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	**Equipment Drapes**
Intended Purpose/Intended Use	Equipment Drapes are intended to cover/wrap various surgical and/or nonsurgical instruments/. It functions as a physical barrier to prevent cross-contamination between the instrument/equipment and medical staff and/or to allow the instrument/equipment to enter a hygienic area [e.g. sterile surgical field] in various clinical settings. It is typically made of flexible plastic and shaped to fit the type of instrument/equipment. This is a single-use device [not to be reprocessed].
Catalogue number(s) and Basic UDI-DI	See attached list
Class per Rule(s)	Is Rule 1 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 25 AUG 2025	Name and Function:  Lam Duong *Person Responsible for Regulatory Compliance*

MEDLINE MICROTEK

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Listing of Devices

Part Number	Trade Name / Part Description	Basic UDI-DI
163-7007-001	ACCELEROMETER COVER ,3IN X 1.3IN X 72IN, STERILE	0748426MI1SED23INZ0JJ
2900UK	VIDEO CAMERA DRAPE, 12.5 X 240 CM	0748426MI1SED23INZ0JJ
3501UK	CLOSED SYSTEM VIDEO CAMERA DRAPE	0748426MI1SED23INZ0JJ
6001-40001	AKTORMED PROBE COVER 30cm X 178cm VE:50	0748426MI1SED24INZ0JV
000-0212	Camera Drape 7" X 96" (Intellijoint)	0748426MI1SED23INZ0JJ
10308181	STERILE DRAPE PACK 30" X 30"	0748426MI1SED23INZ0JJ
418-HDE-S	BIG CASE BACK TABLE COVER DRAPE, 54" X 81 1/4"	0748426MI1SED23INZ0JJ
419-HDE-S	BIG CASE BACK TABLE COVER, 54" X 93"	0748426MI1SED23INZ0JJ
420-HDE-S	BIG CASE BACK TABLE COVER, 54" X 105"	0748426MI1SED23INZ0JJ
4969UK	DUBACH MAYO STAND COVER, LATEX FREE	0748426MI1SED23INZ0JJ
22531	ULTRASOUND REGISTRATION Phantom Drape, 23cm x 8cm x 26cm	0748426MI1SED23INZ0JJ
3823	Banded Bag, Circular, 191 cm (75 in)	0748426MI1SED23INZ0JJ
17587	BANDED BAG 65X130CM CIRCLE	0748426MI1SED23INZ0JJ
17589	BANDED BAG 25X55CM CIRCLE	0748426MI1SED23INZ0JJ
17596	BANDED BAG 35X70CM CIRCLE	0748426MI1SED23INZ0JJ
17598	BANDED BAG 40X80CM CIRCLE	0748426MI1SED23INZ0JJ
17599	BANDED BAG 60X120CM CIRCLE	0748426MI1SED23INZ0JJ
17600	BANDED BAG 80X45CM	0748426MI1SED23INZ0JJ
17636	BANDED BAG 95X130CM	0748426MI1SED23INZ0JJ
17639	BANDED BAG 50X100CM CIRCLE	0748426MI1SED23INZ0JJ
17648	BANDED BAG 95X85CM	0748426MI1SED23INZ0JJ
3816UK	BANDED BAG 76CM (30IN) CIRCLE	0748426MI1SED23INZ0JJ
3818UK	BANDED BAG 152CM (60IN) CIRCLE	0748426MI1SED23INZ0JJ
3962UK	BANDED BAG 91X71CM	0748426MI1SED23INZ0JJ
4962UK	BANDED BAG 91X76CM	0748426MI1SED23INZ0JJ
60020S	BANDED BAG 101CM (20IN) CIRCLE	0748426MI1SED23INZ0JJ
60040S	BANDED BAG WITH ELASTIC OPENING, CIRCULAR	0748426MI1SED23INZ0JJ
60050S	BANDED BAG WITH ELASTIC OPENING, CIRCULAR	0748426MI1SED23INZ0JJ
63030RT	BANDED BAG WITH RUBBER BAND AND TAPE	0748426MI1SED23INZ0JJ
63630RT	BANDED BAG WITH RUBBER BAND AND TAPE	0748426MI1SED23INZ0JJ
63654RT	BANDED BAG W/RUBBERBAND & TAPE, 36" X 54"	0748426MI1SED23INZ0JJ
