EC Declaration of Conformity

We

CIVCO Medical Instruments Co., Inc. dba CIVCO Medical Solutions
102 First Street South
Kalona, Iowa 52247 United States
Phone: 319.248.6757
Fax: 319.656.4451
SRN: US-MF-000008229

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

Sterile and Non-sterile Standoffs – Couplants
as specified in master list ML 000007-1

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

as a *Class IIa* product following *Rule 5 (body orifice invasive, short-term use) and Rule 7 (surgically invasive, short-term use)* from *Annex IX of Council Directive 93/42/EEC*,

and is subject to the procedure set out in *Annex II (excluding Section 4) of Directive 93/42/EEC as amended by 2007/47/EC* under the supervision of *Notified Body number 1639*, *SGS Belgium NV, SGS House-Noorderlaan 87, Antwerp 2030 Belgium*. Article 120 Transitional provisions under MDR, SGS No, Certificate US19/819943508 is valid from 06 May 2020 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
Fax: 49 6442 32578
SRN: DE-AR-000005009

Lawrence Marshall Jr

Person Responsible for Regulatory Compliance (PRRC)

Date: Sept. 7, 2021

Date	Rev	Description	Issued By
1 Nov 2019	1	Release new Declaration of Conformity, notified body SGS Belgium	Kg
3 Sept 2021	2	Add Article 120 MDR Reference	kg

Master List ML 000007

Technical File Number: 000007-1

Device: Sterile and Non-sterile Standoffs - Couplants (Class IIa)

Part Number:	Description:
610-898	STANDOFF-LATEX-FREE BALLOON 2 X 14CM
UA0059	STANDOFF ENDO-BRACHYBALLOON