EC Declaration of Conformity

We

CIVCO Medical Instruments Co., Inc. dba CIVCO and CIVCO Medical Solutions
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Single Registration Number (SRN): US-MF-000008229

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

TD 301C Tracked Steppers
as specified in master list ML 301C Tracked Steppers
EU UDI-DI: 0841436101TD301CLM

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 13 from Annex VIII and Annex IX 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
Fax: 49 6442 32578

Person Responsible for Regulatory Compliance

Name: Laurence Marshall Jr

Signature: Laurence Marshall Jr **Date:** 3/16/2023

Date	Rev	Description	Issued By
26 May 2020	1	Initial MDR Release	Kg
28 June 2021	2	Add SRN, update EU UDI-DI from 0841436101TD301CLL to 0841436101TD301CLM	Kg

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31 Oct 2022	3	Change Rule from 1 to 13, add Annex IX	Kg
14 March 2023	4	Add EAR SRN	kg

TD 301C Tracked Steppers Intended Use Statement:

The equipment is intended to hold and manipulate ultrasound imaging probes and report position during prostate brachytherapy, cryotherapy, transperineal template-guided biopsy and/or fiducial marker placement procedures (including volume determination of the prostate gland) and/or the application of radionuclide source(s) into the body during brachytherapy.