



## EC Declaration of Conformity

We,

MEDTEC, Inc., d/b/a CIVCO Medical Solutions and CIVCO Radiotherapy  
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declare under our sole responsibility that the products described hereafter...

### **Radiation Shielding Products and Accessories** *as specified in Master List ML OC0002*

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 5 (Eye Shields) and Rule 12 (Alloy Melters) 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 Limited Systems & Services Certification, Unit 202B, Worle Parkway, Weston-super-Mare, North Somerset BS22 6WA, United Kingdom.

Orange City, Iowa USA October 18, 2018

European Regulatory Representative:

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 Director of Product Development, RA, QA			Date: <u>11/2/18</u>
 President			Date: <u>November 2, 2018</u>
Date	Rev	Description	Issued By
13-Apr-07	1	Initial Release	AED
21-Jan-10	2	Added classification criteria rule from annex IX, added MEDTEC to company title to match CE certs	JMJ
3-Jul-13	3	Added master list reference	JAL
18-Oct-18	4	Updated to template QR.14.16.01 Rev. 3, changed from rule 1 in Annex IX to rule 5 (eye shields) and rule 12 (alloy melters).	ANN

# Master List ML OC0002

Technical File Number: OC0002

Device: Radiation Shielding Products and Accessories

Part Number:	Description:
MTT45L	Eyeshield,coated Tungsten, Lrg
MTT45M	Eyeshield,coated Tungsten, Med
MTT45S	Eyeshield,coated Tungsten,smal
MT801.5D	Melter, Alloy 1.0 Gallon
MT801.5DEX	Alloy Melter, 1 Gal 230 Vt
MT801.5DEXA	Alloy Melter 4qt 230v A Coneun
MT801.5DEXC	Alloy Melter 4qt 230v C Aust R