

EC Declaration of Conformity

We,

MEDTEC, Inc., dba CIVCO Medical Solutions, Inc.

1401 8th St. SE

Orange City, Iowa 51041 USA

Phone: 712 / 737-8688 Fax: 712 / 737-8654

declare under our sole responsibility that the medical imaging accessory products described

hereafter...

Patient Positioning Device

are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC for Medical Devices,

as a Class I product following Rule 1 from Annex IX of Council Directive 93/42/EEC.

and are subject to the procedure set out in Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd Systems & Services Certification, Unit 202B, Worle Parkway, Weston-super-Mare, North Somerset BS22 6WA, United Kingdom.

Orange City, Iowa USA 1/21/10

European Regulatory Representative:

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Regulatory Manage Date: 1/28/10
Vice President

Date: 2/2/10

Date: 2/2/10

Date: 2/2/10

Date	Rev	Description	DCN	Issued By
09-Dec-09	1	Initial Release	NA	JMJ
21-Jan-10	2	Added Classification Criteria Rule from Annex IX, added MEDTEC to company title to match CE certificate	NA	JMJ

Master List

Technical File Number: OC0014 Device: Patient Positioning Devices

Part Number	Description
MT6X200TE	Protura, Siemens Txt,eu
MT6X200TER	Protura, Siemens Txt,eu,recond
MT6X200TU	Protura, Siemens Txt,us
MT6X200TUR	Protura, Siemens Txt,us,recond
MT6X300TE	Protura, Varian Exact,eu
MT6X300TER	Protura, Varian Ex, Eu, Recond
MT6X300TU	Protura, Varian Exact,us
MT6X300TUR	Protura, Varian Ex, Us, Recond
MT6X400TE	Protura, Elekta Precise,eu
MT6X400TER	Protura, Elek Pr Txt,eu,recond
MT6X400TU	Protura, Elekta Precise,us
MT6X400TUR	Protura, Elek Pr Txt,us,recond
MT6XCALS	Protura Alignment Fixture

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