DECLARATION OF CONFORMITY (DoC)

We

Name + address of manufacturer:	**Microtek Medical, Inc.** **(An Ecolab Company)** 1 Ecolab Place St. Paul, MN 55102 U.S.A.

Authorised EU Representative:	**Microtek Medical BV** Hekkehorst 24 7207 BN Zutphen The Netherlands

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)	IIa 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:

EN ISO 13485:2016	Certificate No. 44 221 117845
Conformity assessment procedure	93/42/EEC Annex II (without 4) CE Certificate No. 44 232 117845
Notified body	TÜV NORD CERT GmbH, CE0044 Am TÜV 1 45307 Essen
Validity	31 December 2028
Place / Date : St. Paul, MN USA 26 Jul 2024	Name and Function:  Matthew Clark Regulatory Specialist

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Listing of Devices

SKU No.	Product Description	Sub-Category
663320	*INTRAOPERATIVE PROBE COVER W/O GEL	Intraoperative
5000364	General Purpose Probe Cover	General Purpose
3787UK	* ONE PIECE ULTRASOUND PROBE DRAPE	Intraoperative
3827	*PROBE DRAPE LATEX FREE	General Purpose
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
GPC396EU	GENERAL PURPOSE PROBE COVER	General Purpose
PC1153	INTRAOPERATIVE ANGLED PROBE COVER LATEX FREE W/GEL	Intraoperative
PC1288	GENERAL PURPOSE PROBE COVER	General Purpose
PC1289	GENERAL PURPOSE PROBE COVER	General Purpose
PC1289PAN	GENERAL PURPOSE PROBE COVER	General Purpose
PC1290N	GENERAL PURPOSE PROBE COVER	General Purpose
PC1290PAN	GENERAL PURPOSE PROBE COVER	General Purpose
PC1292N	INTRAOPERATIVE PROBE COVER,	Intraoperative
PC1293	INTRAOPERATIVE PROBE COVER	Intraoperative
PC1295N	*INTRAOPERATIVE PROBE COVER	Intraoperative
PC1296N	GENERAL PURPOSE PROBE COVER W/GEL	General Purpose
PC1308	INTRAOPERATIVE PROBE COVER W/GEL	Intraoperative
PC1308N	INTRAOPERATIVE PROBE COVER	Intraoperative
PC1355NS	ENDOCAVITY TAPER	Endocavity
PC3687	ULTRASOUND T-SHAPED PROBE CVR	Intraoperative
PC3687N	ULTRASOUND T-SHAPED PROBE CVR"	Intraoperative
PC3787	PROBE DRAPE W/GEL LATEX FREE	Intraoperative
PC3787N	PROBE COVER	Intraoperative
PC4515	LARGE ULTRASOUND T-SHAPED PROBE COVER	Intraoperative
PN-1020751-001	General Purpose Probe Cover	General Purpose

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SKU No.	Product Description	Sub-Category
WPC0612	Wireless Probe Cover 6” X 12”	Intraoperative
WPC0612N	Wireless Probe Cover 6” X 12”, Non-Sterile	Intraoperative
WAPC0612	Wireless Adhesive Probe Cover 6” X 12”	Intraoperative
WAPC0612N	Wireless Adhesive Probe Cover 6” X 12”, Non-Sterile	Intraoperative