


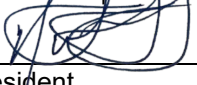


EC Declaration of Conformity

Manufacturer Name:	MEDTEC, Inc., d/b/a CIVCO Medical Solutions and CIVCO Radiotherapy
Manufacturer Address:	1401 8th St. SE Orange City, Iowa 51041 – United States
Manufacturer Contact Information:	Phone: +1 (712) 737 – 8688 Fax: +1 (319) 248 – 4049
Single Registration Number:	US-MF-000002608
Authorized Representative:	CEpartner4U Esdoornlaan 13, 3951 DB Maarn, The Netherlands SRN: NL-AR-000000111 Phone: +31 (0)6.516.536.26 Fax: +31 (0)343.442.162 Email: office@cepartner4u.com
Device Name:	Head, Neck, and Shoulder Devices
Basic UDI-DI:	Reference Master List ML OC0005
Product Code:	Reference Master List ML OC0005
Risk Class:	Class I
Classification Rule:	Rule 1 according to Annex VIII of 2017/745
Intended Purpose:	Device is intended for patient positioning and immobilization.
Conformity Assessment Route:	Annex II and Annex III of Directive 2017/745.

This declaration of conformity is issued under our sole responsibility. We hereby declare that the medical device as specified in Master List ML OC0005 meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Orange City, Iowa, United States – May 13, 2021

 _____ Person Responsible for Regulatory Compliance	Date: <u>5-17-21</u>
 _____ President	Date: <u>May 17, 2021</u>
Revision: 2	

Master List ML OC0005

Technical File Number: OC0005

Device: Head, Neck and Shoulder

Part Number:	Description:	B-UDI:	GMDN:
CHS01	Customizable Head Sup, Posi	8414391OC0005R01AQ	61132
CHS02	Customizable Head Sup, Type-s	8414391OC0005R01AQ	61132
CHS14	Ratq Solstat, Vrccms	8414391OC0019R01BX	61132
MTACLTYPE51	Accuform Cushion,type-s	8414391OC0005R01AQ	40894
MTACL001	Positioner, Accuform	8414391OC0005R01AQ	40894
MTACL14242	Accuform Cushion 20x25cm	8414391OC0005R01AQ	40894
MTACL14242RF	Accuform Cushion, Rf, 20x25cm	8414391OC0005R01AQ	40894
MTACL1520	Accuform Cushion 15x20cm	8414391OC0005R01AQ	40894
MTACL2035	Accuform Cush, 20x35cm, Chamf	8414391OC0005R01AQ	40894
MTACL2035HF	Accuform Cush, 20x35hf, Chamf	8414391OC0005R01AQ	40894
MTACL2045	Accuform Cushion, 20x45cm	8414391OC0005R01AQ	40894
MTACL4060	Accuform Cushion, 40x60cm	8414391OC0005R01AQ	40894
MTACL6060	Accuform Cushion, 60x60cm	8414391OC0005R01AQ	40894
MTCBPBITE	Mouthpiece, Precise Bite	8414391OC0005R05AY	61130
MTCBPBITES	Mouthpiece,precise Bite, Small	8414391OC0005R05AY	61130
MTCBPBITETD	Precise Bite, Tongue	8414391OC0005R05AY	61130
MTCBPBITETDS	Precise Bite, Tongue, Small	8414391OC0005R05AY	61130
MTCFHNV	Type-s Extension, Varian	8414391OC0005R01AQ	40897
MTCFHNVAB01	Type-s Variable Axis Baseplate	8414391OC0005R01AQ	61129
MTCFHN006	Overlay, Fixator	8414391OC0005R01AQ	40897
MTCFHN006SUB6	Shoulder Cup, Fixator	8414391OC0005R01AQ	40897
MTIHS01	Indiv,head Support,normal,posi	8414391OC0005R01AQ	61132
MTIHS02	Indiv. Head Support,hyper,posi	8414391OC0005R01AQ	61132
MTIHS03	Ind. Head Supp,normal,type S	8414391OC0005R01AQ	61132
MTLTBP	Lateral Treatment Baseplate	8414391OC0005R01AQ	61129
MTLTBPIAT01	Head Support,lateral Treatment	8414391OC0005R01AQ	61132
MTMRHNPN	Type-s Head/neck, Mri Narrow	8414391OC0005R01AQ	40897
MTMRHNTPES	Type-s Head/neck, Mri	8414391OC0005R01AQ	40897
MTPFC02	Prone Face Cushion	8414391OC0005R01AQ	61132
MTPLC01	Positioner, Prone-lok	8414391OC0005R01AQ	61132
MTPT1002	Proton Arch With Nose Piece	8414391OC0005R01AQ	40897
MTPT210001	Hitachi Proton Extension	8414391OC0005R01AQ	40897
MTPT210002	Hitachi Proton Overlay	8414391OC0005R01AQ	40897
MTSHIMS	Shim, Silverman Cutout	8414391OC0005R01AQ	61132
MTSHIMT	Shim, Timo	8414391OC0005R01AQ	61132
MTSHIM01	Shim, Silverman Solid	8414391OC0005R01AQ	61132
MTSHIM01S	Shim, Type-s H/n/s	8414391OC0005R01AQ	61132
MTSILVER2	Headrests Silverman2 Trim Set	8414391OC0005R01AQ	61132
MTSILVER2A	Silverman2 Headrest, Trim, A	8414391OC0005R01AQ	61132
MTSILVER2B	Silverman2 Headrest, Trim, B	8414391OC0005R01AQ	61132
MTSILVER2C	Silverman2 Headrest, Trim, C	8414391OC0005R01AQ	61132
MTSILVER2D	Silverman2 Headrest, Trim, D	8414391OC0005R01AQ	61132
MTSILVER2E	Silverman2 Headrest, Trim, E	8414391OC0005R01AQ	61132
MTSILVER2F	Silverman2 Headrest, Trim, F	8414391OC0005R01AQ	61132