64040RT	BANDED BAG WITH RUBBER BAND AND TAPE	0748426MI1SED23INZ0JJ
64436ST	BANDED BAG WITH TAPE, SEWN 44" x 36"	0748426MI1SED23INZ0JJ
16508M	Equipment cover, Microscope drape for Zeiss, 117 cm X 267 cm, 65 mm	0748426MI1SED23INZ0JJ
16502M	EQUIPMENT COVER, MICROSCOPE DRAPE FOR ZEISS, 117 CM X 163 CM, 65 CM	0748426MI1SED23INZ0JJ
2169200H	Microscope 1 Drape, 117 cm x 267 cm (46 in x 105 in)	0748426MI1SED23INZ0JJ
2169400HUK	Microscope 1 Drape, 137 cm x 81 cm x 163 cm (54 in x 32 in x 64 in)	0748426MI1SED23INZ0JJ
2903UK	Microscope Laser Drape, with Laser Arm, 104 cm x 305 cm (41 in x 120 in)	0748426MI1SED23INZ0JJ
2938CL	Microscope Drape, For Zeiss OPMI with ClearLens, 104 cm x 305 cm (41 in x 120 in)	0748426MI1SED23INZ0JJ
2952CLEU	Microscope Drape, For Leica with ClearLens, 104 cm x 163 cm (41 in x 64 in)	0748426MI1SED23INZ0JJ
2952UK	MICROSCOPE DRAPE FOR LEICA, 41" X 64"	0748426MI1SED23INZ0JJ
2955CL	Microscope Drape, For Leica with ClearLens, 104 cm x 305 cm (41 in x 120 in)	0748426MI1SED23INZ0JJ

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2955CLEU	MICROSCOPE DRAPE FOR LEICA WITH CLEARLENS, 41" X 120"	0748426MI1SED23INZ0JJ
2955UK	Microscope Drape, For Leica, 104 cm x 305 cm (41 in x 120 in)	0748426MI1SED23INZ0JJ
3260UK	Microscope Handle Drape, 15 cm x 36 cm (6 in x 14 in)	0748426MI1SED23INZ0JJ
3548EU	Microscope Drape, For Leica, 117 cm x 267 cm (46 in x 105 in)	0748426MI1SED23INZ0JJ
3598UK	Microscope Drape, For Leica M680, 117 cm x 305 cm (46 in x 120 in)	0748426MI1SED23INZ0JJ
3652CL	Microscope Drape For Leica with ClearLens, 137 cm x 381 cm (54 in x 150 in)	0748426MI1SED23INZ0JJ
3652UK	Microscope Drape, For Leica, 137 cm x 381 cm (54 in x 150 in)	0748426MI1SED23INZ0JJ
3717UK	Microscope Head Drape, For Zeiss MD, 61 cm (24 in)	0748426MI1SED23INZ0JJ
40101.000	MICROSCOPE HEAD COVER	0748426MI1SED23INZ0JJ
40100.000	UNIVERSAL MICROSCOPE DRAPE, 41" X 81" (104.14cm x 205.74cm)	0748426MI1SED23INZ0JJ
4821UK	Microscope Drape, For Zeiss MD, 51 cm x 163 cm (20 in x 64 in)	0748426MI1SED23INZ0JJ
4831UK	Microscope Drape, For Zeiss MD, 102 cm x 61 cm x 163 cm (40 in x 24 in x 64 in)	0748426MI1SED23INZ0JJ
4831UKCL	Microscope Drape, For Zeiss MD with ClearLens, 102 cm x 61 cm x 163 cm (40 in x 24 in x 64 in)	0748426MI1SED23INZ0JJ
4838CL	MICROSCOPE DRAPE FOR ZEISS MD FEATURING CLEARLENS, 46" X 120"	0748426MI1SED23INZ0JJ
4838CLEU	Microscope Drape For Zeiss MD with ClearLens, 117 cm x 305 cm (46 in x 120 in)	0748426MI1SED23INZ0JJ
4838UK	MICROSCOPE DRAPE FOR ZEISS MD	0748426MI1SED23INZ0JJ
4840CL	MICROSHIELD MICROSCOPE DRAPE FOR ZEISS MD FEATURING CLEARLENS, 46" X 105"	0748426MI1SED23INZ0JJ
4840UK	Microscope Drape For Zeiss MD, 117 cm x 267 cm (46 in x 105 in)	0748426MI1SED23INZ0JJ
4840UKCL	MICROSCOPE DRAPE FOR ZEISS MD WITH CLEARLENS	0748426MI1SED23INZ0JJ
4841CLEU	Microscope Drape, For Zeiss MD with ClearLens, 117 cm x 163 cm (46 in x 64 in)	0748426MI1SED23INZ0JJ
