



DECLARATION OF CONFORMITY

We

Name + address of manufacturer:	Microtek Medical, Inc. 602 Lehmberg Road Columbus, MS 39702 U.S.A.
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European Representative:	Microtek Medical BV Hekkehorst 24 7207 BN Zutphen The Netherlands
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Declare on our own responsibility that

The medical device:	Probe Covers
Type:	See attached list
Classification: according to:	Ila Rule 7

Meets all the provisions of the Medical Device Directive 93/42/EEC

Applied harmonized standards:	EN ISO 13485 EN ISO 14971 EN 62366 EN ISO 11607-1 EN ISO 11607-2 EN ISO 11135-1 EN ISO 11137-1 EN ISO 11137-2 EN 556-1 EN ISO 15223-1 EN 1041 ISO 11737-1	ISO 11737-2 EN ISO 17664 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-7 EN ISO 10993-10 EN ISO 10993-11 EN ISO 10993-12 EN ISO 14644-1 EN ISO 14644-2 EN ISO 14698-1 EN ISO 14698-2
	All applicable standards have been applied	
Notified body:	TÜV NORD CERT GmbH CE 0044 Langemarckstr. 20 D-45141 Essen	
Conformity assessment:	93/42/EEC Annex II (without 4) CE Certificate No. 44 232 117845	
Validity:	14 August 2023	
Place / Date : St. Paul, MN USA 4 April 2019	Name and Function: Sr. Regulatory Specialist II	

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Attachment 1 – List of Applicable Part Numbers

Row Labels	Part Number	Part Description	Sterilization Method
Endocavity Probe Covers	9020209C	*CUSTOM TRANSDUCER COVER DRAPE 9" X 12"	ETO
	91179N	PROBE COVER, POLYISOPRENE STRAIGHT SHEATH	N/S
	PC0905	PROBE COVER, ROLLED W/RUBBERBANDS, .8" X 8"	GAMMA
	PC0905NS	PROBE COVER, ROLLED W/RUBBERBANDS, .8" X 8"	N/S
	PC0906	PROBE COVER, ROLLED, W/RUBBERBANDS, 1" X 8"	GAMMA
	PC0906NB	PROBE COVER, ROLLED, 2.6CM X 20CM, BULK, 100/CS	N/S
	PC0906NS	ROLLED PROBE COVER W/RUBBERBANDS, 1" X 8", BN/S	N/S
	PC0907	PROBE COVER, ROLLED, W/RUBBERBANDS, 1.4" X 8"	GAMMA
	PC0907NB	PROBE COVER, ROLLED 3.5CM X 20CM, BULK, 144/CS	N/S
	PC0907NS	PROBE COVER, ROLLED, W/RUBBERBANDS, 1.3" X 8"	N/S
	PC1355NS	ENDOCAVITY TAPER 10CM X 4.4CM X 25CM, NON/STERILE	N/S
	VPC0109NB	*[PL]PROBE COVER, ROLLED, 3.5CM X 20CM, BULK	N/S
	VPC0808NB	*[PL]PROBE COVER, ROLLED, 2.0CM X 20CM, BULK	N/S
General Purpose Probe Covers	3827	*PROBE DRAPE 7" X 72" LATEX FREE	ETO
	3827EU	PROBE DRAPE 7" X 72" LATEX FREE	ETO
	5000363	{PL}BAG, 6" X 48"	N/S
	5000364	{PL}BAG, 3" X 6" X 96"	N/S
	5000365	[PL]POLYURETHANE BAG, 5 3/8" X 12"	N/S
	APC1288	ADHESION GENERAL PURPOSE PROBE COVER W/GEL, FEATURING ISOSIL	ETO
	APC1289	ADHESION GENERAL PURPOSE PROBE COVER W/GEL, FEATURING ISOSIL	ETO
	APC1290	ADHESION GENERAL PURPOSE PROBE COVER W/GEL, FEATURING ISOSIL	ETO
	APC1291	ADHESIVE PROBE DRAPE, 5" X 24"	ETO
	APC1296	ADHESION GENERAL PURPOSE PROBE COVER W/GEL, FEATURING ISOSIL	ETO
	APC1416	ADHESION GENERAL PURPOSE PROBE COVER W/GEL,FEATURING ISOSILK	ETO
	GPC396	GAMMA PROBE COVER, 8CM X 244CM (3" X 96")	ETO
	GPC396EU	*GAMMA PROBE COVER, 8CM X 244CM (3" X 96")	ETO
	GPC415	CORDLESS GAMMA PROBE COVER	ETO
	LC279	*LC PROBE COVER 2 1/8" X 79" (5.4CM X 201CM)	ETO
	PC1287	GENERAL PURPOSE PROBE COVER, 8CM X 122CM (3" X 48")	ETO
	PC1288	GENERAL PURPOSE PROBE COVER, 4" X 48"	ETO
	PC1289	GENERAL PURPOSE PROBE COVER, 5" X 48"	ETO
	PC1289PAN	GENERAL PURPOSE PROBE COVER, 5" X 48" PREASSEMBLED	N/S
	PC1290	GENERAL PURPOSE PROBE COVER, 6" X 48"	ETO
	PC1290N	GENERAL PURPOSE PROBE COVER, 6" X 48"	N/S
	PC1290NR	GENERAL PURPOSE PROBE COVER W/RUBBERBANDS, 6" X 48"	N/S
	PC1290PAN	GENERAL PURPOSE PROBE COVER, 6" X 48" PREASSEMBLED	N/S
	PC1291	GENERAL PURPOSE PROBE COVER, 5" X 24"	ETO
	PC1291NBP	*GENERAL PURPOSE PROBE CVR, 5"X24" W/STERI STRIPS & RBANDS	N/S
	PC1296	GEN PURPOSE PROBE COVER, 4" X 24"	ETO
	PC1296N	GENERAL PURPOSE PROBE COVER W/GEL, 4" X 24"	N/S
	PC1297	GENERAL PURPOSE PROBE COVER, 3" X 24"	ETO
	PC1415	*GENERAL PURPOSE PROBE COVER, 8" X 24"	ETO
	PC1416	GENERAL PURPOSE PROBE COVER, 6" X 24"	ETO
	PC1417	GENERAL PURPOSE PROBE COVER, 9X24	ETO
	PC1417EU	*GENERAL PURPOSE PROBE COVER, 9" X 24"	ETO
	PC1419	GENERAL PURPOSE PROBE COVER, 2" X 24"	ETO
	PN-1020751-001	PROBE DRAPE, 18CM X 183CM	ETO
	T-01451-005A	*[P/L] N/S GENERAL PURPOSE PROBE COVER, 5" X 48"	N/S
Intraoperative Probe Covers	15340-00	*ULTRASOUND PROBE COVER	N/S
	15342-00	*ULTRASOUND T-SHAPED PROBE COVER, 6" X 96"	N/S
	15344-00	*ULTRASOUND PROBE DRAPE, 5" X 96"	N/S

