



DECLARATION OF CONFORMITY (DoC)

We


Name + address of manufacturer:	Microtek Medical, Inc. (An Ecolab Company) 1 Ecolab Place St. Paul, MN 55102 USA
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Authorised EU Representative:	Microtek Medical BV Hekkehorst 24 7207 BN Zutphen The Netherlands
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declare that the DoC is issued under our sole responsibility and belongs to the following product(s):

Trade Name/Device Description	Equipment Drapes – General Purpose
Catalogue number(s)	See Attached list
Class per Rule(s)	Is Rule 1 of Annex IX of MDD

The product described above conforms to the relevant provisions of the EC Council Directive 93/42/EEC concerning medical devices and the following standards:

Notified body	TÜV NORD CERT GmbH, CE0044 Langemarckstr. 20 D-45141 Essen
Conformity assessment procedure	93/42/EEC Annex V for sterilization procedure CE Certificate No. 44 237 117845 valid until 14 August 2023
EN ISO 13485:2016	Certificate No. 44 221 117845 valid until 14 August 2021
Place / Date : St. Paul, MN USA July 13, 2021	Name and Function:  Steven Deline, MS RAS Senior Regulatory Specialist II



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Applicable SKU List

SKU No.	Product Description
3823	BANDED BAG CIRCULAR
4954	X-RAY CASSETTE DRAPE, LARGE, 24" X 25"
22531	ULTRASOUND REGISTRATION PHANTOM DRAPE
890016	UNIVERSAL X-RAY EQUIPMENT DRAPE, 41" X 65"
890017	UNIVERSAL X-RAY EQUIPMENT DRAPE, 318 CM
10308181	STERILE DRAPE PACK FOR 30" X 30" FLAT DETECTOR
100160-01	TRABECTOME DRAPING SYSTEM
134-00-00	LATERAL JACK STERILE COVER, 13" X 62"
163-7007-001	ACCELEROMETER COVER, 2" X 1.3" X 72"
315-S	BACK TABLE COVER, 80" X 90"
418-HDE-S	BIG CASE BACK TABLE COVER DRAPE
419-HDE-S	BIG CASE BACK TABLE COVER
420-HDE-S	BIG CASE BACK TABLE COVER DRAPE
4969UK	DUBACH MAYO COVER
60040S	BANDED BAG WITH ELASTIC OPENING, CIRCULAR
60050S	BANDED BAG WITH ELASTIC OPENING, CIRCULAR
63030RT	BANDED BAG WITH RUBBER BAND AND TAPE
63630RT	BANDED BAG WITH RUBBER BAND AND TAPE
63654RT	BANDED BAG WITH RUBBER BAND AND TAPE, 36" X 54"
64040RT	BANDED BAG WITH RUBBER BAND AND TAPE
64436ST	BANDED BAG WITH TAPE, SEWN 44" x 36"
KB1277	KEYBOARD DRAPE, 26" X 36"