



Certificate Number US18/711041498  
The management system of

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

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

Facility identification number : F002933

has been audited against the criteria stated below and found to conform to those criteria for the scope  
contained in this certificate

## MDSAP (ISO 13485:2016)

Australia:  
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full  
Quality Assurance Procedure [including design]

Brazil:  
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009

Canada:  
Medical Devices Regulations – Part 1 SOR 98/282

Japan:  
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act

United States:  
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

**See second page for the scope.**

The certificate is valid from  
Effective Date: 2021-06-09 until Expiry Date: 2024-05-18  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-05-18  
Issue 6. Certified since 2018-10-11



Authorised by L Henderson  
Business Manager

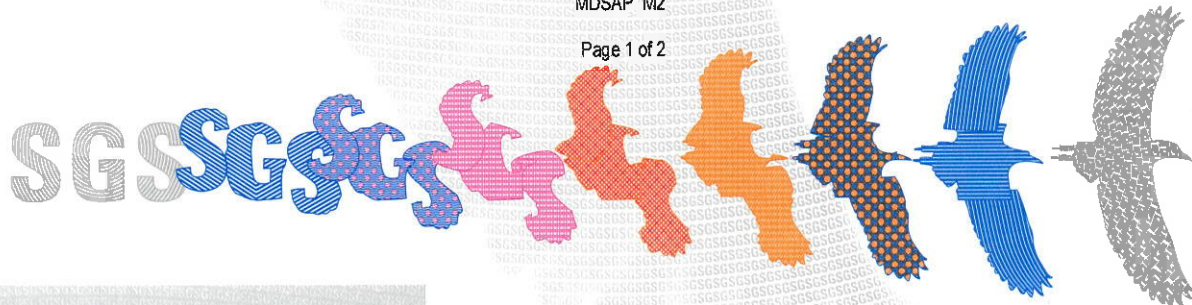


*L Henderson*

SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 3506666 www.sgs.com  
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MDSAP M2

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Certificate Number US18/711041498, continued

The management system of

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



## MDSAP (ISO 13485:2016)

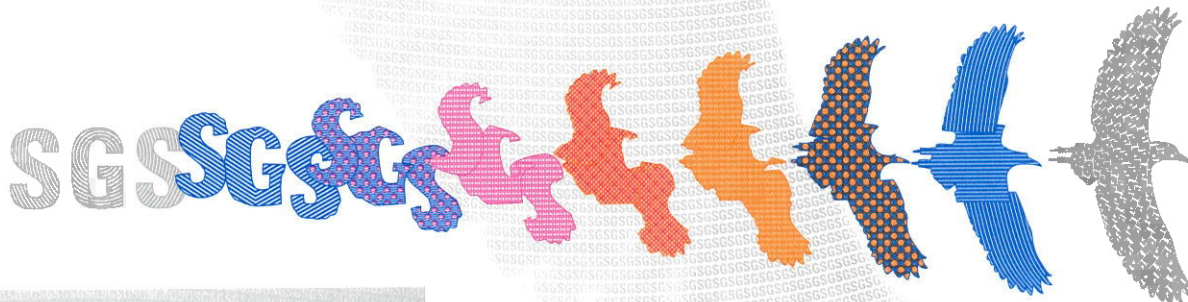
Issue 6

Detailed scope

**Design and manufacture of sterile and non-sterile instrument covers,  
sterile and non-sterile drapes,  
Sterile and non-sterile needle guides and Non-sterile Brackets,  
ElectroMagnetic Tracking System with sterile needle  
guides, electromagnetic sensors, sterile electromagnetic sensor  
covers for imaging procedures.  
Design, manufacture, and servicing of high level disinfection devices  
and manual and electromechanical ultrasound  
transducer stepping and stabilization devices.**

Additional facilities

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



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