

Declaration of Conformity

Manufacturer's Name: Swann-Morton Limited

Manufacturer's Address: Penn Works, Owlerton Green, Sheffield S6 2BJ, England

Single registration Number: 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 EC Directive 93/42/EEC and the amending Directive 2007/47/EC.

The Notified Body used for our conformity assessment in accordance with Annex II and Annex VII of the above Directive is BSI NL (2797).

Certificates Issued:

CE 00482 in respect of: The design and manufacture of sterile and non-sterile stainless steel and carbon steel surgical blades, scalpels and skin graft 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 AND CANADA – Medical Devices Regulations – Part 1 - SOR 92/282: USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A-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.

Product Family:	STERILE FINE SURGICAL BLADES
Intended Use:	SKIN AND TISSUE CUTTING
Product Codes:	See Page 3
Classification:	Class IIA (Annex IX, Rule 6)(EU) Class II (MDR Schedule 1, Part 1, Rule 1(1) (Health Canada) Class 1 (FDA CFR 878.4800) (U.S.A – FDA)
Standards Used:	See Page 2
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 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

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

SIGNATURE	
PRINT FULL NAME	Darren Hall
POSITION	QA/RA Systems Manager
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 7 th November 2019

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann Morton Sterile Fine Surgical Blade	SM61	5901	5033955059019
Swann Morton Sterile Fine Surgical Blade	SM62	5902	5033955059026
Swann Morton Sterile Fine Surgical Blade	SM63	5903	5033955059033
Swann Morton Sterile Fine Surgical Blade	SM64	5904	5033955059040
Swann Morton Sterile Fine Surgical Blade	SM65	5905	5033955059057
Swann Morton Sterile Fine Surgical Blade	SM65A	5906	5033955059064
Swann Morton Sterile Fine Surgical Blade	SM67	5907	5033955059071
Swann Morton Sterile Fine Surgical Blade	SM68	5908	5033955059088
Swann Morton Sterile Fine Surgical Blade	SM69	5909	5033955059095
Swann Morton Sterile Fine Surgical Blade	Single Bevel Fine SM61	5911	5033955059118
Swann Morton Sterile Fine Surgical Blade	Single Bevel Fine SM62	5912	5033955059125
Swann Morton Sterile Fine Surgical Blade	Fine 90 (SP)	5921	5033955059217
Swann Morton Sterile Fine Surgical Blade	Fine 91 (SP)	5922	5033955059224

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The Notified Body used for our conformity assessment in accordance with Annex II and VII of the above Directive is BSI NL (2797). Certificates Issued:

CE 00482 in respect of: The design and manufacture of sterile and non-sterile stainless steel and carbon steel surgical blades, scalpels and skin graft 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 AND CANADA – Medical Devices Regulations – Part 1 - SOR 92/282: USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A-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.

Product Family:	STERILE SURGICAL BLADES
Intended Use:	SKIN AND TISSUE CUTTING
Product Codes:	See Pages 3 to 6
Classification:	Class IIA (Annex IX Rule 6)(EU) Class II (MDR Schedule 1, Part 1, Rule 1(1) (Health Canada) Class 1 (FDA CFR 878.4800) (U.S.A – FDA)
Harmonised Standards Used:	See Page 2
GMDN Term & Definition	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.

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

Harmonized standards used 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 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

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

SIGNATURE	
PRINT FULL NAME	Darren Hall
POSITION	QA/RA Systems Manager
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 7 th November 2019

