

EC Design Examination Certificate: Certificate US15/842375

MEDTEC, Inc. dba CIVCO

Medical Solutions and CIVCO

Radiotherapy

1401 8th St. SE,
Orange City, IA, 51041, United States

Device Identification:
Sterile Fiducial Market Kit.

Intended Purpose of Device:
Fiducial markers intended to be placed into soft tissue or bone to establish a permanent and accurate internal reference system.

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 05 April 2019 until 31 December 2020

Issue 2

Certification is based on report number(s) WW/ME 601821 dated 24 September 2015

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
05 April 2019	Extension of certificate validity due to no deal Brexit

Authorised by

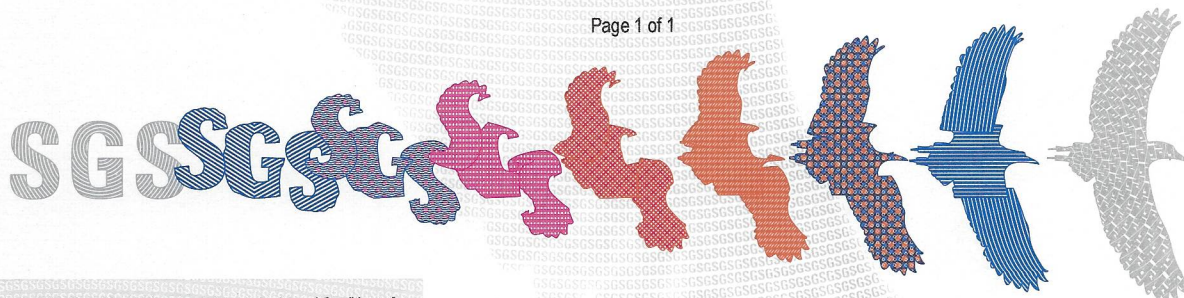


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