EC Declaration of Conformity

We

CIVCO Medical Instruments Co., Inc. dba CIVCO Medical Solutions
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Kalona, Iowa 52247 United States
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SRN: US-MF-000008229

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

Sterile Needle Guides
as specified in master list ML 000008-1

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* Device 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
Borngasse 20
35619 Braunfels, Germany
Phone: 49 6442 32370
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SRN: DE-AR-000005009

Lawrence Marshall Jr

Date: 9/2/2021

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 MDR Article 120 reference	kg

Master List ML 000008

Technical File Number: 000008-1

Device: Sterile needle guidance template

Part Number:	Description:
610-905	TEMPLATE GRID-STERILE 17GA
610-906	TEMPLATE GRID-STERILE 18GA
610-977	PERCUTANEOUS INSTRUMENT GUIDE
UA2005	GRID-ACCUCARE ST 18GA
UA2006	GRID-ACCUCARE ST 17GA