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MTTIMO	Headrests, Timo Set	8414391OC0005R01AQ	61132
MTTIMOA	Headrests, Timo A	8414391OC0005R01AQ	61132
MTTIMOAL	Headrests, Timo A W/ Lexan	8414391OC0005R01AQ	61132
MTTIMOB	Headrests, Timo B	8414391OC0005R01AQ	61132
MTTIMOBBB	Headrests Timo B For Bb T	8414391OC0005R01AQ	61132
MTTIMOBL	Headrests, Timo B W/ Lexan	8414391OC0005R01AQ	61132
MTTIMOC	Headrests, Timo C	8414391OC0005R01AQ	61132
MTTIMOCL	Headrests, Timo C W/ Lexan	8414391OC0005R01AQ	61132
MTTIMOD	Headrests, Timo D	8414391OC0005R01AQ	61132
MTTIMODBB	Headrests Timo D For Bb T	8414391OC0005R01AQ	61132
MTTIMODL	Headrests, Timo D W/ Lexan	8414391OC0005R01AQ	61132
MTTIMOE	Headrests, Timo E	8414391OC0005R01AQ	61132
MTTIMOEBB	Headrests Timo E For Bb T	8414391OC0005R01AQ	61132
MTTIMOEL	Headrests, Timo E W/ Lexan	8414391OC0005R01AQ	61132
MTTIMOF	Headrests, Timo F	8414391OC0005R01AQ	61132
MTTIMOFBB	Headrests Timo F For Bb T	8414391OC0005R01AQ	61132
MTTIMOFL	Headrests, Timo F W/ Lexan	8414391OC0005R01AQ	61132
MTTIMOL	Headrests, Timo Set W/ Lexan	8414391OC0005R01AQ	61132
MTVRB100	Ratq Baseplate, Vrccms	8414391OC0005R01AQ	61129
MT201SC	Swivel Clamp, One Asseby	8414391OC0005R01AQ	61129
MT20100	Baseplate, Acr Standard Supine	8414391OC0005R01AQ	61129
MT20100CF	Baseplate, Cf Standard Supine	8414391OC0005R01AQ	61129
MT20103CF	Baseplate, Cf Tilting	8414391OC0005R01AQ	61129
MT20103CFU	Upgrade, Tilting Baseplate	8414391OC0005R01AQ	61129
MT20104	Baseplate, Acr Cutout Base	8414391OC0005R01AQ	61129
MT20108	Baseplate, Accuray	8414391OC0005R01AQ	61129
MT20109	Ge, Mri Baseplate	8414391OC0005R01AQ	61129
MT202	Head Holder, Prone	8414391OC0005R01AQ	61129
MT20215	Shell, Prone Head Support	8414391OC0005R01AQ	61129
PRO340	Proform Registration Film	8414391OC0005R01AQ	40894
PRO350	Proform Cushion Guide	8414391OC0005R01AQ	40894
101019	Posifix-1	8414391OC0005R01AQ	61129
102021	Posifix-2bd Assembly	8414391OC0005R01AQ	61129
104021	Posifix 4bd Baseplate Assembly	8414391OC0005R01AQ	61129
105021	Posifix 5bd	8414391OC0005R01AQ	61129
107010	Positilt-b	8414391OC0005R01AQ	61129
107020	Ptcf-bd	8414391OC0005R01AQ	61129
107065	Posi Variable Axis Baseplate	8414391OC0005R01AQ	61129
107101	Wedge, 2.5 Deg	8414391OC0005R01AQ	61132
107102	Wedge, 5 Deg	8414391OC0005R01AQ	61132
107103	Spacer, 20mm	8414391OC0005R01AQ	61132
107104	Spacer, 30mm	8414391OC0005R01AQ	61132
107106	Wedge And Spacer Set	8414391OC0005R01AQ	61132
108010	Posifix Ext, Va5p Imrt	8414391OC0005R01AQ	40897
108020	Posifix-ext Src Imrt	8414391OC0005R01AQ	40897

