


HOSPITAL EQUIPMENT MANUFACTURING CO.
D-313, Sector-63, Noida, U.P. – 201 301, India. **GSTIN : 09AANFH5903Q1ZN**
TEL: +91-120-4088 888 Email: info@hemcmedical.com

DECLARATION OF CONFORMITY

Name and Description of Product	Medical Devices Class I External Fixator for Forearm & Metacarpals, Tubular External Fixator, Ilizarov External Fixator
Application of Council Directive	Medical Device Directive 93/42/EEC
Conformity Declared to Standarts	ISO 13485:2016, ISO 16061:2008, ISO 7153-1:2001, ASTM F899 - 12b, ISO/FDIS 7153-1, ISO 7151:1988, ISO 7740:1985, ISO 7741:1986, ISO 13402:1995, ISO 3318:1965, IEC 60601-2-52:2009, ISO/DTR 60601-4-1, IEC 80601-2-35:2009, ASTM A751-14a, ASTM A555 / A555M-16, ASTM A313 / A313M-13, ISO 14630:2012, ISO 15223:2012, ISO 14971:2007
Classification of Products	Class I [MDD 93/42/EEC - Annex IX, Rule 6 – All surgically invasive devices intended for transient use (reusable surgical instruments)]
Conformity Assessment Procedure	Annex VII MDD 93/42/EEC
 Manufacturer	Hospital Equipment MFG Co. Address: D-313, Sector-63, Noida, UP - 201301, India

The undersigned declares that the above named product conforms to the above Directives and Standards as applicable on the devices.

Date: 04.05.2023

Name: Himanshu Sachdeva
Position: Managing Partner


Himanshu Sachdeva
Managing Partner
Hospital Equipment Mfg. Co. India

List of products is attached in Annexure I



Annexure I

List of Product with product code

Class I

External Fixators

Product Name	Product Code	Diameter (mm)	Length (mm)	Wide (mm)	No. of Holes
Ilizarov External Fixator, Full Ring S.S.	551.008	80			
	551.010	100			
	551.012	120			
	551.014	140			
	551.016	160			
	551.018	180			
	551.020	200			
	551.022	220			
	551.024	240			
	551.026	260			
Ilizarov External Fixator, 5/8 Ring S.S.	552.010	100			
	552.012	120			
	552.014	140			
	552.016	160			
	552.018	180			
	552.020	200			
	552.022	220			
	552.024	240			
	552.026	260			
	Ilizarov External Fixator, 1/2 Ring S.S.	553.008	80		
553.010		100			
553.012		120			
553.014		140			
553.016		160			
553.018		180			
553.020		200			
553.022		220			
553.024		240			
553.026		260			
Omega Ring S.S.	554.012	120			
	554.014	140			
	554.016	160			
	554.018	180			
	554.020	200			
Italian Femoral Arch 90°, S.S.	557.090.10	100			
	557.090.12	120			
	557.090.14	140			
	557.090.16	160			
	557.090.18	180			
	557.090.20	200			
	557.090.22	220			
	557.090.24	240			
	557.090.26	260			
Italian Femoral Arch 120°, S.S.	557.120.10	100			
	557.120.12	120			
	557.120.14	140			

	557.120.16	160			
	557.120.18	180			
	557.120.20	200			
	557.120.22	220			
	557.120.24	240			
	557.120.26	260			
Tubular Rod Ø 11 mm	558.100		100		
	558.150		150		
	558.200		200		
	558.250		250		
	558.300		300		
	558.350		350		
	558.400		400		
	558.450		450		
	558.500		500		
Connecting Rod Ø 4.0 mm, S.S.	559.410		100		
	559.415		150		
	559.420		200		
	559.425		250		
	559.430		300		
Connecting Rod Ø 5.0 mm, S.S.	559.510		100		
	559.515		150		
	559.520		200		
	559.525		250		
	559.530		300		
Connecting Rod Ø 8.0 mm, S.S.	559.810		100		
	559.815		150		
	559.820		200		
	559.825		250		
	559.830		300		
Small Single Pin Clamp	560.001	4.0x2.0mm			
Small Connecting Clamp	560.002	4.0x4.0mm			
Radius Fixator with spanner & T-Wrench	560.005				
Wrist Fixator, Small	560.008				
Wrist Fixator, Large	560.009				
Radius Fixator	560.011				
Dynamic External Fixator	560.012				
Rail External Fixator	560.014				
T-type Fixator, Small	560.017				
Limb Fixator	560.018				
Elbow Fixator	560.020				
Multiaxis I Clamp 3 pin for 8mm Double Rod Fixation	560.022				
Multiaxis I Clamp 5 pin for 8mm Double Rod Fixation	560.025				
Multiaxis Mono Straight Clamp Fixation 5 pin	560.028				
Multiaxis L Clamp 5 pin for 8mm Fracture fixation S.S.	560.029S				
Multiaxis L Clamp 5 pin for 8mm Fracture fixation AL.	560.029A				
Multiaxis Z Clamp Big for 8mm double Rod fixation	560.033				
External Fixator -Tube to Tube 8 x 8mm S.S.	560.034S				
External Fixator -Tube to Tube 8 x 8mmAL.	560.034A				
Straight-Post-8.0mm	560.035				
30° Angled Post-8.0mm	560.036				
Bushing 20mm	561.002				
Bushing 30mm	561.003				
Bushing 40mm	561.004				
Bushing 50mm	561.005				

