



DECLARATION OF CONFORMITY

We,

MicroSurgical Technology Inc.

8415 154th Ave NE

Redmond, WA 98052 USA

Ph: 425-556-0544

Fax: 425-556-0437

declare under our sole responsibility that the class IIa product(s) listed on the product list attachment to which this declaration relates is in conformity with the European Community Council Directive (Medical Device Directive) 93/42/EEC, Annex II excluding (4), including the Swedish Medical Products Agency norms for the medical devices LVFS 2003:11 and the following standards or other normative documents.

Standard ID	Title
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological Evaluation of medical devices – Part 5: Tests for cytotoxicity, invitro method
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 17665-1:2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 17664:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 556-1:2001/AC 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 11137-1:2015	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose



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Following the provisions of EC Directive 93 / 42 / EEC and all applicable amendments which apply to them, as stated in Annex II, Article 3 of this directive.

Certification for a Full Quality Management System:

Certificate N.: 41377505-00
Issued by: Intertek SEMKO AB
Torshamnsgatan 43
Box 1103
SE-164 22 Kista,
Sweden
Notified Body Number: 0413

The Technical File is maintained at:

MicroSurgical Technology Inc. 8415 154th Ave NE Redmond, WA 98052 USA

The authorized representative located within the Community is:

MDSS GmbH Schiffgraben 41 30175 Hannover, Germany

This declaration shall be made available to national authorities for inspection for no less than 5 years after the last product has been manufactured.

Date of issue: August 17, 2018

Place of issue: Redmond, WA

Cecil Chrisinger
Regulatory Affairs Manager
MicroSurgical Technology Inc.



MICROSURGICAL TECHNOLOGY™

MST Irrigation/Aspiration

This product list belongs to the MST Irrigation/Aspiration Declaration of Conformity and specifies the CE-marked products concerned that MicroSurgical Technology Inc. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC, concerning medical devices. The following list identifies the products.

MST Irrigation/Aspiration Products	
Model	Brand Name
AHP-0001	Reusable Handle for Allegro Single Use Silicone I/A Tip System
AT-0001-P	Allegro Single Use Silicone I/A Tip
AT-0001-R	Allegro Single Use Silicone I/A Tip
ASP-0001-P	Allegro sp Single Use Silicone System
ASP-0001-R	Allegro sp Single Use Silicone System
BI-302	I/A B-Manual 21G Curved Aspirator
BI-322	I/A B-Manual Curved 23G Aspirator
BI-323	I/A B-Manual 23G Curved Capsule Polisher
BI-501	I/A B-Manual 21G Straight Closed End Irrigator
BI-502	I/A B-Manual 21G Curved Closed End Irrigator
BI-521	I/A B-Manual 23G Straight .4mm Irrigator
BI-522	I/A B-Manual 23G Curved .4mm Irrigator
Bi-98302	I/A B-Manual 21G Curved .3mm 1xPort Aspirator
Bi-98322	I/A B-Manual 23G Curved .3mm1x Port Aspirator
Bi-98323	I/A B-Manual 23G Curved .3mm1x Port Aspirator
Bi-98501	I/A B-Manual 21G Straight.5mm2x Port Irrigator
Bi-98502	I/A B-Manual 21G Curved.5mm 2x Port Irrigator
Bi-98522	I/A B-Manual 23G Curved .4mm2x Port Irrigator
Bi-98523	Bi M, 21g Curved, 0.3mm Aspirator. Capsule Polisher
BRT-1028-G	BRT V2 Strt, Cap PI, 0.3 A1 0.7 gld
BRT-1028-P	BRT V2 Strt, Cap PI, 0.3 A1 0.7 prp
BRT-1028-R	BRT V2 Strt, Cap PI, 0.3 A1 0.7 red
BRT-1029-G	BRT V2 Bnt, Cap PI, 0.3 A1 0.7 gld
BRT-1029-P	BRT V2 Bnt, Cap PI, 0.3 A1 0.7 prp
BRT-1029-R	BRT V2 Bnt, Cap PI, 0.3 A1 0.7 red
BRT-1030-G	BRT V2 Cvd, Cap PI, 0.3 A1 0.7 gld
BRT-1030-P	BRT V2 Cvd, Cap PI, 0.3 A1 0.7 prp
BRT-1030-R	BRT V2 Cvd, Cap PI, 0.3 A1 0.7 red
BRT-1031	BRT V2, 21g straight, cap pl, 0.3 pt
BRT-1032	BRT V2, 21g straight, cap pl, 0.3 pt
BRT-1033-B	BRT V2 Strt, Cap PI 0.3, 0.7 blu
BRT-1033-G	BRT V2 Strt, Cap PI, 0.3 0.7 gld
BRT-1033-GX1	BRT V2 Strt, 0.3 0.7 gld
BRT-1033-Y	BRT V2 Strt, Cap PI, 0.3 0.7 yel
BRT-1034-B	BRT V2 Bnt, Cap PI, 0.3, 0.7 blu
BRT-1034-G	BRT V2 Bnt, Cap PI, 0.3, 0.7 gld
BRT-1034-GX1	BRT V2 Bnt, 0.3, 0.7 gld
BRT-1034-GX2	BRT V2 Bnt, Cap PI, 0.4,0.7 gld



