005245
Swann-Morton Sterile Disposable Scalpels	E11	0525	05033955005252
Swann-Morton Sterile Disposable Scalpels	SGD	0527	05033955005276
Swann-Morton Sterile Disposable Scalpels	13	0539	05033955005399
Swann-Morton Sterile Disposable Scalpels	Sabre E11	0563	05033955005634
Swann-Morton Sterile Disposable Scalpels	Sabre D15	0565	05033955005658
Swann-Morton Sterile Disposable Scalpels	Sabre B23	0570	05033955005702
Swann-Morton Sterile Disposable Scalpels	11P	0591	05033955005917
Swann-Morton Sterile Disposable Scalpels	15T	0592	05033955005924

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PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Sterile Disposable Scalpels with Guard	10	6601	05033955066017
Swann-Morton Sterile Disposable Scalpels with Guard	11	6603	05033955066031
Swann-Morton Sterile Disposable Scalpels with Guard	15	6605	05033955066055
Swann-Morton Sterile Disposable Scalpels with Guard	20	6606	05033955066062
Swann-Morton Sterile Disposable Scalpels with Guard	21	6607	05033955066079
Swann-Morton Sterile Disposable Scalpels with Guard	22	6608	05033955066086
Swann-Morton Sterile Disposable Scalpels with Guard	23	6610	05033955066109
Swann-Morton Sterile Disposable Scalpels with Guard	24	6611	05033955066116
Swann-Morton Sterile Disposable Scalpels with Guard	10R	6690	05033955066901

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Sterile Retractable Scalpels	10	3901	05033955039011
Swann-Morton Sterile Retractable Scalpels	10A	3902	05033955039028
Swann-Morton Sterile Retractable Scalpels	12	3904	05033955039042
Swann-Morton Sterile Retractable Scalpels	15	3905	05033955039059
Swann-Morton Sterile Retractable Scalpels	20	3906	05033955039066
Swann-Morton Sterile Retractable Scalpels	21	3907	05033955039073
Swann-Morton Sterile Retractable Scalpels	22	3908	05033955039080
Swann-Morton Sterile Retractable Scalpels	23	3910	05033955039103
Swann-Morton Sterile Retractable Scalpels	24	3911	05033955039110
Swann-Morton Sterile Retractable Scalpels	25A	3915	05033955039158
Swann-Morton Sterile Retractable Scalpels	14	3919	05033955039196
Swann-Morton Sterile Retractable Scalpels	15C	3921	05033955039219
Swann-Morton Sterile Retractable Scalpels	10R	3990	05033955039905
Swann-Morton Sterile Retractable Scalpels	11P	3991	05033955039912

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PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Swann-Morton Sterile Retractable Scalpels	10	4901	05033955049010
Swann-Morton Sterile Retractable Scalpels	10A	4902	05033955049027
Swann-Morton Sterile Retractable Scalpels	12	4904	05033955049041
Swann-Morton Sterile Retractable Scalpels	15	4905	05033955049058
Swann-Morton Sterile Retractable Scalpels	20	4906	05033955049065
Swann-Morton Sterile Retractable Scalpels	21	4907	05033955049072
Swann-Morton Sterile Retractable Scalpels	22	4908	05033955049089
Swann-Morton Sterile Retractable Scalpels	23	4910	05033955049102
Swann-Morton Sterile Retractable Scalpels	24	4911	05033955049119
Swann-Morton Sterile Retractable Scalpels	25A	4915	05033955049157
Swann-Morton Sterile Retractable Scalpels	14	4919	05033955049195
Swann-Morton Sterile Retractable Scalpels	15C	4921	05033955049218
Swann-Morton Sterile Retractable Scalpels	10R	4990	05033955049904
Swann-Morton Sterile Retractable Scalpels	11P	4991	05033955049911

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Lance Sterile Disposable Scalpels	10	L501	05033955115012
Lance Sterile Disposable Scalpels	11	L503	05033955115036
Lance Sterile Disposable Scalpels	12	L504	05033955115043
Lance Sterile Disposable Scalpels	15	L505	05033955115050
Lance Sterile Disposable Scalpels	20	L506	05033955115067
Lance Sterile Disposable Scalpels	21	L507	05033955115074
Lance Sterile Disposable Scalpels	22	L508	05033955115081
Lance Sterile Disposable Scalpels	23	L510	05033955115104
Lance Sterile Disposable Scalpels	24	L511	05033955115111
Lance Sterile Disposable Scalpels	15T	L592	05033955115920

PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Paragon Sterile Disposable Scalpel	10	P501	05033955105013
Paragon Sterile Disposable Scalpel	11	P503	05033955105037
Paragon Sterile Disposable Scalpel	12	P504	05033955105044
Paragon Sterile Disposable Scalpel	15	P505	05033955105051
Paragon Sterile Disposable Scalpel	20	P506	05033955105068
Paragon Sterile Disposable Scalpel	21	P507	05033955105075

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PRODUCT DESCRIPTION	BLADE SHAPE	PRODUCT CODE	UDI
Paragon Sterile Disposable Scalpel	22	P508	05033955105082
Paragon Sterile Disposable Scalpel	23	P510	05033955105105
Paragon Sterile Disposable Scalpel	24	P511	05033955105112
Paragon Sterile Disposable Scalpel	15T	P592	05033955105921

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

SIGNATURE	
PRINT FULL NAME	Sally Shield
POSITION	QA/RA Assistant
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 21st October 2024

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