4841UK	Microscope Drape, For Zeiss MD, 117 cm x 163 cm (46 in x 64 in)	0748426MI1SED23INZ0JJ
4842CLEU	Microscope Drape, For Zeiss MD with ClearLens, 137 cm x 267 cm (54 in x 105 in)	0748426MI1SED23INZ0JJ
4842UK	Microscope Drape, For Zeiss MD, 137 cm x 267 cm (54 in x 105 in)	0748426MI1SED23INZ0JJ
4861EU	Microscope Drape, For Zeiss with Handle Covers, 163 cm x 76 cm (64 in x 30 in)	0748426MI1SED23INZ0JJ
4862UK	Microscope Drape, for Zeiss MD, 117 cm x 203 cm (46 in x 80 in)	0748426MI1SED23INZ0JJ
4862UKCL	Microscope Drape, for Zeiss MD with ClearLens, 117 cm x 203 cm (46 in x 80 in)	0748426MI1SED23INZ0JJ
4863CLEU	Microscope Drape, For Zeiss MD with ClearLens, 137 cm x 381 cm (54 in x 150 in)	0748426MI1SED23INZ0JJ
4865CLEU	Microscope Drape For Zeiss MD with ClearLens, 137 cm x 381 cm (54 in x 150 in)	0748426MI1SED23INZ0JJ
4921CL	Microscope Drape, For Zeiss OPMI with ClearLens, 51 cm x 163 cm (20 in x 64 in)	0748426MI1SED23INZ0JJ
4921UK	Microscope Drape, For Zeiss OPMI, 51 cm x 163 cm (20 in x 64 in)	0748426MI1SED23INZ0JJ
4931UK	Microscope Drape, For Zeiss OPMI, 102 cm x 61 cm x 163 cm (40 in x 24 in x 64 in)	0748426MI1SED23INZ0JJ
4932UK	Microscope Drape, For Zeiss OPMI, 137 cm x 81 cm x 163 cm (54 in x 32 in x 64 in)	0748426MI1SED23INZ0JJ
4940CL	Microscope Drape, For Zeiss OPMI with ClearLens, 104 cm x 267 cm (41 in x 105 in)	0748426MI1SED23INZ0JJ
4940UK	Microscope Drape, For Zeiss OPMI, 104 cm x 267 cm (41 in x 105 in)	0748426MI1SED23INZ0JJ
4941UK	Microscope Drape, For Zeiss OPMI, 104 cm x 163 cm (41 in x 64 in)	0748426MI1SED23INZ0JJ
4941UKCL	Microscope Drape, For Zeiss OPMI with ClearLens, 104 cm x 163 cm (41 in x 64 in)	0748426MI1SED23INZ0JJ
5952UK	MICROSCOPE DRAPE FOR LEICA, 54" X 105"	0748426MI1SED23INZ0JJ
5952UKCL	Microscope Drape, For Leica with ClearLens, 137 cm x 267 cm (54 in x 105 in)	0748426MI1SED23INZ0JJ

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5986CLEU	Microscope Drape, For Leica with ClearLens, 104 cm x 267 cm (41 in x 105 in)	0748426MI1SED23INZ0JJ
5986UK	Microscope Drape, For Leica, 104 cm x 267 cm (41 in x 105 in)	0748426MI1SED23INZ0JJ
6100EU	Microscope Drape, For Zeiss with Vari-Lens, 122 cm x 203 cm (48 in x 80 in)	0748426MI1SED23INZ0JJ
6100VL2	MICROSCOPE DRAPE FOR ZEISS WITH VARI-LENS II	0748426MI1SED23INZ0JJ
6110EU	Microscope Drape, For Zeiss MD with Vari-Lens, 122 cm x 305 cm (48 in x 120 in)	0748426MI1SED23INZ0JJ
6110VL2	MICROSCOPE DRAPE FOR ZEISS WITH VARI-LENS II	0748426MI1SED23INZ0JJ
6120EU	Microscope Drape, For Zeiss MD with Vari-Lens, 132 cm x 381 cm (52 in x 150 in)	0748426MI1SED23INZ0JJ
6120VL2	MICROSCOPE DRAPE FOR ZEISS WITH VARI-LENS II	0748426MI1SED23INZ0JJ
6130VL2	MICROSCOPE DRAPE FOR LEICA WITH VARI-LENS II	0748426MI1SED23INZ0JJ
6135EU	Microscope Drape, For Leica with Vari-Lens, 132 cm x 305 cm (52 in x 120 in)	0748426MI1SED23INZ0JJ
6140EU	Microscope Drape, For Leica with Vari-Lens, 132 cm x 381 cm (52 in x 150 in)	0748426MI1SED23INZ0JJ
