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DECLARATION OF CONFORMITY (DoC)

We

Name + address + Single Registration Number of manufacturer:	**Microtek Medical, Inc.** **(An Ecolab Company)** 1 Ecolab Place St. Paul, MN 55102 USA **SRN:** The obligation for submission of UDI data in the EUDAMED database applies from 26 November 2022 for medical devices.

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	**General Purpose Equipment Drapes**
Catalog number(s) & Basic UDI-DI	See attached list
Class per Rule(s)	I 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:

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 2024
Place / Date : St. Paul, MN USA July 15, 2021	Name and Function:  Lam Duong Person Responsible for Regulatory Compliance

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Listing of Devices

Part Number	Trade Name / Part Description	Basic UDI-DI
15-2802-01	*[P/L]SET-UP COVER, 44'' X 70''	748426MI01ED01INZ0UZ
15-2802-02	*[P/L]SET-UP COVER, 44'' X 90''	748426MI01ED01INZ0UZ
15-2802-05	*[P/L]SET-UP COVER, 44" X 70" W/LABEL & TAPE,	748426MI01ED01INZ0UZ
15-2802-06	*[P/L]SET-UP COVER, 54''X 90'',W/LABEL	748426MI01ED01INZ0UZ
15-2802-13	*[P/L]SET UP COVER, 54" X 90"	748426MI01ED01INZ0UZ
17401N	*TABLE BASE COVER FOR PHILLIPS ALLURA XPER	748426MI01ED01INZ0UZ
17404N	*TABLE COVER FOR PHILIPS ALLURA	748426MI01ED01INZ0UZ
2420FSN	FOOTSWITCH DRAPE, 24" X 20", NON STERILE	748426MI01ED01INZ0UZ
419-HDE-NS	*[P/L]BIG CASE BACK TABLE COVER, 54" X 93"	748426MI01ED01INZ0UZ
44023-3	*54X72 BTC (1000/CS)	748426MI01ED01INZ0UZ
44066-3	*TABLE COVER, 80'' X 90'' (240/CS)	748426MI01ED01INZ0UZ
44082-0	*54" X 90" ABSORBENT BTC (300/CS)	748426MI01ED01INZ0UZ
4470SUC	*[P/L]SET UP COVER, 44'' X 70'' W/LABEL	748426MI01ED01INZ0UZ
47000-0	*SEWN BAND BAG # 701 30" X 30", BULK N/S	748426MI01ED01INZ0UZ
47001-0	*SEWN BAND BAG #702, 30'' X 15'', BULK N/S	748426MI01ED01INZ0UZ
47002-0	*SEWN BAND BAG # 703 30'' X 24'', BULK N/S	748426MI01ED01INZ0UZ
47004-0	*SEWN BAND BAG # 705, 44'' X 36'', BULK N/S	748426MI01ED01INZ0UZ
4926N	FOOT SWITCH DRAPE BULK NS 14" X 30"	748426MI01ED01INZ0UZ
4953N	X-RAY CASSETTE DRAPE SMALL, BULK N/S	748426MI01ED01INZ0UZ
812-1418-001	*[P/L]REV B - INSTRUMENT DRAPE W/ADH 11" X 18	748426MI01ED01INZ0UZ
3260N	*UNIVERSAL HANDLE COVER, 6" X 14"	748426MI01ED02INZ0VC