CIVCO Medical Instruments Co., Inc. DBA CIVCO
and CIVCO Medical Solutions
102 First Street South,
Kalona, IA, 52247, United States

April 10, 2023

Confirmation Letter Reference: CLNB1639 – WW/MC/08460

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer :

CIVCO Medical Instruments Co., Inc. DBA CIVCO
and CIVCO Medical Solutions
102 First Street South,
Kalona, IA, 52247, United States
SRN Number: US-MF-000008229

Authorized representative
Medical Product Service GmbH (MPS)
Address: Borngasse 20, 3516 Braunfels, Germany

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Ian How

PP
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile and Non-sterile Instruments covers Basic UDI-DI: 0841436101TD201ALA 0841436101TD201BLC 0841436101TD201CLE	Class IIa	N/A	US19/819943508 NB1639

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile and Non-sterile needle guides and Non-sterile Brackets Basic UDI-DI: 0841436101TD101AL3 0841436101TD101BL5 0841436101TD101CL7 0841436101TD102AL6	Class IIa	N/A	US19/819943508 NB1639
Non-sterile standoffs-couplants Basic UDI-DI: 0841436101TD303ALP	Class IIa	N/A	US19/819943508 NB1639
ElectroMagnetic Tracking System with Sterile needle guides, electromagnetic sensors, sterile electromagnetic sensor covers Basic UDI-DI: 0841436101TD103A2NK 0841436101TD103BLB 0841436101TD103DLF	Class IIa	N/A	US19/819943508 NB1639
Sterile Needle guidance template Basic UDI-DI: 0841436101TD301DLP	Class IIa	N/A	US19/819943508 NB1639
Sterile drape Basic UDI-DI: 0841436101TD202ALD	Class I devices placed on the market in sterile condition	N/A	US19/819943508 NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/04/12	Version 1	Initial issue
YYYY/MM/DD	Version 2	Addition of device XYZ to the list
YYYY/MM/DD	Version 3	Removal of device XYZ to the list