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)	I Rule 1 of Annex VIII of MDR

Common Specifications	None applicable
Other applicable Union legislation requiring an EU DoC	None applicable
Conformity assessment procedure	Regulation (EU) 2017/745 Annex II and III for Technical Documentation (self-assessment)
EN ISO 13485:2016	Certificate No. 44 221 117845 valid until 14 August 2027
Place / Date : St. Paul, MN USA 23 OCT 2025	Name and Function:  Lam Duong *Person Responsible for Regulatory Compliance*

Listing of Devices

Part Number	Trade Name / Part Description	Basic UDI-DI
8167N	AUXILIARY DRAPE, 36 CM X 58 CM	0748426MI01ED23INZ0RT
3317495	Banded Bag, 50 cm x 100 cm (19.5 in x 39 in)	0748426MI01ED23INZ0RT
3317496	Banded Bag, 35 cm x 70 cm (13.5 in x 27 in)	0748426MI01ED23INZ0RT
3317498	Banded Bag, 40 cm x 80 cm (15.5 in x 31 in)	0748426MI01ED23INZ0RT
3317499	Banded Bag, 60 cm x 120 cm (23.5 in x 47 in)	0748426MI01ED23INZ0RT

DECLARATION OF CONFORMITY (DoC)

3317589	Banded Bag, 25 cm x 55 cm (9.8 in x 21.6 in)	0748426MI01ED23INZ0RT
3317600	Banded Bag, 80 cm x 45 cm (31.5 in x 17.5 in)	0748426MI01ED23INZ0RT
3317636	Banded Bag, 95 cm x 130 cm (37 in x 51 in)	0748426MI01ED23INZ0RT
3317648	Banded Bag, 95 cm x 85 cm (37 in x 33 in)	0748426MI01ED23INZ0RT
0030S	Banded Bag, Circular, 76 cm (30 in)	0748426MI01ED23INZ0RT
0036S	Banded Bag, Circular, 91 cm (36 in)	0748426MI01ED23INZ0RT
0040S	Banded Bag, Circular, 101 cm (40 in)	0748426MI01ED23INZ0RT
0050S	Banded Bag, Circular, 127 cm (50 in)	0748426MI01ED23INZ0RT
0060S	Banded Bag, Circular, 152 cm (60 in)	0748426MI01ED23INZ0RT
15-2802-01	SET UP COVER, 44" X 70"	0748426MI01ED23INZ0RT
15-2802-02	SET UP COVER, 44" X 90"	0748426MI01ED23INZ0RT
15-2802-05	SET UP COVER WITH LABEL AND TAPE, 44" X 70"	0748426MI01ED23INZ0RT
15-2802-06	SET UP COVER W/LABEL, 54" X 90"	0748426MI01ED23INZ0RT
15-2802-13	SET UP COVER, 54" X 90"	0748426MI01ED23INZ0RT
17401N	TABLE BASE COVER FOR PHILIPS ALLURA XPER	0748426MI01ED23INZ0RT
17404N	TABLE COVER FOR PHILIPS ALLURA	0748426MI01ED23INZ0RT
2420FSN	FOOT SWITCH DRAPE	0748426MI01ED23INZ0RT
2502N	STERI-STRIP FOR 8170F	0748426MI01ED23INZ0RT
2952N	MICROSCOPE DRAPE FOR LEICA, 41" X 64"	0748426MI01ED23INZ0RT
2955CLN	MICROSCOPE DRAPE FOR LEICA WITH CLEARLENS, 41" X 120"	0748426MI01ED23INZ0RT
3030RT	Banded Bag with Rubberband and Tape, 76 cm x 76 cm (30 in x 30 in)	0748426MI01ED23INZ0RT
3036RT	Banded Bag with Rubberband and Tape, 76 cm x 91 cm (30 in x 36 in)	0748426MI01ED23INZ0RT
3260N	MICROSCOPE HANDLE DRAPE, 6" X 14"	0748426MI01ED23INZ0RT
3548N	MICROSCOPE DRAPE FOR LEICA M840	0748426MI01ED23INZ0RT
3630RT	Banded Bag with Rubberband and Tape, 91 cm x 76 cm (36 in x 30 in)	0748426MI01ED23INZ0RT
3636RT	Banded Bag with Rubberband and Tape, 91 cm x 91 cm (36 in x 36 in)	0748426MI01ED23INZ0RT
3640RT	Banded Bag with Rubberband and Tape, 91 cm x 101 cm (36 in x 40 in)	0748426MI01ED23INZ0RT
3717N	MICROSCOPE HEAD DRAPE FOR ZEISS MD, 24"	0748426MI01ED23INZ0RT
4030RT	Banded Bag with Rubberband and Tape, 101 cm x 76 cm (40 in x 30 in)	0748426MI01ED23INZ0RT
4040RT	Banded Bag with Rubberband and Tape, 101 cm x 101 cm (40 in x 40 in)	0748426MI01ED23INZ0RT
4238RT	Banded Bag with Rubberband and Tape, 106 cm x 96 cm (42 in x 38 in)	0748426MI01ED23INZ0RT
4260RT	Banded Bag with Rubberband and Tape, 106 cm x 152 cm (42 in x 60 in)	0748426MI01ED23INZ0RT
4470SUC	SET UP COVER WITH LABEL, 44" X 70"	0748426MI01ED23INZ0RT
4514N	C-ARM DRAPE, 41" X 72"	0748426MI01ED23INZ0RT
4588N	DRILL DRAPE, 3" X 60"	0748426MI01ED23INZ0RT
47000-0	BANDED BAG, 30" X 30"	0748426MI01ED23INZ0RT
47001-0	BANDED BAG, 30" X 15"	0748426MI01ED23INZ0RT
47002-0	BANDED BAG, 30" X 24"	0748426MI01ED23INZ0RT
4838CLN	MICROSCOPE DRAPE FOR ZEISS MD WITH CLEARLENS, 46" X 120"	0748426MI01ED23INZ0RT
4838N	MICROSHIELD MICROSCOPE DRAPE FOR ZEISS MD	0748426MI01ED23INZ0RT

