



DECLARATION OF CONFORMITY (DoC)

We

Name + address of manufacturer:	Microtek Medical, Inc. (An Ecolab Company) 1 Ecolab Place St. Paul MN USA
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Authorised EU Representative:	Microtek Medical BV Hekkehorst 24 7207 BN Zutphen The Netherlands
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declare that the DoC is issued under our sole responsibility and belongs to the following product(s):

Trade Name/Device Description	Probe Covers
Catalogue number(s)	See attached list
Class per Rule(s)	Ila Rule 7 of Annex IX of MDD

The product described above conforms to the relevant provisions of the EC Council Directive 93/42/EEC concerning medical devices and the following standards:

Notified body	TÜV NORD CERT GmbH, CE0044 Langemarckstr. 20 D-45141 Essen
Conformity assessment procedure	93/42/EEC Annex II (without 4) CE Certificate No. 44 232 117845 valid until 14 August 2023
EN ISO 13485:2016	Certificate No. 44 221 117845 valid until 14 August 2024
Place / Date : St. Paul, MN USA August 09, 2021	Name and Function:  Steven Deline, MS RAS Sr. Regulatory Affairs Specialist II



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Applicable SKU List

SKU No.	Product Description	Sub-Category
8212	*[P/L] PROBE DRAPE, W/ GEL, TSK-2LF	Intraoperative
663320	*INTRAOPERATIVE PROBE COVER W/O GEL	Intraoperative
5000364	General Purpose Probe Cover	General Purpose
0354-0014	INTRAOPERATIVE PROBE COVER,	Intraoperative
15342-00	INTRAOPERATIVE PROBE COVER	Intraoperative
15344-00	Intraoperative Probe Cover	Intraoperative
3787	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	Intraoperative
3787N	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	Intraoperative
3787UK	* ONE PIECE ULTRASOUND PROBE DRAPE	Intraoperative
3827	*PROBE DRAPE LATEX FREE	General Purpose
3827N	GENERAL PURPOSE PROBE COVER	General Purpose
9020209C	ENDOCAVITY PROBE COVER	Endocavity
91179N	PROBE COVER, POLYISOPRENE STRAIGHT SHEATH	General Purpose
APC1288	ADHESION GENERAL PURPOSE PROBE COVER W/GEL, FEATURING ISOSIL	General Purpose
APC1289	ADHESION GENERAL PURPOSE PROBE COVER W/GEL, FEATURING ISOSIL	General Purpose
APC1290	ADHESION GENERAL PURPOSE PROBE COVER W/GEL, FEATURING ISOSIL	General Purpose
APC1290N	Adhesion General Purpose Probe Cover	General Purpose
APC1290PAN	Adhesion General Purpose Probe Cover with Gel	General Purpose
APC1291	ADHESIVE PROBE DRAPE	General Purpose
APC1292	4ADHESION INTRAOPERATIVE PROBE COVER W/GEL, FEATURING ISOSILK	Intraoperative
APC1292PAN	Adhesion Intraoperative Probe Cover with Gel	Intraoperative
APC1292S	ADHESION INTRAOPERATIVE PROBE COVER W/GEL, FEATURING ISOSILK	Intraoperative
APC1295	ADHESION INTRAOPERATIVE PROBE COVER W/GEL, FEATURING ISOSILK	Intraoperative
APC1296	ADHESION GENERAL PURPOSE PROBE COVER W/GEL, FEATURING ISOSIL	Intraoperative
APC1308	ADHESION INTRAOPERATIVE PROBE COVER W/GEL, FEATURING ISOSILK	Intraoperative
APC1416	ADHESION GENERAL PURPOSE PROBE COVER W/GEL,FEATURING ISOSILK	General Purpose
APC1416PAN	Adhesion General Purpose Probe Cover with Gel	General Purpose
AR2037	PROBE DRAPE	Intraoperative
AR2087	ARMATEC INTRAOPERATIVE PROBE COVER	Intraoperative
GPC396	GENERAL PURPOSE PROBE COVER	General Purpose
GPC396EU	GENERAL PURPOSE PROBE COVER	General Purpose
GPC415	GENERAL PURPOSE PROBE COVER	General Purpose
PC0905	ROLLED PROBE COVER	Endocavity
PC0905NS	ROLLED PROBE COVER	Endocavity
PC0906	ROLLED PROBE COVER	Endocavity
PC0906NB	ROLLED PROBE COVER	Endocavity
PC0906NS	ROLLED PROBE COVER	Endocavity



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PC0907	ROLLED PROBE COVER	Endocavity
PC0907NB	ROLLED PROBE COVER	Endocavity
PC0907NS	ROLLED PROBE COVER	Endocavity
PC1153	INTRAOPERATIVE ANGLED PROBE COVER LATEX FREE W/GEL	Intraoperative
PC1287	GENERAL PURPOSE PROBE COVER	General Purpose
PC1288	GENERAL PURPOSE PROBE COVER	General Purpose
PC1289	GENERAL PURPOSE PROBE COVER	General Purpose
PC1289PAN	GENERAL PURPOSE PROBE COVER	General Purpose
PC1290	GENERAL PURPOSE PROBE COVER	General Purpose
PC1290N	GENERAL PURPOSE PROBE COVER	General Purpose
PC1290PAN	GENERAL PURPOSE PROBE COVER	General Purpose
PC1291	GENERAL PURPOSE PROBE COVER	General Purpose
PC1291NBP	GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	General Purpose
PC1292	INTRAOPERATIVE PROBE COVER W/GEL	Intraoperative
PC1292N	INTRAOPERATIVE PROBE COVER,	Intraoperative
PC1292NG	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	Intraoperative
PC1292PAN	INTRAOPERATIVE PROBE COVER	Intraoperative
PC1293	INTRAOPERATIVE PROBE COVER	Intraoperative
PC1295	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	Intraoperative
PC1295N	*INTRAOPERATIVE PROBE COVER	Intraoperative
PC1296	GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	General Purpose
PC1296N	GENERAL PURPOSE PROBE COVER W/GEL	General Purpose
PC1297	GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	General Purpose
PC1308	INTRAOPERATIVE PROBE COVER W/GEL	Intraoperative
PC1308N	INTRAOPERATIVE PROBE COVER	Intraoperative
PC1308PAN	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	Intraoperative
PC1355NS	ENDOCAVITY TAPER	Endocavity
PC1415	GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	General Purpose
PC1416	GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	General Purpose
PC1417	GENERAL PURPOSE PROBE COVER	General Purpose
PC1419	GENERAL PURPOSE PROBE COVER	General Purpose
PC2630NS	ROLLED PROBE COVER	Endocavity
PC3687	ULTRASOUND T-SHAPED PROBE CVR	Intraoperative
PC3687N	ULTRASOUND T-SHAPED PROBE CVR"	Intraoperative
PC3687PAN	PROBE COVER FEATURING ISOSILK	Intraoperative
PC3787	PROBE DRAPE W/GEL LATEX FREE	Intraoperative
PC3787N	PROBE COVER	Intraoperative
PC3787PAN	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	Intraoperative
PC4515	LARGE ULTRASOUND T-SHAPED PROBE COVER	Intraoperative
PC-6X96	Intraoperative Probe Cover	Intraoperative
PN-1020751-001	General Purpose Probe Cover	General Purpose
T-01451-005A	General Purpose Probe Cover	General Purpose