

Certificate Number US19/81841460

The quality management system of

MEDTEC, Inc. dba CIVCO Medical Solutions and CIVCO Radiotherapy

1401 8th St. SE, Orange City, IA, 51041, United States
Dun & Bradstreet D-U-N-S identification number: 10-397-7526

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

**Design, manufacture, distribution, installation and servicing of devices for
patient positioning and radiation oncology devices (shielding, ion chambers
and phantoms). Design, manufacture, distribution of sterile fiducial markers.**

This certificate is valid from
Effective Date: 2019-03-21 until Expiry Date: 2022-03-20
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2021-06-29
Issue 1. Certified since 2019-03-21

Authorised by J Hall
Business Manager

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