6140VL2	MICROSCOPE DRAPE FOR LEICA WITH VARI-LENS II	0748426MI1SED23INZ0JJ
6150VL2	MICROSCOPE DRAPE FOR LEICA WITH VARI-LENS II	0748426MI1SED23INZ0JJ
8033621EU	Microscope Drape, For Leica M680, 117 cm x 305 cm (46 in x 120 in)	0748426MI1SED23INZ0JJ
8033650EU	Microscope Drape For Leica, 137 cm x 381 cm (51 in x 150 in)	0748426MI1SED23INZ0JJ
8033651EU	Microscope Drape For Leica, 117 cm x 305 cm (46 in x 120 in)	0748426MI1SED23INZ0JJ
8033652EU	Microscope Mini Drape For Leica, 117 cm x 302 cm (46 in x 80 in) w/ drawcord	0748426MI1SED23INZ0JJ
8033654EU	Microscope Drape For Leica M720/OH5, 117 cm x 305 cm (46 in x 120 in)	0748426MI1SED23INZ0JJ
AR8033650	ARMATEC MICROSCOPE DRAPE FOR LEICA OH4/OK3/OHS/MS2/MS3/F40, 54" X 150"	0748426MI1SED23INZ0JJ
AR8033651	ARMATEC MICROSCOPE DRAPE FOR LEICA OH4/OK3/OHS/MS2/MS3/F40, 46" X 120"	0748426MI1SED23INZ0JJ
OME-V2-D	Microscope Drape OME-V2-D	0748426MI1SED23INZ0JJ
4951	C-Arm / Mobile X-Ray Drape, 104 cm x 188 cm (41 in x 74 in)	0748426MI1SED23INZ0JJ
17307	C-Arm Cover, For Zeego, 41 cm x 133 cm (16 in x 52.4 in)	0748426MI1SED23INZ0JJ
17308	C-ARM DRAPE SET FOR ZEEGO, LARGE	0748426MI1SED23INZ0JJ
17309	C-ARM DRAPE SET FOR ZEEGO, SMALL	0748426MI1SED23INZ0JJ
17315	POCKETED TAPE DRAPE SET FOR MOBILE C-ARM	0748426MI1SED23INZ0JJ
17400	C-ARM COVER SET FOR PHILIPS ALLURA FD20	0748426MI1SED23INZ0JJ
17405	C-ARM COVER SET FOR PHILIPS ALLURA FD10	0748426MI1SED23INZ0JJ
17415	C-Arm Cover Set for Philips Azurion Flex Arm/Flex Move	0748426MI1SED23INZ0JJ
17515	FLAT DETECTOR C-ARM DRAPE, 36" X 120"	0748426MI1SED23INZ0JJ
17661	COVER SET FOR C-ARM SIEMENS CIOS ALPHA	0748426MI1SED23INZ0JJ
17680	C-BOW SET GE, GE9600/9800/8800 9"	0748426MI1SED23INZ0JJ
17681	C-BOW SET GE, GE9600/9800/8800 12"	0748426MI1SED23INZ0JJ
17682	C-BOW COVER FOR GE, GE9600/9800/8800	0748426MI1SED23INZ0JJ
110788	MINI C-ARM COVER	0748426MI1SED23INZ0JJ
10308184	STERILE C-ARM DRAPE	0748426MI1SED23INZ0JJ
10308181	STERILE DRAPE PACK FOR 30" X 30" FLAT DETECTOR	0748426MI1SED23INZ0JJ
2951AUK	C-ARM DRAPE FULL COVERAGE, 42" X 89"	0748426MI1SED23INZ0JJ
2951UK	C-ARM DRAPE FULL COVERAGE, 152 cm x 267 cm (60 in x 105 in)	0748426MI1SED23INZ0JJ
4951E	UNIVERSAL C-ARM DRAPE FEATURING ELASTIFIT BANDS, 41" X 84"	0748426MI1SED23INZ0JJ
4951R	C-Arm / Mobile X-Ray Drape, with Rubberbands, 104 cm x 188 cm (41 in x 74 in)	0748426MI1SED23INZ0JJ
8888MEU	Mini C-Arm Drape For Fluoroscan, 137 cm x 198 cm (54 in x 78 in)	0748426MI1SED23INZ0JJ

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ART-DRP-2-001	Spectrum Drape	0748426MI1SED23INZ0JJ
C9-008MEU	Mini C-Arm Drape Set, For GE OEC 6800	0748426MI1SED23INZ0JJ
C9-106MEU	Mini C-Arm Drape, For GE OEC 6600, 104 cm x 213 cm (41 in x 84 in)	0748426MI1SED23INZ0JJ
TSM-01	TOUCH SCREEN MODULE DRAPE FOR PHILIPS, 19.75" X 24"	0748426MI1SED23INZ0JJ
5500EU	Positioning Arm Drape, for AESOP™ Robotic System, 38 cm x 163 cm (15 in x 64 in)	0748426MI1SED24INZ0JV