Bushing 60mm	561.006				
Connecting Clamp	561.010				
Cannulated Angled Wrench 10mm	561.014				
Double Adjustable Clamp, Straight	561.019				
Double Adjustable Clamp, Curved	561.020				
Open Single Pin Clamp	561.023				
Single Pin Clamp	561.024				
Double Pin Clamp	561.025				
Self-Holding Clamp	561.026				
Transvers Clamp	561.027				
Tube to Tube Clamp	561.028				
Wire Tensioner Dynamometer	561.030				
Hinge Joint	561.034				
Hinge Male	561.035				
Hinge Female	561.036				
Hinge 90°	561.037				
Multi Pin Fixator Clamp	561.038				
Repofix device	561.040				
Pin Post Coupling for 3.0mm, 4.0mm & 5.0mm Pins	561.041				
Pin Rod Coupling for 3.0mm, 4.0mm, 5.0mm Pins & 8.0mm Rod	561.042				
Rod Rod Coupling	561.043				
Schanz Pin Introducer	561.044				
Triple Trocar Set with Handle	561.050				
Triple Trocar Set with Handle, Extra Long	561.051				
Connection Bolt	562.004				
Single Pin Fixation Bolt	562.007				
Wire Fixation Bolt, Slotted	562.013				
Wire Fixation Bolt, Cannulated	562.018				
Oblique Support without Thread	562.021				
Oblique Support with Thread	562.022				
Wire Buckle	562.026				
Nut 10mm	562.029				
Nylon Insert Nut	562.034				
Spacing Washer	562.036				
Flat Sided Washer	562.038				
Slotted Washer	562.040				
Conical Washer Couple	562.042				
Washer Hanger	562.045				
Compression Distraction Device, Small	563.001				
Compression Distraction Device, Standard	563.002				
Carbon Italian Arch 90°	564.090.17	120 x 170			
	564.090.19	140 x 190			
	564.090.21	160 x 210			
	564.090.23	180 x 230			
	564.090.25	200 x 250			
Carbon Italian Arch 120°	564.120.17	120 x 170			
	564.120.19	140 x 190			
	564.120.21	160 x 210			
	564.120.23	180 x 230			
	564.120.25	200 x 250			
Short Connection Plate	567.002				2
	567.003				3
	567.004				4
	567.005				5

	567.006				6
	567.007				7
	567.008				8
	567.009				9
	567.010				10
Curved Plate	568.003				3
	568.004				4
	568.005				5
	568.006				6
Twisted Plate	569.002				2
	569.003				3
	569.004				4
Post Male	570.002				2
	570.003				3
	570.004				4
Post Female	571.002				2
	571.003				3
	571.004				4
Threaded Socket	572.020		20		
	572.030		30		
	572.040		40		
	572.060		60		
Connection Plate with threaded end	573.005				5
	573.007				7
	573.009				9
	573.011				11
Wrenchocubes	574.001				1
	574.002				2
	574.003				3
	574.004				4
Carbon Half Rings, Paediatric	575.080.112	80 x 112			
	575.090.122	90 x 122			
	575.100.132	100 x 132			
	575.120.152	120 x 152			
Carbon 5/8 Rings, Paediatric	576.080.112	80 x 112			
	576.090.122	90 x 122			
	576.100.132	100 x 132			
	576.120.152	120 x 152			
Carbon 3/4 Rings, Paediatric	577.080.112	80 x 112			
	577.090.122	90 x 122			
	577.100.132	100 x 132			
	577.120.152	120 x 152			
Threaded Rod	579.075		75		
	579.100		100		
	579.125		125		
	579.150		150		
	579.200		200		
	579.250		250		
	579.300		300		
	579.350		350		
	579.400		400		
	579.450		450		
Threaded Rod, Slotted	580.075		75		
	580.100		100		
	580.125		125		
	580.150		150		