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	3687	ULTRASOUND T-SHAPED PROBE CVR	ETO
	3688	ULTRASOUND PROBE COVER	ETO
	3787	PROBE DRAPE ,5" X 96"	ETO
	3787N	PROBE DRAPE ,5" X 96"	N/S
	3787UK	* ONE PIECE ULTRASOUND PROBE DRAPE	ETO
	4515	LARGE ULTRASOUND T-SHAPED	ETO
	663320	*INTRAOPERATIVE PROBE COVER W/O GEL, 6" X 96"	ETO
	APC1292	4ADHESION INTRAOPERATIVE PROBE COVER W/GEL,FEATURING ISOSILK	ETO
	APC1292S	ADHESION INTRAOPERATIVE PROBE COVER W/GEL, FEATURING ISOSILK	ETO
	APC1295	ADHESION INTRAOPERATIVE PROBE COVER W/GEL, FEATURING ISOSILK	ETO
	APC1308	ADHESION INTRAOPERATIVE PROBE COVER W/GEL, FEATURING ISOSILK	ETO
	AR2037	ARMATEC PROBE DRAPE	ETO
	AR2087	*ARMATEC INTRAOPERATIVE PROBE COVER, 6" X 96"	ETO
	PC1153	INTRAOPERATIVE ANGLED PROBE COVER, 5" X 96" LATEX FREE W/GEL	ETO
	PC1292	INTRAOPERATIVE PROBE COVER W/GEL 6" X 96"	ETO
	PC1292N	INTRAOPERATIVE PROBE COVER, 6" X 96"	N/S
	PC1292NG	INTRAOPERATIVE PROBE COVER W/OUT GEL 6" X 96"	ETO
	PC1292PAN	SURGICAL/INTRAOPERATIVE PROBE COVER, 6" X 96" PREASSEMBLED	N/S
	PC1293	INTRAOPERATIVE PROBE COVER, 3" X 96"	ETO
	PC1295	INTRAOPERATIVE PROBE COVER W/GEL, 4" X 96"	ETO
	PC1295N	*INTRAOPERATIVE PROBE COVER, 4" X 96", 10CM X 244CM BULK	N/S
	PC1308	INTRAOPERATIVE PROBE COVER W/GEL 5" X 96"	ETO
	PC1308N	INTRAOPERATIVE PROBE COVER, 12CM X 244CM, 5" X 96"	N/S
	PC1308PAN	SURGICAL/INTRAOPERATIVE PROBE COVER, 5" X 96" PREASSEMBLED	N/S
	PC3687	ULTRASOUND T-SHAPED PROBE CVR	ETO
	PC3687N	ULTRASOUND T-SHAPED PROBE CVR, 6" X 96"	N/S
	PC3687PAN	SURGICAL/INTRAOPERATIVE PROBE COVER W/SMALL T TIP, 6" X 96"	N/S
	PC3688	ULTRASOUND PROBE COVER	ETO
	PC3787	PROBE DRAPE W/GEL, 5" X 96" LATEX FREE	ETO
	PC3787N	PROBE COVER, 5" X 96"	N/S
	PC3787PAN	SURGICAL/INTRAOPERATIVE PROBE COVER W/STRAIGHT TIP, 5" X 96	N/S
	PC4515	LARGE ULTRASOUND T-SHAPED PROBE COVER	ETO