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann Morton Sterile Carbon Steel Surgical Blade	10	0201	5033955002015
Swann Morton Sterile Carbon Steel Surgical Blade	10A	0202	5033955002022
Swann Morton Sterile Carbon Steel Surgical Blade	11	0203	5033955002039
Swann Morton Sterile Carbon Steel Surgical Blade	12	0204	5033955002046
Swann Morton Sterile Carbon Steel Surgical Blade	15	0205	5033955002053
Swann Morton Sterile Carbon Steel Surgical Blade	20	0206	5033955002060
Swann Morton Sterile Carbon Steel Surgical Blade	21	0207	5033955002077
Swann Morton Sterile Carbon Steel Surgical Blade	22	0208	5033955002084
Swann Morton Sterile Carbon Steel Surgical Blade	22A	0209	5033955002091
Swann Morton Sterile Carbon Steel Surgical Blade	23	0210	5033955002107
Swann Morton Sterile Carbon Steel Surgical Blade	24	0211	5033955002114
Swann Morton Sterile Carbon Steel Surgical Blade	25	0212	5033955002121
Swann Morton Sterile Carbon Steel Surgical Blade	26	0213	5033955002138
Swann Morton Sterile Carbon Steel Surgical Blade	27	0214	5033955002145
Swann Morton Sterile Carbon Steel Surgical Blade	25A	0215	5033955002152
Swann Morton Sterile Carbon Steel Surgical Blade	6	0216	5033955002169
Swann Morton Sterile Carbon Steel Surgical Blade	9	0217	5033955002176
Swann Morton Sterile Carbon Steel Surgical Blade	12D	0218	5033955002183
Swann Morton Sterile Carbon Steel Surgical Blade	14	0219	5033955002190
Swann Morton Sterile Carbon Steel Surgical Blade	15A	0220	5033955002206
Swann Morton Sterile Carbon Steel Surgical Blade	15C	0221	5033955002213
Swann Morton Sterile Carbon Steel Surgical Blade	16	0222	5033955002220
Swann Morton Sterile Carbon Steel Surgical Blade	18	0223	5033955002237
Swann Morton Sterile Carbon Steel Surgical Blade	19	0224	5033955002244
Swann Morton Sterile Carbon Steel Surgical Blade	E11	0225	5033955002251
Swann Morton Sterile Carbon Steel Surgical Blade	36	0236	5033955002367
Swann Morton Sterile Carbon Steel Surgical Blade	13	0239	5033955002398
Swann Morton Sterile Carbon Steel Surgical Blade	40	0240	5033955002404
Swann Morton Sterile Carbon Steel Surgical Blade	E11 (Sabre)	0263	5033955002633
Swann Morton Sterile Carbon Steel Surgical Blade	D15 (Sabre)	0265	5033955002657
Swann Morton Sterile Carbon Steel Surgical Blade	11P	0291	5033955002916
Swann Morton Sterile Carbon Steel Surgical Blade	15T	0292	5033955002923

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann Morton Sterile Stainless Steel Surgical Blade	10	0301	5033955003012
Swann Morton Sterile Stainless Steel Surgical Blade	10A	0302	5033955003029
Swann Morton Sterile Stainless Steel Surgical Blade	11	0303	5033955003036
Swann Morton Sterile Stainless Steel Surgical Blade	12	0304	5033955003043
Swann Morton Sterile Stainless Steel Surgical Blade	15	0305	5033955003050
Swann Morton Sterile Stainless Steel Surgical Blade	20	0306	5033955003067
Swann Morton Sterile Stainless Steel Surgical Blade	21	0307	5033955003074
Swann Morton Sterile Stainless Steel Surgical Blade	22	0308	5033955003081
Swann Morton Sterile Stainless Steel Surgical Blade	22A	0309	5033955003098
Swann Morton Sterile Stainless Steel Surgical Blade	23	0310	5033955003104
Swann Morton Sterile Stainless Steel Surgical Blade	24	0311	5033955003111
Swann Morton Sterile Stainless Steel Surgical Blade	25	0312	5033955003128
Swann Morton Sterile Stainless Steel Surgical Blade	26	0313	5033955003135
Swann Morton Sterile Stainless Steel Surgical Blade	27	0314	5033955003142
Swann Morton Sterile Stainless Steel Surgical Blade	25A	0315	5033955003159
Swann Morton Sterile Stainless Steel Surgical Blade	6	0316	5033955003166
Swann Morton Sterile Stainless Steel Surgical Blade	9	0317	5033955003173
Swann Morton Sterile Stainless Steel Surgical Blade	12D	0318	5033955003180
Swann Morton Sterile Stainless Steel Surgical Blade	14	0319	5033955003197
Swann Morton Sterile Stainless Steel Surgical Blade	15A	0320	5033955003203
Swann Morton Sterile Stainless Steel Surgical Blade	15C	0321	5033955003210
Swann Morton Sterile Stainless Steel Surgical Blade	16	0322	5033955003227
Swann Morton Sterile Stainless Steel Surgical Blade	18	0323	5033955003234
Swann Morton Sterile Stainless Steel Surgical Blade	19	0324	5033955003241
Swann Morton Sterile Stainless Steel Surgical Blade	E11	0325	5033955003258
Swann Morton Sterile Stainless Steel Surgical Blade	13	0339	5033955003265
Swann Morton Sterile Stainless Steel Surgical Blade	10R	0390	5033955003906
Swann Morton Sterile Stainless Steel Surgical Blade	11P	0391	5033955003395
Swann Morton Sterile Stainless Steel Surgical Blade	15T	0392	5033955003913

