

euroTECH

Certificate of Conformity

We confirm that the Technical Documentation for the below mentioned Product (Medical Devices of the Class I) according to the Council Directive 93/42/EEC as amended (2007/47/EC)

Hospital Furniture, Hospital Hollowware, Rehabilitation Aids & Orthopaedic Instruments (Non-sterile)

(For Detailed Specifications, Refer to Annexure of this Certificate, Pages 04)

Manufactured by Company

D4 SURGICALS (INDIA) PVT. LTD.

307, SAMRUDDHI COMMERCIAL COMPLEX, CHINCHOLI BUNDER ROAD, OFF LINK ROAD, MALAD (WEST), MUMBAI - 400 064, INDIA

complies with the applicable requirements of the Directive 93/42/EEC as amended (2007/47/EC).

Referring to the intended use, the Certification Body has conducted with successful results the review of the Manufacturer's Technical documentation of the certified product according to above mentioned Directive and appropriate Harmonized European Standards.

This Certificate is issued under the following conditions:

1. The Manufacturer's Technical Documentation, as required for Class I Devices, has been reviewed and found to comply with the requirements in Annex VII, Section 3.
2. It applies only to the above mentioned Medical Devices.
3. The Manufacturer is obligated to assure conformity of all the Medical Devices of the respective model to the type assessed by the mean of this Certificate.
4. Any significant changes in the Design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require special audit by Eurotech Assessment and Certification Services Pvt. Ltd. The product liability rests with the Manufacturer or his Representative in accordance with Council Directive.
5. After fulfilling the relevant EU Legislation Requirements, the Manufacturer shall affix to each Medical Device, CE Marking according to the following example:

CE



Handwritten signature in green ink

Certificate No. : ET/MDD/2015/994

Authorized Signature

Issued On : May 14, 2015

Valid Up To : May 13, 2020

Eurotech Assessment and Certification Services Pvt. Ltd.

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Annexure to Certificate

No. ET/MDD/2015/994

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List of the Medical Devices covered by the EC Certificate:

Product Group 1 – Hospital Furniture	
Product	Type of Model/ Variants
Hospital Bed	Plain Hospital Bed - Deluxe, Plain Hospital Bed – Standard, Back Rest Bed - Manual, Semi Fowler Bed, Semi Fowler Bed with Metal Panel, Fowler Bed, ICU Bed with 3 Movements, ICU Bed with 4 Movements, Hospital Bed Orthopaedic, ICU Bed - Electric, Hospital Bed with Baby Cradle, Baby Cradle, Paediatric Bed, Home Care Bed - Electric
Gynecological Examination and Delivery Table	Obstetric Delivery Table (3 Section Top), Labour Table (Telescopic), Labour Table (Foot End Folding), Examination cum Gynaecology Table, Delivery Table (Adjustable Height), Gynaecology Examination Couch, Obstetric Delivery Table (3 Section Top)
General Examination Table	Examination Table Plain, Examination Table (2 Section), Examination cum Gynaecology Table, Examination Couch
Tables, Trolleys & Stands	Bed Side Table - Standard, Bed Side Table - Deluxe, Bed Side Table – ABS, Over Bed Table, Food Trolley, Over Bed Table - Wooden Top, O. T. Table Fixed Height, O. T. Table Height Adjustable, O. T. Table Hydraulic, O. T. Table Electric, Orthopaedic attachments for O. T. Table
Trolleys	Emergency Trolley, Patient Trolley with Fixed Cushioned 2 Section Top, Mayo's Trolley, Instrument Trolley, Dressing Trolley, Monitor Trolley (for Scopic Surgery), Soiled Linen Trolley, Linen Change Trolley, Emergency Trolley, Drug Trolley, Patient Record Trolley, ECG Trolley, Oxygen Trolley, Stretcher Trolley, Stretcher on Trolley, Baby Trolley, Casualty Trolley, Instrument Trolley with Three Shelves, Instrument Trolley with Drawer
Stands	Drip Stand, Kick Bucket with Basin, Hand Wash Basin Stand (Single) with Basin, Kick Bucket and Bowl Stand – Double, Bed Side Screen (3 Panels), Bed Side Screen (4 Panels)
Stools	Foot Step – Single, Foot Step – Double, Surgeon Stool, Revolving Stool -Cushioned Top, Revolving Stool – SS, Revolving Stool - (Powder Coated), Blood Donor Chair cum Bed, Patient Stool Power Coated, Patient Stool S. S.
Cabinet	Instrument Cabinet, Single Door, Five Shelves, Instrument Cabinet, Double Door, Four Shelves
Accessories	Trapeze Type Bed Surface, Perforated Sheet Bed Surface, ABS Plastic Bed Surface, S. S. Swing Type Bed Side Railing, S. S. Collapsible Bed Side Railing, Aluminum Collapsible Bed Side Railing, ABS Plastic Swing Type Railing, SS Metal Bows, ABS Plastic Swing Type Railing, MS Power Coated Bows, Standard Castor, Delux Castor



