



## EC Declaration of Conformity

We

CIVCO Medical Instruments Co., Inc. dba CIVCO Medical Solutions  
 102 First Street South  
 Kalona, Iowa 52247 United States  
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declare under our sole responsibility that the medical imaging accessory product described hereafter...

**ElectroMagnetic Tracking System with Sterile and Non-sterile Brackets, Sterile Tracking Needles, Sterile Needle Guides, ElectroMagnetic Sensor Covers, Non-sterile Patient Trackers as specified in master list ML 000018**

is in conformity with the general safety and performance requirements and provisions of *Council Directive 93/42/EEC* for Medical Devices,

as a *Class IIa* product following *Rules from Annex IX of Council Directive 93/42/EEC*,  
*Rule 9 and 6 for eTRAX Needle*  
*Rule 9 for Sensor, VirtuTRAX Tracker and Active Fiducial Marker (OmniTRAX)*  
*Rule 2 for eTRAX Needle Guide, Bracket and Covers*

and is subject to the procedure set out in *Annex II of Directive 93/42/EEC as amended by 2007/47/EC* under the supervision of *Notified Body 1639, SGS Belgium NV, SGS House-Noorderlaan 87, Antwerp 2030 Belgium*.

Kalona, Iowa USA December 2019

European Regulatory Representative:

MPS  
 Medical Product Service GmbH  
 Borngasse 20  
 35619 Braunfels, Germany  
 Phone: 49 6442 32370  
 Fax: 49 6442 32578

			Date: <u>Dec-2019</u>
Person Responsible for Regulatory Compliance (PRRC)			
Date	Rev	Description	Issued By
1 Nov 2019	1	Release new Declaration of Conformity, notified body SGS Belgium	kg

# Master List ML 000018

Technical File Number: 000018

Device: ElectroMagnetic Tracking System

Part Number:	Description:
10441183	STARTER KIT TRACKING BRACKET - TRACKING W/UPII 4C1, 6C1 HD
10441184	STARTER KIT TRACKING BRACKET 4C1, 6C1 HD
10441187	STARTER KIT TRACKING BRACKET - TRACKING W/UPII 4V1
10441188	STARTER KIT TRACKING BRACKET 4V1
10441189	STARTER KIT TRACKING BRACKET - TRACKING W/UPII 6C2
10441627	GP SENSOR DRIVEBAY
10441628	ETRAX NEEDLE STARTER KIT
11506900	Tracking Bracket Starater Kit - 7L2 Verza Needle Guide w/CIV-Flex Cover
10854388	STARTER KIT ETRAX-DRIVEBAY 18GA X 18CM ETRAX NEEDLE
10855226	STR KIT ETRAX-DRIVEBAY W/ 14GA X 17CM ETRAX NEEDLE
10855227	STR KIT ETRAX-DRIVEBAY W/ 12GA X 17CM ETRAX NEEDLE
11287649	Starter Kit 10L4 Verza Tracking
11287651	Starter Kit 5C1 Verza Tracking
11287652	Starter Kit DAX Verza Tracking
11292181	9L4 Tracking Starter Kit
11292182	9L4 UPII Tracking Starter Kit
11504341	VERZA GUIDANCE SYSTEM TRACKING STARTER KIT - 9C2 VERZA NEEDLE GUIDE W/CIV-FLEX COVI
11506900	VERZA GUIDANCE STARTER KIT - 7L2 VERZA NEEDLE GUIDE w/ COVER
11508588	VERZA GUIDANCE SYSTEM TRACKING STARTER KIT - 15L4 VERZA NEEDLE GUIDE W/CIV-FLEX COV
5350924	STARTER KIT ETRAX DRIVEBAY WITH 16GA X 17.7CM ETRAX NEEDLE AND ULTRA PRO E GDE
5350925	STARTER KIT VIRTUTRAX-DRIVEBAY
5416625	SENSOR-GENERAL PURPOSE DRIVEBAY 8MM
5438658	OMNITRAX PATIENT TRACKER STARTER KIT
5451117	STARTER KIT ETRAX-DRIVEBAY W/ 18GA X 18CM ETRAX NEEDLE AND UPE GUIDE
5483528	STARTER KIT ETRAX DRIVEBAY WITH 12GA X 17CM ETRAX NEEDLE AND ULTRO-PRO E
5483544	STARTER KIT ETRAX DRIVEBAY WITH 14GA X 17CM ETRAX NEEDLE AND ULTRO-PRO E
5670091	MR OMNITRAX PATIENT TRACKER STARTER KIT
610-1055	STARTER KIT ETRAX DRIVEBAY WITH 16GA x 17.7CM eTRAX NEEDLE
610-1057	NEEDLE KIT ETRAX 16GA x 17.7CM WITH CIV-FLEX COVER QTY 10