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Lance Sterile Carbon Steel Surgical Blade	10	L201	5033955112011
Lance Sterile Carbon Steel Surgical Blade	11	L203	5033955112042
Lance Sterile Carbon Steel Surgical Blade	12	L204	5033955112059
Lance Sterile Carbon Steel Surgical Blade	15	L205	5033955112066
Lance Sterile Carbon Steel Surgical Blade	20	L206	5033955112073
Lance Sterile Carbon Steel Surgical Blade	21	L207	5033955112080
Lance Sterile Carbon Steel Surgical Blade	22	L208	5033955112103
Lance Sterile Carbon Steel Surgical Blade	23	L210	5033955112929
Lance Sterile Carbon Steel Surgical Blade	15T	L292	5033955112011

BRAND NAME	PATTERN	PRODUCT CODE	UDI
Lance Sterile Stainless Steel Surgical Blade	10	L301	5033955113018
Lance Sterile Stainless Steel Surgical Blade	11	L303	5033955113032
Lance Sterile Stainless Steel Surgical Blade	12	L304	5033955113049
Lance Sterile Stainless Steel Surgical Blade	15	L305	5033955113056
Lance Sterile Stainless Steel Surgical Blade	20	L306	5033955113063
Lance Sterile Stainless Steel Surgical Blade	21	L307	5033955113070
Lance Sterile Stainless Steel Surgical Blade	22	L308	5033955113087
Lance Sterile Stainless Steel Surgical Blade	23	L310	5033955113100
Lance Sterile Stainless Steel Surgical Blade	24	L311	5033955113117
Lance Sterile Stainless Steel Surgical Blade	25A	L315	5033955113155
Lance Sterile Stainless Steel Surgical Blade	15T	L392	5033955113926

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Paragon Sterile Carbon Steel Surgical Blade	10	P201	5033955102012
Paragon Sterile Carbon Steel Surgical Blade	11	P203	5033955102036
Paragon Sterile Carbon Steel Surgical Blade	12	P204	5033955102043
Paragon Sterile Carbon Steel Surgical Blade	15	P205	5033955102050
Paragon Sterile Carbon Steel Surgical Blade	20	P206	5033955102067
Paragon Sterile Carbon Steel Surgical Blade	21	P207	5033955102074
Paragon Sterile Carbon Steel Surgical Blade	22	P208	5033955102081
Paragon Sterile Carbon Steel Surgical Blade	23	P210	5033955102104
Paragon Sterile Carbon Steel Surgical Blade	24	P211	5033955102111
Paragon Sterile Carbon Steel Surgical Blade	15T	P292	5033955102920

BRAND NAME	PATTERN	PRODUCT CODE	UDI
Paragon Sterile Stainless Steel Surgical Blade	10	P301	5033955103019
Paragon Sterile Stainless Steel Surgical Blade	11	P303	5033955103033
Paragon Sterile Stainless Steel Surgical Blade	12	P304	5033955103040
Paragon Sterile Stainless Steel Surgical Blade	15	P305	5033955103057
Paragon Sterile Stainless Steel Surgical Blade	20	P306	5033955103064
Paragon Sterile Stainless Steel Surgical Blade	21	P307	5033955103071
Paragon Sterile Stainless Steel Surgical Blade	22	P308	5033955103088
Paragon Sterile Stainless Steel Surgical Blade	23	P310	5033955103101
Paragon Sterile Stainless Steel Surgical Blade	24	P311	5033955103118
Paragon Sterile Stainless Steel Surgical Blade	25	P312	5033955103125
Paragon Sterile Stainless Steel Surgical Blade	25A	P315	5033955103156
Paragon Sterile Stainless Steel Surgical Blade	6	P316	5033955103163
Paragon Sterile Stainless Steel Surgical Blade	15T	P392	5033955103927