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List of the Medical Devices covered by the EC Certificate:

Product Group 2 – Hospital Holloware	
Product	Type of Model/ Variants
Stainless Steel	Instrument Tray with/ without Cover, Kidney Tray with/ without Cover, Douche Can, Graduated Jar/ Measuring Jug, Urinal- Male, Urinal- Female, Feeding Cup, Medicine Cup, Sputum Mug, Galli - Pot with Cover, Forceps - Jar/ Thermometer Jar, Dressing Jar, Bed Pan- Female (Jointed), Bed Pan- Male (Jointed), Catheter Tray with Cover, Lotion Bowl, Basins, Dressing Drum Jointed (Seamless), Dressing Drum Jointed, Dustbin Pedestal with Plastic Bucket
Plastic	Bed Pan , Commode, Douche Can , Eye Wash Cup, Kidney Tray , Measuring Cup - Graduated, Conical Shape, Specimen Container, Stool Container, Steam Inhaler, Veterinary Syringes, Urine Pot – Female, Urine Pot – Male, Urine Pot - Large Male, Urine Pot - Large 2 in 1
Product Group 3 – Rehabilitation Aids	
Finger Splint	Finger Cot, Finger Extension Splint, Frog Splint, Thumb Spica Splint, Mallet Finger Splint
Traction Kits	Cervical Traction Kit (Sitting), Skin Traction Set (PUF Liner), Leg Traction Brace, Pelvic Traction Kit, Cervical Traction Kit (Sleeping)
Body Belts & Braces	Abdominal Support, Tummy Trimmer/ Abdominal Belt, Lumbo Sacral Belt, Rib belt, Chest binder, Lumbo Support Uni, Taylor's Brace Short / Long, Ash Brace (Hyper Extension Brace), Contoured L. S. Support
Physiotherapy Aids	Weight Cuff, Exercising Ball
Allied Products	Tourniquet, Compression Stocking (Mid-Thigh), Compression Stocking (Below Knee)
Cervical Aids	Collar Soft (Firm Density), Cervical Orthosis (Philadelphia), Cervical Collar Soft, Cervical Pillow Regular, Cervical Collar Soft with support, Cervical Collar (Hard Adjustable Height), Shoulder Brace
Walking Aids	Walking Stick (Soft Top Handle), Walking Stick (L Type), Walking Stick Quadripod
Silicon Products	Insole Full Silicon (Pair), Heel Cushion Silicon (Pair), Toe Separator Silicon (Pair), Heel Cup Silicon (Pair), Metatarsal Pad Silicon (Pair)
Fracture Aids	Pouch Arm Sling, Universal Shoulder Immobilizer, Cast Shoe, Clavicle Brace with Buckle
Knee & Ankle Support	Ankle Binder, Anklet, Ankle Brace, F. Drop Splint with Ace, Elastic Knee Support, Knee Cap, Thigh Support, Knee Brace Long Type, Knee Brace Short Type, Knee Cap (with Rigid Hinge), Knee Cap (Open Patella), Knee Cap (with Flex Hinge), Rom Knee Brace

