EC Certificate Full Quality Assurance System: Certificate US07/1181

The management system of

MEDTEC, Inc. dba CIVCO Medical Solutions and CIVCO Radiotherapy

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

Sterile Fiducial Marker Kits with absorbable sutures, spacers and couplers
Sterile fiducial markers for ensuring accurate target localization for tumors or organs which move in respect to external anatomy, and for precise localization for stereotactic and typical fractionated radiotherapy treatment

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.

This certificate is valid from 11 December 2018 until 01 November 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 August 2019
Issue 10. Certified since 01 November 2007

Certification is based on reports numbered WW/MC 600600

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215