Swann-Morton® LIMITED

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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	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 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: 114374
Brazilian RDC number: 10302860222 & 10302860224
Japan MHLW registration number: BG20500131

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

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

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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

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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

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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

SIGNATURE	
PRINT FULL NAME	Darren Hall / Sally Shield
POSITION	QA/RA Systems Manager / QA/RA Assistant
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 15th November 2023