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MST Irrigation/Aspiration Products	
Model	Brand Name
BRT-1034-Y	BRT V2 Bnt, Cap Pl, 0.3, 0.7 yel
BRT-1035-B	BRT V2 Cvd, Cap Pl, 0.3, 0.7 blu
BRT-1035-G	BRT V2 Cvd, Cap Pl, 0.3, 0.7 gld
BRT-1035-GX1	BRT V2 Cvd, 0.2, 0.7 gld
BRT-1035-Y	BRT V2 Cvd, Cap Pl, 0.3, 0.7 yel
Du-A2020	20g Duet BiManual System
Du-A2021	21g Duet BiManual System
Du-02021	Duet System Starter Kit 21g
Du-A2022	19g Duet BiManual System
Du-02022	Duet System Starter Kit 19g
Du-02023	Duet System Starter Kit 20g
Du-02100	Duet Aspiration
Du-02200	Duet Irrigation
Du-02301	20g Curved Irrigator, Closed Ended
Du-02302	20g Curved Aspiration .3mm Port
Du-02302X1	20g Curved Aspirator, .2mm Port
Du-02302X3	20g Curved Aspirator, .2mm Port
Du-02302X5	20g Curved Aspirator, .4mm Port
Du-02303	20g Olson Style Irrigating Chopper
Du-02304	20g Nagahara Style Irrigating Chopper Left
Du-02305	20g Fine Irrigating Chopper
Du-02306	21g Curved Closed Ended Irrigator
Du-02307	21g Curved Aspiration .3mm Port
Du-02308	21g Olson Style Irrigating Chopper
Du-02309	21g Nagahara Style Irrigating Chopper Left
Du-02310	21g Fine Irrigating Chopper
Du-02311	20g Curved Irrigator, Open End
Du-02312	21g Curved Irrigator, Open End
Du-02313	20g Olson II Style Irrigating Chopper
Du-02314	21g Olson II Style Irrigating Chopper
Du-02315	20g Nagahara Style Irrigating Chopper RH
Du-02316	21g Nagahara Style Irrigating Chopper RH
Du-02317	20g Tsuneoka Irrigating Chopper
Du-02318	21g Tsuneoka Irrigating Chopper
Du-02319	20g Braga-Mele Irrigating Chopper, Ported
Du-02320	21g Braga-Mele Irrigating Chopper, Ported
Du-02321	20g Chang Irrigating Chopper
Du-02322	21g Chang Irrigating Chopper
Du-02323	20g Agarwal Irrigating Chopper
Du-02324	21g Agarwal Irrigating Chopper
Du-02325	20g Aguirre Irrigating Chopper
Du-02326	21g Aguirre Irrigating Chopper
Du-02327	20g Irrigating Nucleus Rotator
Du-02328	21g Irrigating Nucleus Rotator
Du-02335	20g Fine/Nagahara Horizontal Chopper
Du-02336	20g Hoffman / Tsuneoka Irrigating Chopper
Du-02337	20g Packer Irrigating Chopper