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Part Number:	Description:
610-1059	GUIDE KIT-VIRTUTRAX W/CIV-FLEX 8.9 >1.3 X 61CM
610-1066	SENSOR-GENERAL PURPOSE DRIVEBAY 8MM
610-1080	STARTER KIT VIRTUTRAX-DRIVEBAY
610-1089	GUIDE KIT UPE 14GA STERILE W/CIV-FLEX 14 X 91.5CM
610-1112	STARTER KIT ETRAX-DRIVEBAY WITH 16GA X 17.7CM ETRAX NEEDLE AND ULTRA-PRO E
610-1133	GUIDE-ULTRA-PRO E 18GA STERILE
610-1134	GUIDE KIT UPE 18GA STERILE W/CIV-FLEX 14 X 91.5CM
610-1137	GUIDE KIT UPE 20GA STERILE W/CIV-FLEX 14 X 91.5CM
610-1153	GUIDE KIT-VIRTUTRAX STERILE W/CIV-FLEX 8.9 > 1.3 x 147CM
610-1213-10	NEEDLE KIT-ETRAX 12GA X 13CM W/CIV-FLEX COVER
610-1217-10	NEEDLE KIT-ETRAX 12GA X 17CM W/CIV-FLEX COVER
610-1227	OMNITRAX PATIENT STARTER KIT
610-1228	OMNITRAX PATIENT REPLACEMENT KIT
610-1254	STARTER KIT ETRAX-DRIVEBAY WITH 12GA X 17CM ETRAX NEEDLE
610-1258	GUIDE KIT UPE 12GA STERILE W/CIV-FLEX 14X91.5CM
610-1299	MR omniTRAX Kit
610-1306	MR OMNITRAX REPLACEMENT KIT
610-1401	STARTER KIT ETRAX-DRIVEBAY WITH 14GA X 17CM ETRAX NEEDLE
610-1413-10	NEEDLE KIT-ETRAX 14GA X 13CM W/CIV-FLEX COVER
610-1417-10	NEEDLE KIT-ETRAX 14GA X 17CM W/CIV-FLEX COVER
610-1613-10	NEEDLE KIT-ETRAX 16GA X 13CM W/CIV-FLEX COVER QTY 10
610-1615-10	NEEDLE KIT-ETRAX 16GA X 15CM W/CIV-FLEX COVER QTY 10
610-1801	STARTER KIT-ETRAX DRIVEBAY 18GA
610-1815-10	NEEDLE KIT-ETRAX 18GA X 15CM W/CIV-FLEX COVER
610-1818-10	NEEDLE KIT-ETRAX 18GA X 18CM W/CIV-FLEX COVER
620-126	General Purpose Sensor
639-031	STARTER KIT TRACKING BRACKET LA332
639-038	STARTER KIT TRACKING BRACKET EC1123
639-039	STARTER KIT TRACKING BRACKET PA240

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Part Number:	Description:
639-040	STARTER KIT TRACKING BRACKET TRT33
639-041	STARTER KIT TRACKING BRACKET CA541
639-042	STARTER KIT TRACKING BRACKET LA533
639-051	BIOPSY STARTER KIT - IOT332 INFINITI NEEDLE GUIDE W.CIV-FLEX COVER 14x9135cm
657-037	STARTER KIT CA1-7A TRACKING
657-038	STARTER KIT L3-12A TRACKING
657-044	LA4-18B Tracking Bracket Starter Kit
657-048	CA3-10A Tracking Bracket Starter Kit
657-056	E3-12A Endocavity Tracking Bracket Starter Kit
657-074	EA2-11AR/EA2-11AV Endocavity Tracking Starter Kit
657-075	EA2-11AR/EA2-11AV Endocavity Tracking Bracket
657-076	Tracking Bracket Starter Kit - LA4-18A w/ CIV-Flex Cover
657-082	CAI-7S Tracking Starter Kit
657-084	Tracking Bracket Starter Kit - EA2-11AR/EA2-11AVw/ CIV-Flex Cover
667-130	STARTER KIT MULTIT-ANGLE TRACKING C5-1 UPII GUIDE
667-131	STARTER KIT MULTI-ANGLE X6-1 TRACKING W/UPII GUIDE
667-132	STARTER KIT SINGLE-ANGLE L12-5 TRACKING W/INFINITI PLUS GUIDE
667-136	STARTER KIT - TRACKING BRACKET S5-1
667-138	STARTER KIT MULTI-ANGLE TRACKING C9-2 UPII GUIDE
667-145	TRACKING BRACKET - C10-4ec STERILE
667-146	C10-4EC TRACKING BRACKET WITH COVERS
667-147	C10-4EC TRACKING BRACKET WITH DISP GUIDE AND COVERS
667-149	Aurora eTRAX 12ga Starter Kit
667-150	Aurora eTRAX 14ga Starter Kit
667-151	Aurora eTRAX 16ga Starter Kit
667-152	Aurora eTRAX 18ga Starter Kit
667-156	Aurora 12ga eTRAX Needle Sensor
667-157	Aurora 14ga eTRAX Needle Sensor
667-158	Aurora 16ga eTRAX Needle Sensor

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Part Number:	Description:
667-159	Aurora 18ga eTRAX Needle Sensor
676-189	Starter Kit Mc9-4 Endocavity Tracking
676-196	Starter Kit Mc9-4 Endocavity Tracking
H40432LF	STARTER KIT MULTI-ANGLE PINK VNAV C1-5-D UPII GUIDE
H40432LK	STARTER KIT MULTI ANGLE PINK VNAV ML6-15-D UPII GUIDE
H40482LF	STARTER KIT C3-10-D TRACKING
H40482LM	STARTER KIT TRACKING BRACKET VNAV C2-7-D
H46332LZ	STARTER KIT TRACKING BRACKET VNAV C2-6B
H4908NB	STARTER KIT MULTI-ANGLE PINK VNAV 9L-D UPII GUIDE
H4908ND	STARTER KIT MULTI-ANGLE PINK VNAV S1-5 UPII GUIDE
H4908NF	STARTER KIT TRACKING BRACKET VNAV IC5-9
H4908NH	STARTER KIT TRACKING BRACKET VNAV PINK L8-18i
H4908NM	STARTER KIT TRACKING BRACKET PINK VNAV M5S-D
H4908NN	STARTER KIT TRACKING BRACKET VNAV PINK S4-10
H4913NK	STARTER KIT TRACKING BRACKET-GE PINK VNAV C1-6, C2-9
H4913NL	STARTER KIT TRACKING BRACKET-GE PINK VNAV C1-5-D
H4913NT	STARTER KIT ETRAX-DRIVEBAY W/18GA X 18CM ETRAX NEEDLE AND UPE NEEDLE GUIDE