Corticotome	584.005			5	
	584.007			7	
	584.010			10	
	584.015			15	
Telescopic Rod S.S.	585.010		100		
	585.015		150		
	585.020		200		
	585.025		250		
	585.030		300		
Telescopic Rod, Graduated S.S.	586.010		100		
	586.015		150		
	586.020		200		
Carbon Rod Ø 4.0 mm	590.04.080	4.0	80		
	590.04.100	4.0	100		
	590.04.125	4.0	125		
	590.04.150	4.0	150		
	590.04.160	4.0	160		
	590.04.175	4.0	175		
	590.04.200	4.0	200		
	590.04.250	4.0	250		
	590.04.300	4.0	300		
	590.04.350	4.0	350		
	590.63.050	6.3	50		
	590.63.100	6.3	100		
	590.63.150	6.3	150		
	590.63.200	6.3	200		
	590.63.250	6.3	250		
	590.080.100	8.0	100		
	590.080.150	8.0	150		
	590.080.200	8.0	200		
	590.080.250	8.0	250		
	590.080.300	8.0	300		
	590.080.350	8.0	350		
	590.080.400	8.0	400		
	590.95.050	9.5	50		
	590.95.100	9.5	100		
	590.95.150	9.5	150		
	590.95.200	9.5	200		
	590.95.250	9.5	250		
	590.95.300	9.5	300		
	590.95.350	9.5	350		
	590.95.400	9.5	400		
	590.11.100	11.0	100		
	590.11.150	11.0	150		
	590.11.200	11.0	200		
590.11.250	11.0	250			
590.11.300	11.0	300			
590.11.350	11.0	350			
590.11.400	11.0	400			
590.11.450	11.0	450			
590.11.500	11.0	500			
590.16.125	16.0	125			

	590.16.150	16.0	150		
	590.16.175	16.0	175		
	590.18.075	1/8 inch	75		
	590.18.100	1/8 inch	100		
	590.18.150	1/8 inch	150		
	590.31.100	3/16 inch	100		
	590.31.150	3/16 inch	150		
	590.31.200	3/16 inch	200		
	590.31.250	3/16 inch	250		
	590.51.100	5/16 inch	100		
	590.51.150	5/16 inch	150		
	590.51.200	5/16 inch	200		
	590.51.250	5/16 inch	250		
Carbon Full Rings, Adult	592.080.120	80 x 120			
	592.100.140	100 x 140			
	592.110.150	110 x 150			
	592.120.160	120 x 160			
	592.130.170	130 x 170			
	592.140.180	140 x 180			
	592.150.190	150 x 190			
	592.160.200	160 x 200			
	592.180.220	180 x 220			
	592.200.240	200 x 240			
	592.220.260	220 x 260			
	592.240.280	240 x 280			
Carbon 3/4 Rings, Adult	593.080.120	80 x 120			
	593.100.140	100 x 140			
	593.110.150	110 x 150			
	593.120.160	120 x 160			
	593.130.170	130 x 170			
	593.140.180	140 x 180			
	593.150.190	150 x 190			
	593.160.200	160 x 200			
	593.180.220	180 x 220			
	593.200.240	200 x 240			
	593.220.260	220 x 260			
Carbon 5/8 Rings, Adult	594.080.120	80 x 120			
	594.100.140	100 x 140			
	594.110.150	110 x 150			
	594.120.160	120 x 160			
	594.130.170	130 x 170			
	594.140.180	140 x 180			
	594.150.190	150 x 190			
	594.160.200	160 x 200			
	594.180.220	180 x 220			
	594.200.240	200 x 240			
	594.220.260	220 x 260			
	594.240.280	240 x 280			
Carbon Half Rings, Adult	595.080.120	80 x 120			
	595.100.140	100 x 140			
	595.110.150	110 x 150			
	595.120.160	120 x 160			
	595.130.170	130 x 170			
	595.140.180	140 x 180			
	595.150.190	150 x 190			

	595.160.200	160 x 200			
	595.180.220	180 x 220			
	595.200.240	200 x 240			
	595.220.260	220 x 260			
	595.240.280	240 x 280			
	595.260.280	260 x 280			
Carbon 3/8 Rings, Adult	596.080.120	80 x 120			
	596.100.140	100 x 140			
	596.110.150	110 x 150			
	596.120.160	120 x 160			
	596.130.170	130 x 170			
	596.140.180	140 x 180			
	596.150.190	150 x 190			
	596.160.200	160 x 200			
	596.180.220	180 x 220			
	596.200.240	200 x 240			
	596.220.260	220 x 260			
	596.240.280	240 x 280			
Carbon 1/4 Rings, Adult	597.080.120	80 x 120			
	597.100.140	100 x 140			
	597.110.150	110 x 150			
	597.120.160	120 x 160			
	597.130.170	130 x 170			
	597.140.180	140 x 180			
	597.150.190	150 x 190			
	597.160.200	160 x 200			
	597.180.220	180 x 220			
	597.200.240	200 x 240			
	597.220.260	220 x 260			
	597.240.280	240 x 280			
	597.260.280	260 x 280			
Carbon Connecting Plate, Long	598		Long		
Carbon Foot Rings	599.001		Short		
	599.002		Long		
T-Handle with Chuck & Key Set	654.001				
Spanner 8mm	655.008				
T-Wrench 8mm	658.008				

Name: Himanshu Sachdeva
Position: Managing Partner


Himanshu Sachdeva
 Managing Partner
 Hospital Equipment Mfg. Co. India