DECLARATION OF CONFORMITY (DoC)

4840CLN	MICROSCOPE DRAPE FOR ZEISS MD WITH CLEARLENS, 46" X 105"	0748426MI01ED23INZ0RT
4840N	MICROSCOPE DRAPE FOR ZEISS MD, 46" X 105"	0748426MI01ED23INZ0RT
4841N	MICROSCOPE DRAPE FOR ZEISS MD, 46" x 64"	0748426MI01ED23INZ0RT
4862CLN	MICROSCOPE DRAPE FOR ZEISS MD WITH CLEARLENS, 46" X 80"	0748426MI01ED23INZ0RT
4862N	Microshield™ Microscope Drape, for Zeiss MD, 117 cm x 203 cm (46 in x 80 in)	0748426MI01ED23INZ0RT
4926N	FOOTSWITCH DRAPE, 14" x 30"	0748426MI01ED23INZ0RT
4951N	C-Arm / Mobile X-Ray Drape, 104 cm x 188 cm (41 in x 74 in)	0748426MI01ED23INZ0RT
4953N	X-RAY CASSETTE DRAPE, 20" X 21"	0748426MI01ED23INZ0RT
4962N	Fluoroscope Drape with Tape, 91 cm x 76 cm (36 in x 30 in)	0748426MI01ED23INZ0RT
4980N	CAMERA DRAPE, 5" X 96"	0748426MI01ED23INZ0RT
5102N	VIDEO CAMERA DRAPE WITH RUBBERBANDS, 7" X 96"	0748426MI01ED23INZ0RT
5952N	MICROSCOPE DRAPE FOR LEICA, 54" X 105"	0748426MI01ED23INZ0RT
8033650EUN	MICROSCOPE DRAPE FOR LEICA, 54" X 150"	0748426MI01ED23INZ0RT
CD5140IN	TUBE COVER, 8 cm x 122 cm (3 in x 48 in)	0748426MI01ED23INZ0RT