



## EC Declaration of Conformity

We

CIVCO Medical Instruments Co., Inc. dba CIVCO Medical Solutions  
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 SRN: US-MF-000008229

declare under our sole responsibility that the medical imaging accessory product described hereafter...

Sterile and Non-sterile Drapes / Covers  
*as specified in master list ML 000013*

is in conformity with the general safety and performance requirements and provisions of *Council Directive 93/42/EEC* for Medical Devices,

as a *Class I* product following *Rule 1 from Annex IX of Council Directive 93/42/EEC*,

and is subject to the procedure set out in *Annex VII and Annex V (for sterile product) of Directive 93/42/EEC as amended by 2007/47/EC* under the supervision of *Notified Body 1639, SGS Belgium NV, SGS House-Noorderlaan 87, Antwerp 2030 Belgium*. . Article 120 Transitional provisions under MDR, SGS No, Certificate US19/819943509 is valid from 06 December 2019 until 18 May 2023.

Kalona, Iowa USA *December 2019*

European Regulatory Representative:

MPS  
 Medical Product Service GmbH  
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 35619 Braunfels, Germany  
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 SRN: DE-AR-000005009

			Date: <u>9/2/2021</u>
Person Responsible for Regulatory Compliance (PRRC)			
Date	Rev	Description	Issued By
1 Nov 2019	1	Release new Declaration of Conformity, notified body SGS Belgium	Kg
31 Aug 2021	2	Add Article 120 MDR reference	kg

# Master List ML 000013

Technical File Number: 000013

Device: Sterile and Non-sterile Drapes/Covers

Part Number:	Description:
DR-000537	COVER SYSTEM DRAPE TELE-FOLD POLY STERILE 45.7X14X73.7CM
608-001	COVER KIT-ACCORDION POLY STERILE 20.3 > 10.8 X 183CM
610-024	COVER-CORD POLY STERILE 7.6 X 244CM
610-025	SYSTEM DRAPE POLY STERILE 76 X 76CM
610-1011	POSITIONING ARM COVER STERILE
610-1037	DRAPE POLY STERILE 50.8 X 71.1CM
610-1050	COVER KIT-FLAT POLY STERILE 15.2 X 25.4CM
610-1131	COVER KIT-TELE CIV-FLEX STERILE 25.3 TAPERED TO 5.1 x 121.9CM
610-1241	DRAPE POLY STERILE 27.9 X 32.4CM
610-698	COVER-FLAT CIV-FLEX STERILE 11.9 > 5 X 91.5CM
610-870	COVER-FLAT POLY STERILE ACCUCARE
610-932	COVER KIT-TELE CIV-FLEX STERILE 25.3 >5.1 X 121.9CM
610-946	COVER KIT - CIV-FLEX STERILE 25.4 > 5.1 X 147CM
612-113	COVER-ACCORDION ACUNAV POLY STERILE 15.2 > 7.6 X 183CM
650-023	COVER-TELE POLY STERILE 30.5 X 117CM
UA0004	COVER-CORD STERILE 7.6 X 244CM
UA2007	DRAPE-ACCUCARE