NON STERILE STAINLESS STEEL HANDLES

Supplied in boxes of 10

Handles in this range:

No.3 Graduated, 3L, No.7, No.9
Fit all No.3 fitment blades

No.4 Graduated, 4L
Fit all No.4 fitment blades

COMPONENT	MATERIAL
HANDLE	Stainless Steel 17-4ph
UNIT PACK	Cellophane Sleeve
UNIT CONTAINER BOX	Coated white lined chipboard

Supplied individually in wallets

Handles in this range:

No.5B, B3
Fit all No.3 fitment blades

No.6B
Fit all No.4 fitment blades

COMPONENT	MATERIAL
HANDLE	Stainless Steel 17-4ph
UNIT PACK	PVC Wallet

All handles are manufactured in accordance with BS 2982 and BS EN 27740.

All Components are manufactured in Europe.

All packets and boxes are marked with the current lot number and expiry dates for traceability.

STERILE CARBON SURGICAL BLADE SPECIFICATIONS

Supplied in boxes of 100

Blades in this range:

6, 9, 10, 10A, 11, 11P, E/11, Sabre E/11, 12, 12D, 13, 14, 15, Sabre D/15, 15A, 15C, 15T, 16, 40
Fit Handles No.3 Graduated, 3L, B3, No.7, No.9

18, 19, 20, 21, 22, 22A, 23, 24, 25, 25A, 26, 27, 36
Fit Handles No.4 Graduated, 4L

COMPONENT	MATERIAL
BLADE	Carbon Steel <u>ANALYSIS:</u> CARBON: 1.2% - 1.3% SILICON: 0.10% - 0.35% MANGANESE: 0.2% - 0.45% CHROMIUM: 0.10% - 0.40% SULPHUR: 0.025% max PHOSPHORUS: 0.035% max
TOP FOIL	Printed Aluminum with Polyethylene
BOTTOM FOIL	Printed Aluminum blade shape with CPP laminate
RUST INHIBITOR	Waxed VCI impregnated kraft paper
UNIT CONTAINER BOX	White lined chipboard with litho machine varnish

Products are manufactured in accordance with BS 2982 and BS EN 27740 (where applicable).

Each box is individually wrapped in cellophane before despatch.

All Components are manufactured in Europe.

All packets and boxes are marked with the current lot number and expiry dates for traceability; boxes are bar coded where applicable.

Products are sterilised by Cobalt 60 Gamma Irradiation by:-Swann-Morton (Services) Limited, Owlerton Green, Sheffield S6 2BJ

NON STERILE FINE HANDLE SPECIFICATIONS

Supplied individually in wallets

Handles in this range:

SF1, SF2, SF3, SF4, SF13, SF23, which fit all blades in our Fine range.

COMPONENT	MATERIAL
HANDLE	Stainless Steel Grade 303S31 <u>ANALYSIS:</u> CARBON: 0.12% max SILICON: 1% max MANGANESE: 2% max PHOSPHORUS: 2% max SULPHUR: 0.15 - 0.35% max CHROMIUM: 17% - 19% NICKEL: 8% - 10% MOLYBDENUM: 1% max NITROGEN: 0.25% max
UNIT CONTAINER	PVC Wallet

All components are manufactured in Europe.

All packs are marked with the current lot number and expiry dates for traceability.

STERILE FINE BLADE SPECIFICATIONS

Supplied in boxes of 25

Blades in this range:

61, 61SB, 62, 62SB, 63, 64, 65, 65A, 67, 68, 69, 90SP, 91SP

These blades fit Handles SF1, SF2, SF3, SF4, SF13, SF23

COMPONENT	MATERIAL
BLADE	Stainless Steel <u>ANALYSIS:</u> CARBON: 0.60% - 0.70% SILICON: 0.50% max MANGANESE: 1% max CHROMIUM: 12% - 13.5% SULPHUR: 0.025% max PHOSPHORUS: 0.03% max NICKEL: 0.5% max
TOP FOIL	Printed Aluminum with Polyethylene, white rayopeel
BOTTOM FOIL	Printed Aluminum blade shape with white CPP laminate
RUST INHIBITOR	Waxed VCI impregnated kraft paper
UNIT CONTAINER BOX	Folding Box Board with selective UV varnish

All Components are manufactured in Europe

All packets and boxes are marked with the current lot number and expiry dates for traceability; boxes are bar coded where applicable.

