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
0020S	BANDED BAG, CIRCULAR, 20"	0748426MI01ED23EXZ0SH
0052S	BANDED BAG, CIRCULAR, 52"	0748426MI01ED23EXZ0SH
2904N	CAMERA DRAPE, 7" X 96"	0748426MI01ED23EXZ0SH
3620ST	BANDED BAG SEWN W/TAPE, 36" X 20"	0748426MI01ED23EXZ0SH
3650RT	BANDED BAG W/RUBBERBAND & TAPE, 36" X 50"	0748426MI01ED23EXZ0SH

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4230RT	BANDED BAG W/RUBBERBAND AND TAPE	0748426MI01ED23EXZ0SH
4604N	CAMERA DRAPE WITH TRANSLUCENT TIP, 18 cm x 244 cm (7 in x 96 in)	0748426MI01ED23EXZ0SH
4650N	CAMERA DRAPE	0748426MI01ED23EXZ0SH
4825ST	BANDED BAG SEWN W/TAPE	0748426MI01ED23EXZ0SH
4954N	X-RAY CASSETTE DRAPE, LARGE	0748426MI01ED23EXZ0SH
5036ST	BANDED BAG SEWN W/TAPE	0748426MI01ED23EXZ0SH
5900N	VIDEO CAMERA DRAPE, 5" X 96"	0748426MI01ED23EXZ0SH
9604N	VIDEO CAMERA LASER DRAPE W/TRANSLUCENT ELASTIC TIP, 7" X 96"	0748426MI01ED23EXZ0SH
9900N	VIDEO CAMERA DRAPE W/ PERFORATED TIP, 5" X 96"	0748426MI01ED23EXZ0SH
9904N	VIDEO CAMERA LASER DRAPE, 7" X 96"	0748426MI01ED23EXZ0SH
9907N	CLOSED SYSTEM COUPLER CAMERA DRAPE WITH TRANSFER STICK, 18 CM X 246 CM	0748426MI01ED23EXZ0SH
MT08079	SET UP COVER, 44" X 77"	0748426MI01ED23EXZ0SH