DECLARATION OF CONFORMITY

We

Name + address of manufacturer:	**Microtek Medical, Inc.** **602 Lehmberg Road** **Columbus, MS 39702** **U.S.A.**

European Representative:	**Microtek Medical BV** **Hekkehorst 24** **7207 BN Zutphen** **The Netherlands**

Declare on our own responsibility that

The medical device:	Name **Equipment Drapes**
Type:	**See attached list**
Class: According to:	**I Sterile** **Rule 1**

Meets all the provisions of the Medical Device Directive 93/42/EEC

Applied harmonized standards:	EN ISO 13485 EN ISO 14971 EN ISO 11607-1 EN ISO 11607-2 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-7	EN ISO 11135-1 EN ISO 11137-1 EN ISO 11137-2 EN 556-1 EN ISO 11737-1 EN ISO 11737-2 EN 62366 All applicable standards have been applied.
Notified body:	TÜV NORD CERT GmbH Langemarckstr. 20 D-45141 Essen **CE 0044**	
Conformity assessment procedure:	93/42/EEC Annex V CE Certificate No. 44 237 117845	
Validity:	14 August 2023	
Place / Date : St. Paul, MN USA 29 November 2018	Name and Function:  Annemarie Erickson Sr. Regulatory Affairs Manager	

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Row Labels	Part Number	Part Description	Sterilization Method
General Purpose - C-Arm	2951AUK	* ONE PIECE C-ARM DRAPE, 20/CASE	ETO
	8888MEU	MINI C-ARM DRAPE FOR FLUOROSCAN 54" X 78" W/ELASTIC OPENING	ETO