

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	Patient Drapes
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 2024
Place / Date : St. Paul, MN USA July 14, 2021	Name and Function:  Steven Deline, MS RAS Senior Regulatory Specialist II

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Applicable SKU List

SKU No.	Product Description	Sub-Category
AD200	ANGIO DRAPE - FEMORAL, 75" X 110"	Angio/Pacemaker/Cardio
AD201	ANGIO DRAPE - FEMORAL, 75" X 125"	Angio/Pacemaker/Cardio
AD202	ANGIO DRAPE - FEMORAL, 86" X 135"	Angio/Pacemaker/Cardio
AD206	ANGIO DRAPE - FEMORAL, 86" X 135"	Angio/Pacemaker/Cardio
AD210-1	PEDIATRIC / THYROID ANGIOGRAPHY DRAPE, 75" X 125"	Angio/Pacemaker/Cardio
AD215	MINOR PROCEDURES DRAPE, 37 1/2" X 55"	Angio/Pacemaker/Cardio
AD218	ANGIO DRAPE - FEMORAL, 86" X 158"	Angio/Pacemaker/Cardio
AD220	PEDIATRIC ANGIO DRAPE, 75" X 153"	Angio/Pacemaker/Cardio
AD2234	ANGIO DRAPE - FEMORAL / RADIAL, 86" X 135"	Angio/Pacemaker/Cardio
AD2234XL	ANGIO DRAPE - FEMORAL / RADIAL, 86" X 150"	Angio/Pacemaker/Cardio
AD228	ANGIO DRAPE - INTRAJUGULAR / SUBCLAVIAN, 75" X 125"	Angio/Pacemaker/Cardio
AD229	SPECIAL PROCEDURES DRAPE - KYPHO, 75" X 135"	Angio/Pacemaker/Cardio
AD235	ANGIO DRAPE - FEMORAL, 86" X 135"	Angio/Pacemaker/Cardio
AD248	ANGIO DRAPE - INTRAJUGULAR / FEMORAL, 75" X 145"	Angio/Pacemaker/Cardio
PD107	PACEMAKER DRAPE, 75" X 135"	Angio/Pacemaker/Cardio
PD201EU	PACEMAKER DRAPE, 86" X 135"	Angio/Pacemaker/Cardio
PD212-1	PACEMAKER DRAPE, 100" X 144"	Angio/Pacemaker/Cardio
8922UK	EYE DRAPE, 18" X 18"	EENT
3670	URO DRAIN BAG, 23" X 24"	Fluid Collection
3886	FLUID COLLECTION POUCH, 19" X 24"	Fluid Collection Pouch
4950UK	PATIENT DRAPE IRRIGATION POUCH, 20" X 20"	Fluid Collection Pouch
ISO1016	IRRIGATION POUCH, 20" X 23"	Fluid Collection Pouch
8911	TOWEL DRAPE - LARGE, 24" X 20"	General Surgery / Isolation
22182	DISPOSABLE PATIENT SCAN DRAPE	General Surgery / Isolation
3750UK	APERTURE POUCH DRAPE, 9" X 18"	General Surgery / Isolation
5960UK	PATIENT ISOLATION DRAPE, 96" X 130"	General Surgery / Isolation
6960UK	PATIENT ISOLATION DRAPE, 130" X 96"	General Surgery / Isolation
ISO1000	ISODRAPE TOWEL DRAPE - SMALL, 18" X 12"	General Surgery / Isolation
ISO1015EU	ISODRAPE U DRAPE, 48" X 48"	General Surgery / Isolation
ISO1019	ISODRAPE U DRAPE - LONG, 48" X 72"	General Surgery / Isolation
ISO1020	ISODRAPE APERTURE DRAPE - SMALL, 16" X 16"	General Surgery / Isolation
ISO1024	ISODRAPE APERTURE DRAPE - SMALL, 16" X 28"	General Surgery / Isolation
ISO1030	ISODRAPE APERTURE DRAPE - MEDIUM, 50" X 32"	General Surgery / Isolation
ISO1051	ISODRAPE INCISE DRAPE, 36" X 36"	General Surgery / Isolation
ISO1061	ISODRAPE APERTURE DRAPE - MEDIUM, 48" X 51"	General Surgery / Isolation
JMHID3224	ISOLATION DRAPE, 126" X 96"	General Surgery / Isolation
JMVID3224	VERTICAL ISOLATION DRAPE, 126" X 96"	General Surgery / Isolation

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SPD212	FISTULAGRAM DRAPE, 45" X 60"	General Surgery / Isolation
SPD2317	CENTRAL LINE / PICC DRAPE, 77" X 120"	General Surgery / Isolation
AE5727I	INSTRUMENT POUCH DRAPE, 11" X 19"	Intrument Pouch
ISO1018EU	INSTRUMENT POUCH DRAPE, 7" X 12"	Intrument Pouch
1514116	ELEKTA STEREOTACTIC DRAPE	Ortho/Neuro
3804UK	KNEE ARTHROSCOPY DRAPE, 100" X 120"	Ortho/Neuro
3904UK	KNEE ARTHROSCOPY DRAPE, 77" X 128"	Ortho/Neuro
1-0815	LINGEMAN PERCUTANEOUS PROCEDURE DRAPE, 132" X 77"	Uro/ OB/GYN
11-800	LINGEMAN IMPERVIOUS SURGICAL CHAIR COVER	Uro/ OB/GYN
2997UK	UNDER BUTTOCKS DRAPE, 39" X 46"	Uro/ OB/GYN
400245-01	STERILE DRAPE UTERINE POSITIONING SYSTEM	Uro/ OB/GYN
ISO1071	ISODRAPE UROLOGICAL DRAPE, 24" X 36"	Uro/ OB/GYN