EC Certificate Production Quality Assurance System: Certificate US19/819943509

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 V**
**Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions**

For the following products

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

This certificate is valid from 06 December 2019 until 18 May 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 04 February 1998
and first certified by SGS Belgium NV since 06 December 2019.

Certification is based on reports numbered WW/MC/ 08460

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

Authorised by

Pieter Weterings
Certification Manager

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

## Directive 93/42/EEC

**on medical devices, Annex V**
**Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions**

Issue 1

Detailed scope

**Sterile Needle guidance template, sterile drape, Sterile examination and biopsy procedure kits.**

Additional facilities

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