



## EC Declaration of Conformity

We

MEDTEC, Inc. doing business as CIVCO Medical Solutions, Inc.  
1401 8<sup>th</sup> 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...

### **Fiducial Marker Kits**

*as specified in master list ML OC0009*

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


as a class III product following rule 8 from Annex IX of Council Directive 93/42/EEC,

and are subject to the procedure set out in Annex II section 4 of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Limited, Unit 202B, Worle Parkway, Weston-super-Mare, North Somerset BS22 6WA, United Kingdom.

Orange City, Iowa USA 11/7/11

#### European Regulatory Representative:

Theo Nusselder  
Director, CEpartner4U  
Esdoornlaan 13  
3951 DB  
Maarn, The Netherlands  
Phone: +31 (0)6-51 65 36 26  
+31 (0)343 442 162  
Email: office@cepartner4u.nl

  
Regulatory Manager

Date: 11/11/11

  
Vice President

Date: 11/10/11

Date	Rev	Description	DCN	Issued By
25-Apr-07	1	Initial Release	NA	AED
5-Oct-09	2	Update as Fiducial Markers Kits	NA	JMJ
4-Oct-11	3	Update for CIVCO manufacturer	NA	JMJ
7-Nov-11	4	Update SGS address	NA	kg

# Master List

**Technical File Number: OC0009**

**Device: Fiducial Marker Kits**

## **Part Number**

MTNW887709  
MTNW887710  
MTNW887711  
MTNW887712  
MTNW887810  
MTNW887866

## **Description**

Coupled Gold Marker Kit .8x3mm  
Coupled Gold Marker Kit 2-pt  
Coupled Gold Marker Kit 3-pt  
Coupled Gold Marker Kit 4-pt  
Loaded Markers Pre-spaced 10mm  
Marker, Absorbable Suture 3