

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

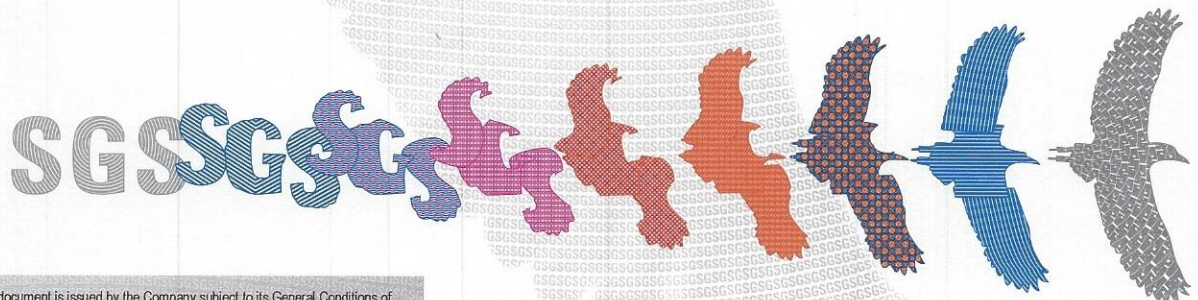
Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noordertaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

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DBA CIVCO
and CIVCO Medical Solutions**

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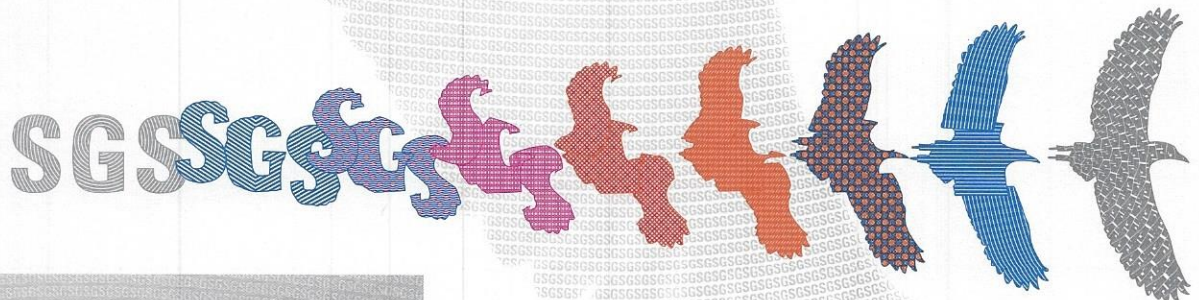
Issue 1

Detailed scope

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

Additional facilities

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



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