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108072	Baseplate, Mi lbeam	8414391OC0005R01AQ	40897
108073	lbeam, Type-s	8414391OC0005R01AQ	40897
20CFHNSUB2	Type-s, Carbon Fiber Overlay	8414391OC0005R01AQ	40897
20CFHNSUB2V	Type-s, Carbon Fiber Extension	8414391OC0005R01AQ	40897
20CFHNSUB7	Type-s Overlay No VI	8414391OC0005R01AQ	40897
20SR01SUB1	Shoulder Retractor Base	8414391OC0005R01AQ	40900
20SR01SUB2	Shoulder Retractor Hand Grip	8414391OC0005R01AQ	40900
20SR02SUB2	Wool Wrist Strap	8414391OC0005R01AQ	40900
20SR02SUB3	Wrist Strap	8414391OC0005R01AQ	40900
301001BLK	Head Support Cushion, Extended	8414391OC0005R01AQ	61132
301002BLK	Head Support, Black	8414391OC0005R01AQ	61132
301003BLK	Head Support, Black	8414391OC0005R01AQ	61132
301004BLK	Head Support, Black	8414391OC0005R01AQ	61132
301005BLK	Head Support, Black	8414391OC0005R01AQ	61132
301008A	Head Support, Extra Wide	8414391OC0005R01AQ	61132
301016	Adapter Piece Adap16	8414391OC0005R01AQ	61129
301022	Head Support Contour, Orange	8414391OC0005R01AQ	61132
301023	Head Support, Cont.,yellow	8414391OC0005R01AQ	61132
301024	Head Support, Cont.,white	8414391OC0005R01AQ	61132
301025	Posifix Headrest, Prone	8414391OC0005R01AQ	61132
301025BLK	Posifix Headrest, Prone	8414391OC0005R01AQ	61132
301026	Headrest, Supine, Pediatric	8414391OC0005R01AQ	61132
301027	Headrest Cushion, Ped, Blue	8414391OC0005R01AQ	61132
301027A	Headrest Cushion,extra Sm Blue	8414391OC0005R01AQ	61132
301029	Mr Posi-s Adapter W/ Backplate	8414391OC0005R01AQ	61129
301030	Headrest, Ext Head Stop, I	8414391OC0005R01AQ	61132
301032	Headrest, Ext Head Stop, li	8414391OC0005R01AQ	61132
301033	Headrest, Ext Head Stop, lii	8414391OC0005R01AQ	61132
301034	Headrests, Ext Head Stop Set	8414391OC0005R01AQ	61132
301035	Mr Posi-s Adapter	8414391OC0005R01AQ	61129
301040	Shoulder Support Cushion	8414391OC0005R01AQ	61131
301081	Wedge Cushion 5 Degree	8414391OC0005R01AQ	40899
301082	Wedge Cushion 10 Degree	8414391OC0005R01AQ	40899
301234	Headrests Contoured Set	8414391OC0005R01AQ	61132
302072	Shoulder Retractors	8414391OC0005R01AQ	40900
305000BLK	Headrests, Posifix Supine Set	8414391OC0005R01AQ	61132
402525	Universal Head Support	8414391OC0005R01AQ	61132