Products are sterilised by Cobalt 60 Gamma Irradiation by:-Swann-Morton (Services) Limited, Owlerton Green, Sheffield S6 2BJ

BLADE REMOVER SPECIFICATIONS

Sterile supplied individually wrapped in boxes of 50

Non-Sterile supplied in boxes of 100 or 500

COMPONENT	MATERIAL
BLADE REMOVER	Phillips K Resin / Grade K R01 butadiene Styrene
TOP WEB - STERILE	Pet / PE MLP12A / 38V (nylon poly)
BOTTOM PAPER - STERILE	60gsm Bleached kraft paper with 10gsm grid laquer
UNIT CONTAINER BOXES STERILE	Coated white lined chipboard with litho machine varnish
UNIT CONTAINER BOXES NON STERILE	Coated white lined chipboard with UV varnish. Non Sterile Blade Removers are double poly bagged.
NON STERILE POLY BAG	Polythene

All components are manufactured in the Europe.

All packs and boxes are marked with the current lot number and expiry dates for traceability.

Sterile products are sterilised by Cobalt 60 Gamma Irradiation by:-Swann-Morton (Services) Limited, Owlerton Green, Sheffield S6 2BJ

Declaration of Conformity

Manufacturer's Name: Swann-Morton Limited

Manufacturer's Address: Penn Works, Owlerton Green, Sheffield S6 2BJ, England

Single Registration Number: 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 EC Directive 93/42/EEC and the amending Directive 2007/47/EC. This declaration is based on Annexes I and VII of this Directive.

These products are Class I non-sterile and therefore there is no requirement for Notified Body involvement. These products have been self-certified with the UK Medicines & Healthcare Regulatory Agency (MHRA) which is the UK Competent Authority.

Certificates Issued:

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 AND CANADA – Medical Devices Regulations – Part 1 - SOR 92/282: USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A-D. The design, manufacture, packaging and distribution of surgical blades, disposable scalpels, handles and blade removers.


Product Family:	NON-STERILE STAINLESS STANDARD METAL SURGICAL HANDLES
Intended Use:	TO HOLD A No.3 OR No.4 FITMENT SURGICAL BLADE
Product Codes:	See Page 2
Classification:	Class I (Re-usable) (Annex IX, Rule 1)
Standards Used:	See Page 2
GMDN Code & Term	12235 Knife/Blade Handle

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

Standards applied in relation to this Declaration are:

STANDARD NUMBER	TITLE
BS 2982	Materials and packaging of surgical scalpels with detachable blades
BS EN 27740/ISO 7740	Instruments for surgery, scalpels with detachable blades, fitting dimensions.
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	Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices

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

SIGNATURE	
PRINT FULL NAME	Darren Hall
POSITION	QA/RA Systems Manager
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 7 th November 2019

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann-Morton Non Sterile standard Surgical Handles	No. 5B	0905	5033955009052
Swann-Morton Non Sterile standard Surgical Handles	No. 6B	0906	5033955009069
Swann-Morton Non Sterile standard Surgical Handles	No. 7	0907	5033955009076
Swann-Morton Non Sterile standard Surgical Handles	No. 9	0909	5033955009090
Swann-Morton Non Sterile standard Surgical Handles	No. 3L	0913	5033955009137
Swann-Morton Non Sterile standard Surgical Handles	No. 4L	0914	5033955009144
Swann-Morton Non Sterile standard Surgical Handles	No. 3 Graduated	0933	5033955009335
Swann-Morton Non Sterile standard Surgical Handles	No. 4 Graduated	0934	5033955009342
Swann-Morton Non Sterile standard Surgical Handles	B3	0923	5033955009236

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These products are Class I non-sterile and therefore there is no requirement for Notified Body involvement. These products have been self-certified with the UK Medicines & Healthcare Regulatory Agency (MHRA) which is the UK Competent Authority.

