



EC Declaration of Conformity

We

CIVCO Medical Instruments Co., Inc. dba CIVCO and CIVCO Medical Solutions
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Kalona, Iowa 52247 United States
Phone: 319.248.6757
Fax: 319.656.4451
Single Registration Number (SRN): US-MF-000008229

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

TD 301A Stabilizers
as specified in master list ML 301A Stabilizers
EU UDI-DI: 0841436101TD301ALH

is in conformity with the general safety and performance requirements and provisions of Medical Device Regulation 2017/745 for Medical Devices,

as a Class I product following Rule 1 from Annex VIII of Medical Device Regulation 2017/745

and is subject to the procedure set out in Annex IX of Medical Device Regulation 2017/745.

Relevant Common Specifications:
None

Kalona, Iowa USA, 26 May 2020

European Regulatory Representative:
SRN: De-AR-000005009
MPS
Medical Product Service GmbH
Borngasse 20
35619 Braunfels, Germany
Phone: 49 6442 32370
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Person Responsible for Regulatory Compliance			
Name: Laurence Marshall Jr			
Signature: <i>Laurence Marshall Jr</i> Date: 3/20/2023			
Date	Rev	Description	Issued By
26 May 2020	1	Initial MDR Release	Kg
19 July 2021	2	Add Single Registration Number (SRN)	Kg
14 March 2023	3	Add EAR SRN	kg



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TD 301A Stabilizers Intended Use Statement:

The equipment is intended to provide fixation, support and manipulation of transrectal ultrasound imaging probes during insertion and final placement.