EC Certificate Full Quality Assurance System: Certificate US19/819943508

The management system of

CIVCO Medical Instruments Co., Inc.
DBA CIVCO
and CIVCO Medical Solutions

102 First Street South,
Kalona, IA, 52247, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 06 May 2020 until 18 May 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 04 February 1998
and first certified by SGS Belgium NV since 06 December 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/MC 08460

Authorised by

SGS Belgium NV, Notified Body 1639
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CIVCO Medical Instruments Co., Inc.
DBA CIVCO
and CIVCO Medical Solutions

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

Sterile and Non-sterile Instruments covers, Sterile and Non-sterile needle guides and Non-sterile Brackets, sterile and non-sterile standoffs – couplants, ElectroMagnetic Tracking System with sterile needle guides, electromagnetic sensors, sterile electromagnetic sensor covers.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

2301 Jones Boulevard, Coralville, IA, 52241, United States