Certificates Issued:

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 AND CANADA – Medical Devices Regulations – Part 1 - SOR 92/282: USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A-D. The design, manufacture, packaging and distribution of surgical blades, disposable scalpels, handles and blade removers.


Product Family:	NON-STERILE FINE HANDLES
Intended Use:	TO HOLD A FINE SURGICAL BLADE
Product Codes:	See Page 2
Classification:	Class I (Re-usable) (Annex IX, Rule 1)
Standards Used:	See Page 2
GMDN Code & Term	12235 Knife/Blade Handle

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

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	Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices

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

SIGNATURE	
PRINT FULL NAME	Darren Hall
POSITION	QA/RA Systems Manager
PLACE & DATE	Swann-Morton Ltd, Sheffield S6 2BJ, England 7 th November 2019

PRODUCT DESCRIPTION	PATTERN	PRODUCT CODE	UDI
Swann Morton Non-Sterile Fine Handle	SF1	6051	5033955060510
Swann Morton Non-Sterile Fine Handle	SF2	6052	5033955060527
Swann Morton Non-Sterile Fine Handle	SF3	6053	5033955060534
Swann Morton Non-Sterile Fine Handle	SF4	6054	5033955060541
Swann Morton Non-Sterile Fine Handle	2 Piece long	6055	5033955060558
Swann Morton Non-Sterile Fine Handle	3 Piece long	6056	5033955060565
Swann Morton Non-Sterile Fine Handle	SF13	6061	5033955060619
Swann Morton Non-Sterile Fine Handle	SF23	6062	5033955060626

PRODUCT HEALTH AND SAFETY INFORMATION

1. **IDENTIFICATION**

Product Name: Swann-Morton Ltd Surgical / Craft, Sterile / Non Sterile.
Product Description: Stainless Steel / Carbon Steel Blades.
Nickel Handles.
Stainless Handles
Plastic Handles.

2. **HAZARD WARNING LABELS**

No special hazard-warning label required.

3. **TRANSPORT CODES**

Not applicable.

4. **SOLVENTS PRESENT**

None.

5. **WORKPLACE EXPOSURE LIMITS (W.E.L)**

Not applicable.

6. **SAFE USAGE**

Blades should not be used unless in conjunction with correct fitment handle.
Loose fitting handles should be discarded.
The sterility of the product is not guaranteed if the packaging is damaged in any way.
Blades must be disposed of in such a manner as to prevent any hazards to other persons.

7. **STORAGE**

Blades and Handles should be stored in a dry atmosphere.
Correct stock rotation is recommended where blades / handles are intended for surgical use.

8. **FIRST AID**

All cuts, however minor, should be treated.
Burns from molten plastics: - Cool as quickly as possible by the best means available.
Make no attempt to remove either molten or solidified material – **SEEK MEDICAL ATTENTION IMMEDIATELY.**
Nickel handles may cause dermatitis in sensitive individuals.

9. **FIRE HAZARDS**

The blades do not constitute a fire hazard.
The nickel handles do not constitute a fire hazard.

Plastic Handles:

Ignition and burning characteristics: - The product will burn readily if ignited and may continue to burn in the presence of air when the source of ignition is removed. Burning may be accompanied by the release of flaming molten droplets of polymer, which may ignite adjacent flammable materials.

Decomposition and combustion products: - The combustion of the product can give rise to a range of products. In common with the combustion of other natural and synthetic organic materials, carbon monoxide is generated. The precise chemical identities and atmospheric concentrations of the individual products will vary with the combustion conditions. (E.g. Temperature, Oxygen availability).

Action in the event of fire: - Water spray, foam, dry chemical and CO₂ are normally suitable fire extinguishing media. Advice from the local Fire Authority is strongly recommended in respect of firefighting equipment and procedures. Care must be taken to avoid inhalation of fumes from the product combustion products. Suitable self-contained breathing apparatus should be available for use by authorised personnel (e.g. Fire Fighters, Rescue teams), where fumes might be present. Qualified medical attention should be sought in the event of injury to personnel.

10. **DISPOSAL**

Blades (Surgical) – Dispose of in a suitable sharps container for clinical waste
Blades (Craft) - Dispose of in a suitable sharps container
Nickel and Stainless Handles – Dispose of in metal scrap
Plastic Handles – Contact local authority for disposal method