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MST Irrigation/Aspiration Products	
Model	Brand Name
Du-02338	20g Crema / Nagahara Irrigating Chopper
Du-02339	Lindstrom / Duet Tri-port Irrigator
Du-02340	19g Curved Irrigator, Closed Ended
Du-02341	19g Curved Aspiration .3mm Port
Du-02341X1	19g Curved Aspiration .4mm Port
Du-02341X2	19g Curved Aspiration .4mm Port
Du-02341X3	19g Curved Aspiration Cap PI .4mm Port
Du-02342	19g Fine/Nagahara Irrigating Chopper
Du-02343	19g Olson II Style Irrigating Chopper
Du-02344	19g Fine Irrigating Chopper
Du-02345	19g Hoffman Irrigating Chopper
Du-02346	19g Aguirre Irrigating Chopper
Du-02347	19g Chang Irrigating Chopper
Du-02348	19g Steinert LH Irrigating Chopper
Du-02349	19g Steinert RH Irrigating Chopper
Du-02350	20g Lemagne Spatula
Du-02351	21g Verges Irrigating Chopper
Du-02352	20g Black Irrigating Chopper
Du-02353	22g Agarwal Microphacoknit Irrigating Chopper
Du-02354	22g Curved Irrigator, Closed Ended
Du-02355	22g Curved Aspirator, .3 mm Port
DU-02355X2	Tip, Aspiration, Curved, 0.4 mm Port, 22g
Du-02356	20g Sourdille Irrigating Chopper
Du-02357	22g Vejarano Irrigating chopper
Du-02358	22g Curved Aspirator. Smooth 0.3mm Port
Du-02359	20g Kearney Omni Manipulator
Du-02360	20g Corydon irrigating chopper
Du-02361	22g Fine/Nagahara Hz Chopper
DU-02361X1	22g Fine/Nagahara Horiz Chopper with Bottom Port
Du-02362	22g Alio Stinger irrigating chopper
Du-02363	22g Mandelberg Irrigating Manipulator
Du-02364	22g Antolin Irrigating Chopper
IH-90200	I/A accy S/S Tip Handle Rnd
IH-90301	I/A tip S/S Straight .3mm
IH-90301X4	Tip, Straight, .4mm
IH-90302	I/A tip S/S Curved .3mm
IH-90303	I/A tip S/S 45deg .3mm
IH-90303X1	Tip, 45 Deg., .5mm
IH-90303X2	Tip, 45 Deg., 0.4mm
IH-90303X3	Tip, 45deg, 0.3mm, Capsule Polish
IH-90303X12	Tip, 45deg, 0.35mm
IH-90304	I/A tip S/S 90deg .3mm
IH-90304X1	I/A tip S/S 90deg .5mm
IH-90304X2	I/A tip S/S 90deg .3mm, Sandblasted
IH-90306	I/A tip S/S Binkhorst .3mm
IH-90306X1	I/A Tip S/S Closed Binkhorst .3mm
IH-90306X4	I/A tip S/S Binkhorst .4mm



