DECLARATION OF CONFORMITY (DoC)

We

Name + address + Single Registration Number of manufacturer:	**Microtek Medical LLC** Three Lakes Drive Northfield, IL 60093 U.S.A. **SRN:** US-MF-000019222

Name + address + Single Registration Number of Authorised EU Representative:	**Microtek Medical BV** Hekkehorst 24 7207 BN Zutphen The Netherlands **SRN:** NL-AR-000006076

declare that the DoC is issued under our sole responsibility and belongs to the following product(s):

Trade Name/Device Description	**Probe Covers**
Intended Purpose/Intended Use	A device intended to be used as a physical barrier for protection against the effects of environmental exposure (e.g., body fluids, gels) and/or to maintain the required hygienic level of various diagnostic or surgical procedures which utilize a transducer (probe). This is a single use device. [Not to be reprocessed.] The devices are further indicated to be used in or on: * Intact or compromised skin * Natural body orifices * Intra-operatively
Catalogue number(s) and Basic UDI-DI	See attached list
Class per Rule(s)	IIa Rule 7 of Annex VIII of MDR

The product described above conforms to the relevant provisions of the Regulation (EU) 2017/745 on medical devices and the following standards:

Common Specifications	None applicable
Other applicable Union legislation requiring an EU DoC	None applicable
Notified body	TÜV NORD CERT GmbH, CE0044 Am TÜV 1 45307 Essen
Conformity assessment procedure	Regulation (EU) 2017/745 Annex IX, Chapters I and III Certificate No. 44 911 117845 valid until 21 July 2030
EN ISO 13485:2016	Certificate No. 44 221 117845 valid until 14 August 2027
Place / Date : St. Paul, MN USA 26 SEP 2025	Name and Function:  Lam Duong [*Person Responsible for Regulatory Compliance*

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Listing of Devices

Part Number	Trade Name / Part Description	Basic UDI-DI
3827	GENERAL PURPOSE PROBE COVER, 7" X 72"	0748426MI2APC23INE2AN
3787UK	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	0748426MI2APP23INE1HH
91179N	Endocavity Probe Cover, 2.86 cm x 8.89 cm (1.125 in x 3.5 in)	0748426MI2APC23INN2BH
APC1288	ADHESION GENERAL PURPOSE PROBE COVER	0748426MI2APP23INE2HK
APC1289	Adhesion™ General Purpose Probe Cover, 13 cm x 122 cm (5 in x 48 in)	0748426MI2APP23INE2HK
APC1290N	Adhesion General Purpose Probe Cover	0748426MI2APC23INN2BH
APC1290PAN	Adhesion General Purpose Probe Cover	0748426MI2APP23INN2JE
APC1290	ADHESION GENERAL PURPOSE PROBE COVER	0748426MI2APP23INE2HK
APC1291	Adhesion™ General Purpose Probe Cover, 13 cm x 60 cm (5 in x 24 in)	0748426MI2APP23INE2HK
APC1292PAN	Adhesion™ Intraoperative Probe Cover, 15 cm x 244 cm (6 in x 96 in)	0748426MI2APP23INN2JE
APC1292	ADHESION INTRAOPERATIVE PROBE COVER	0748426MI2APP23INE2HK
APC1292S	ADHESION INTRAOPERATIVE PROBE COVER	0748426MI2APP23INE2HK
APC1295	Adhesion™ Intraoperative Probe Cover, 10 cm x 244 cm (4 in x 96 in)	0748426MI2APP23INE2HK
APC1296	Adhesion™ General Purpose Probe Cover, 10 cm x 60 cm (4 in x 24 in)	0748426MI2APP23INE2HK
APC1308	Adhesion™ Intraoperative Probe Cover, 13 cm x 240 cm (5 in x 96 in)	0748426MI2APP23INE2HK
APC1416PAN	Adhesion General Purpose Probe Cover	0748426MI2APP23INN2JE
APC1416	Adhesion™ General Purpose Probe Cover, 15 cm x 60 cm (6 in x 24 in)	0748426MI2APP23INE2HK
GPC396EU	General Purpose Probe Cover, 8 cm x 244 cm (3 in x 96 in)	0748426MI2APC23INE2AN
PC1153	Intraoperative Probe Cover Featuring IsoSilk™, 13 cm x 244 cm (5 in x 96 in)	0748426MI2APP23INE2HK
PC1288	GENERAL PURPOSE PROBE COVER	0748426MI2APC23INE2AN
PC1289PAN	GENERAL PURPOSE PROBE COVER	0748426MI2APP23INE2HK
PC1289PANFEU	General Purpose Probe Cover Kit	0748426MI2APP23INN2JE
PC1289	GENERAL PURPOSE PROBE COVER	0748426MI2APP23INE2HK
PC1290N	GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	0748426MI2APC23INN2BH
PC1290NREU	General Purpose Probe Cover Featuring IsoSilk™	0748426MI2APC23INN2BH
PC1290PAN	General Purpose Probe Cover, 15 cm x 122 cm (6 in x 48 in)	0748426MI2APP23INN2JE
PC1290EU	General Purpose Probe Cover, 15 cm x 122 cm (6 in x 48 in)	0748426MI2APP23INE2HK
PC1292N	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	0748426MI2APC23INN2BH
PC1292NEU	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	0748426MI2APC23INN2BH
PC1292PANEU	Intraoperative Probe Cover featuring IsoSilk™	0748426MI2APP23INN2JE
PC1292EU	INTRAOPERATIVE PROBE COVER	0748426MI2APP23INE2HK
PC1295N	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	0748426MI2APC23INN2BH
PC1293	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	0748426MI2APP23INE2HK
PC1296N	GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	0748426MI2APP23INN2JE
PC1308N	Intraoperative Probe Cover featuring IsoSilk®, 12 cm x 244 cm (5 in x 96 in)	0748426MI2APC23INN2BH
PC1308PANEU	Intraoperative Probe Cover featuring IsoSilk™	0748426MI2APP23INN2JE
PC1355NS	ENDOCAVITY PROBE COVER, 4" X 2" X 10"	0748426MI2APC23INN2BH
PC1308	INTRAOPERATIVE PROBE COVER FEATURING ISOSILK	0748426MI2APP23INE2HK
PC1416NREU	GENERAL PURPOSE PROBE COVER FEATURING ISOSILK	0748426MI2APC23INN2BH

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PC3687N	Intraoperative Probe Cover featuring IsoSilk®, 15 cm x 244 cm (6 in x 96 in)	0748426MI2APC23INN2BH
PC3687	Intraoperative Probe Cover Featuring IsoSilk™, 15 cm x 244 cm (6 in x 96 in)	0748426MI2APP23INE2HK
PC3787N	Intraoperative Probe Cover featuring IsoSilk®, 13 cm x 244cm (5 in x 96 in)	0748426MI2APC23INN2BH
PC3787	INTRAOPERATIVE PROBE COVER, 5" X 96"	0748426MI2APP23INE2HK
PC4515	INTRAOPERATIVE PROBE COVER	0748426MI2APP23INE2HK