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	**Patient Drapes**
Intended Purpose/Intended Use	Patient drapes consist of synthetic materials, as well as natural materials (specific to some product types) and are intended to be used as a protective patient covering during surgical procedures. The primary purpose of the drape is to isolate a site of surgical incision from microbial or other contamination. 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 SEP 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
11-800	LINGEMAN IMPERVIOUS SURGICAL CHAIR COVER	0748426MI1SPD29INZ0T5
2997UK	UNDER BUTTOCKS DRAPE, 39" X 46"	0748426MI1SPD29INZ0T5
3804UK	KNEE ARTHROSCOPY DRAPE, 100" X 120"	0748426MI1SPD29INZ0T5
3904UK	KNEE ARTHROSCOPY DRAPE, 77" X 128"	0748426MI1SPD29INZ0T5
4950UK	PATIENT DRAPE IRRIGATION POUCH, 20" X 20"	0748426MI1SPD30INZ0QF
5960UK	PATIENT ISOLATION DRAPE, 96" X 130"	0748426MI1SPD28INZ0SS
6960UK	PATIENT ISOLATION DRAPE, 130" X 96"	0748426MI1SPD28INZ0SS
8922UK	EYE DRAPE, 18" X 18"	0748426MI1SPD29INZ0T5
AD200	ANGIO DRAPE - FEMORAL, 75" X 110"	0748426MI1SPD29INZ0T5
AD201	ANGIO DRAPE - FEMORAL, 75" X 125"	0748426MI1SPD29INZ0T5
AD202	ANGIO DRAPE - FEMORAL, 86" X 135"	0748426MI1SPD29INZ0T5
AD206	ANGIO DRAPE - FEMORAL, 86" X 135"	0748426MI1SPD29INZ0T5
AD210-1	PEDIATRIC / THYROID ANGIOGRAPHY DRAPE, 75" X 125"	0748426MI1SPD29INZ0T5
AD215	MINOR PROCEDURES DRAPE, 37 1/2" X 55"	0748426MI1SPD29INZ0T5
AD218	ANGIO DRAPE - FEMORAL, 86" X 158"	0748426MI1SPD29INZ0T5
AD220	PEDIATRIC ANGIO DRAPE, 75" X 153"	0748426MI1SPD29INZ0T5
AD2234	ANGIO DRAPE - FEMORAL / RADIAL, 86" X 135"	0748426MI1SPD29INZ0T5
AD2234XL	ANGIO DRAPE - FEMORAL / RADIAL, 86" X 150"	0748426MI1SPD29INZ0T5
AD228	ANGIO DRAPE - INTRAJUGULAR / SUBCLAVIAN, 75" X 125"	0748426MI1SPD29INZ0T5
AD229	SPECIAL PROCEDURES DRAPE - KYPHO, 75" X 135"	0748426MI1SPD29INZ0T5
AD235	ANGIO DRAPE - FEMORAL, 86" X 135"	0748426MI1SPD29INZ0T5
AD248	ANGIO DRAPE - INTRAJUGULAR / FEMORAL, 75" X 145"	0748426MI1SPD29INZ0T5
AE5727I	INSTRUMENT POUCH DRAPE, 11" X 19"	0748426MI1SPD30INZ0QF
ISO1000	Patient Drape ISODrape Towel Drape - Small, 46 cm x 30 cm (18 in x 12 in)	0748426MI1SPD30INZ0QF
ISO1015EU	ISODRAPE U DRAPE, 48" X 48"	0748426MI1SPD30INZ0QF
ISO1016	IRRIGATION POUCH, 20" X 23"	0748426MI1SPD30INZ0QF
ISO1018EU	INSTRUMENT POUCH DRAPE, 7" X 12"	0748426MI1SPD30INZ0QF
ISO1019	ISODRAPE U DRAPE - LONG, 48" X 72"	0748426MI1SPD30INZ0QF
ISO1020	ISODRAPE APERTURE DRAPE - SMALL, 16" X 16"	0748426MI1SPD30INZ0QF
ISO1024	ISODRAPE APERTURE DRAPE - SMALL, 16" X 28"	0748426MI1SPD30INZ0QF
ISO1030	ISODRAPE APERTURE DRAPE - MEDIUM, 50" X 32"	0748426MI1SPD30INZ0QF
ISO1051	ISODRAPE INCISE DRAPE, 36" X 36"	0748426MI1SPD28INZ0SS
ISO1061	ISODRAPE APERTURE DRAPE - MEDIUM, 48" X 51"	0748426MI1SPD30INZ0QF
PD107	PACEMAKER DRAPE, 75" X 135"	0748426MI1SPD29INZ0T5
PD201EU	PACEMAKER DRAPE, 86" X 135"	0748426MI1SPD29INZ0T5
PD212-1	PACEMAKER DRAPE, 100" X 144"	0748426MI1SPD29INZ0T5
SPD212	FISTULAGRAM DRAPE, 45" X 60"	0748426MI1SPD29INZ0T5