



DECLARATION OF CONFORMITY

We,

MicroSurgical Technology Inc.

8415 154th Ave NE

Redmond WA 98006

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 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
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; Supplement 2: Test for in-vitro Cytotoxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
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 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 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 11138-3:2009	Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization

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.



MST Silicone Sleeves & Spare Parts Kits

This product list belongs to the MST Silicone Sleeves and Spare Parts Kits 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 Silicone Sleeves and Spare Parts Kits	
Model	Brand Name
SPK-0001	MST Yellow Silicone Sleeve and MST Phaco Wrench (six)
SPK-0002	MST Dark Blue Silicone Sleeve and MST Phaco Wrench (six)
SPK-0003	MST Light Blue Silicone Sleeve and MST Phaco Wrench (six)
SPK-0004	MST Gold Silicone Sleeve and MST Phaco Wrench (six)
SPK-0005	MST BL Blue Silicone Sleeve and MST Phaco Wrench (six)
SPK-0007	MST A1 Red Silicone Sleeve and MST Phaco Wrench (six)
SPK-0008	MST A1 Gold Silicone Sleeve and MST Phaco Wrench (six)
SPK-0010	MST A1 Purple Silicone Sleeve and MST Phaco Wrench (six)
SPK-0011	One Irrigation Port Purple Silicone Sleeve for MST/Packard A1 0.7mm phaco tip and MST Plastic Wrench
SPK-0012	MST Blue 0.7 Silicone Sleeve and MST Plastic Wrench (six)
SPK-0013	MST A1 Purple 0.7 Silicone Sleeve and MST Plastic Wrench (six)
SPK-0014	MST Yellow 0.7 Silicone Sleeve and MST Plastic Wrench (six)
SS-2201	MST Lt Blue Silicone Sleeve, 6
SS-2205	MST A1 Red Silicone Sleeve, 6
SS-2206	MST A1 Gold Silicone Sleeve, 6
SS-2207	MST Gold Silicone Sleeve, 6
SS-2209	MST A1 Purple Silicone Sleeve, 6
SS-2210	MST Dark Blue Silicone Sleeve, 6
SS-2211	MST Yellow Silicone Sleeve, 6
SS-2212	MST BL Blue Silicone Sleeve, 6
SS-2213	One Irrigation Port Purple Silicone Sleeve for MST/Packard A1 0.7mm phaco tip, 6
SS-2214	MST Blue Silicone Sleeve for MST/Packard A1 0.7 phaco tip, 6
SS-2215	MST A1 Purple Silicone Sleeve for MST/Packard 0.7 phaco tip, 6
SS-2216	MST Yellow Silicone Sleeve for MST/Packard 0.7 phaco tip, 6
SS-2217	MST Green Silicone Sleeve for MST/Packard 0.7 phaco tip
SS-2218	MST A1 0.9mm 1 Port Red Silicone Sleeve
SS-2219	MST 0.7mm 1 Port Green Silicone Sleeve