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MST Irrigation/Aspiration Products	
Model	Brand Name
IH-90306X7	I/A tip S/S Binkhorst .3mm Right Hd
IH-90306X8	I/A tip S/S Binkhorst .3mm Left Hnd
IH-90307	I/A tip S/S Silicone Sleeve Std
IH-90307X14	I/A tip S/S 90° Silicone Slv. .3mm
IH-90308	I/A tip S/S Luer Adaptor Tip
IH-90309	I/A tip S/S Curved Silicone Sleeve Std
IH-90309X3	I/A tip S/S Bent Silicone Slv 0.4mm
IH-90309X10	I/A tip S/S Crvd Silicone Slv. .3mm
IH-90313	I/A tip S/S 45deg Silicone Sleeve Tip
IH-90321	I/A tip S/S .5mm Straight Visco Removal
IH-90322	I/A tip S/S .5mm Curved Visco Removal
IH-90330	I/A tip S/S Replacement O-rings
IH-90337	Phaco tip S/S Silicone Sleeve non-sterile
IH-90339	Phaco accy test chambers (5 /bag)
IH-90340	I/A tip-2 flushkit (5 / bag)
S-IA-02020-1	Soft I/A™, 20g Straight, .3 Port, Qty 1
S-IA-02020-6	Soft I/A™, 20g Straight, .3 Port, Qty 6
S-IA-02021-1	Soft I/A™, 20g Curved, .3 Port, Qty 1
S-IA-02021-6	Soft I/A™, 20g Curved, .3 Port, Qty 6
S-IA-02022-1	Soft I/A™, 20g 45 d, .3 Port, Qty 1
S-IA-02022-6	Soft I/A™, 20g 45 d, .3 Port, Qty 6
SA-01340	I/A Adapter S/S Handle Silicone I/A
Si-98200	InterTip Handle
Si-98301	I/A tip S/S Straight
Si-98302	I/A tip S/S Curved
Si-98303	I/A tip S/S 45deg,
Si-98304	I/A tip S/S 90deg
Si-98306	I/A tip S/S Binkhorst 150deg Return
Si-98307	I/A tip S/S Straight Silicone Sleeve
Si-98309	I/A tip S/S Curved Silicone Sleeve
Si-98313	I/A tip S/S 45deg Silicone Sleeve
TA-01332	Soft I/A Adapter For Push On Handle
Ti-98100	I/A h.p. Ti Handle
Ti-98100X1	I/A h.p.Ti Handle PURPLE
Ti-98301	I/A tip Straight Ti
Ti-98302	I/A tip Curved Ti
Ti-98303	I/A tip 45deg Ti
TI-98303X2	I/A tip 45deg Purple special port
TI-98303X14	I/A Tip, 45 Deg, Full Cap Polish
Ti-98304	I/A tip 90deg Ti
Ti-98306	I/A tip Binkhorst Ti 150deg Return
Ti-98307	I/A tip Straight Ti Silicone Sleeve
Ti-98309	I/A tip Curved Ti Silicone Sleeve
Ti-98313	I/A tip Ti 45deg Silicone Sleeve
TT-93100	I/A h.p. Handle Standard Grip Neutral
Ti-98431	PhacoFit, Barrett V2, 21g straight, cap pl, 0.3pt
Ti-98432	PhacoFit, Barrett V2, 21g bent, cap pl, 0.3pt



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MST Irrigation/Aspiration Products	
Model	Brand Name
Ti-98500	MST Barrett V2 Phaco Fit Kit
TT-93100	Intertip-T Titanium I/A Handle
TT-93301	I/A tip Straight Neutral .3mm
TT-93302	I/A tip Curved Neutral .3mm
TT-93302X4	I/A tip Curved .4mm
TT-93303	I/A tip 45deg Neutral .3mm
TT-93303X7	InterTip-T, 45 Deg, 0.4mm
TT-93303X10	InterTip-T, 45 Deg, 0.5mm
TT-93304	I/A tip 90deg Neutral .3mm
TT-93304X7	I/A tip 90deg Neutral .5mm
TT-93306	I/A tip Binkhorst Neutral .3mm
TT-93306X1	I/A Tip, Binkhorst, 0.4mm, closed end
TT-93307	I/A tip Silicone Sleeve Neutral .3mm
TT-93307X8	Tip, Threaded, .4mm
TT-93307X21	Tip, Threaded, .4mm Cap PI
TT-93308	I/A tip Luer Adaptor
TT-93309	I/A tip Silicone Sleeve Curved Neutral
TT-93313	I/A tip Silicone Sleeve 45deg Neutral
TT-93313X6	Intertip-T Titanium I/A 45deg 0.4mm Port
TT-93318	I/A tip Luer Adaptor Aspiration
TT-93321	I/A tip Straight .5mm Neutral
TT-93322	I/A tip Curved .5mm Neutral
TT-93323	45 deg Ti InterTip Tip w Cap Polish
TT-93324	45 deg Ti InterTip Sleeve w Cap Polish
TT-93324X1	45 deg Ti Intertip Slv w Cap Polish
MHP-0001	MST Maestro I/A Handpiece
MK-0001	MST Maestro I/A Kit