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Product Group 3 – Rehabilitation Aids	
Product	Type of Model/ Variants
Wrist & Forearm Products	Tennis Elbow Support, Cock up Splint Half (Static), Wrist & Forearm Splint Elastic Wrist Splint, Elbow Support, Wrist Brace with Thumb, Wrist Brace with Double Lock
Neoprene Products	Knee Support Hinged (Neoprene), Knee Cap Open Patella (Neoprene), Knee Wrap (Neoprene), ABS Wrap (Neoprene), Wrist Wrap (Neoprene), Wrist Brace with Thumb (Neoprene)
Product Group 4 – Orthopaedic Instruments (Non-sterile)	
External Fixator	Dynamic Axial External Fixator, Dynamic Axial External Fixator Small, Dynamic Axial External Fixator Medium, Dynamic Axial External Fixator Big, Compression & lengthening System, Ortho Fixator Small, Ortho Fixator Medium, Ortho Fixator Big, Wagner Big, Wagner Med, Wagner Small, Limb Reconstruction System, Rail Small 240 mm, Rail Med 300 mm, Rail Big 400 mm, End Clamp, Central Clamp, Swivel Clamp, Ball & Socket Joint Clamp, T' Ball & Socket Joint Clamp, Central Distance Unit 40 mm, Central Distance Unit 80 mm, Central Distance Unit 100 mm
Plaster Cutter	Electrical Plaster Cutting Saw with Two Blades, Plaster Saw Blade Small, Plaster Saw Blade Big
Bone Cutting, Reaming & Drilling System	Driving Unit (Driving Unit includes Motor Stand, Foot Control) Flexible Shaft, Tool Kit, Oil Bottle & Special Container, Cannulated Drill Hand Piece, Reaming Hand Piece, Sagittal Saw Hand Piece, Oscillating Saw Hand Piece, Flexible Reamer Shaft 6 mm Fixed Head, Flexible Reamer Shaft 7 mm Fixed Head, Flexible Reamer Shaft 8 mm Fixed Head, Flexible Reamer Shaft 9 mm Fixed Head, Flexible Reamer Shaft 10 mm Fixed Head, Flexible Reamer Shaft 11 mm Fixed Head, Flexible Reamer Shaft 12 mm Fixed Head, Flexible Reamer Shaft 13 mm Fixed Head, Flexible Reamer Shaft 14 mm Fixed Head, Flexible Reamer Shaft 15 mm Fixed Head
Ilizarove (The Ring Fixator System Includes)	Half Ring 80 - 110 mm, Half Ring 120-150 mm, Half Ring 160-180 mm, Half Ring 200-240 mm, Half Ring 260-300 mm, 5/8 Ring 130-150 mm, 5/8 Ring 160-180 mm, 5/8 Ring 200 mm, Italian Arches 90°, 120° (Small, Big), Threaded Rods up to 100 mm, Threaded Rods 120-150 mm, Threaded Rods 200-250 mm, Threaded Rods Slotted up to 100 mm, Telescopic Rods 100 mm, Telescopic Rods 150 mm, Telescopic Rods 200 mm, Telescopic Rods 250 mm, Graduated Telescopic Rods 60-150 mm, Graduated Telescopic Rods 200-250mm, Post Male/Female 2,3,4 Holes, Hinges Male/ Female 90°, Short Connection Plate 2 to 6 Holes, Short Connection Plate 7 to 10 Holes, Long Connection Plate 8, 12, 17 Holes, Threaded End Connector Plate 5, 7 Holes



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Product Group 4 – Orthopaedic Instruments (Non-sterile)	
Product	Type of Model/ Variants
Ilizarove (The Ring Fixator System Includes)	Threaded End Connector Plate 9, 11 Holes, Curved Plate 3 Holes, Twisted Plate 2, 3, 4 Holes, Bushing, Threaded Socket 20 mm, Threaded Socket 30 mm, Threaded Socket 40 mm, Threaded Socket 60 mm, Connection Bolt 10 mm, Connection Bolt 16 mm, Connection Bolt 20 mm, Connection Bolt 30 mm, Nut 6 mm, Nut 13 mm, Thin Nut 6 mm, Square Nut, Spacing Washer 1.5 mm, Split Locking Washer 2.0 mm, Flat Sided Washer 2.0 mm, Flat Sided Washer 4.0 mm, Slotted Washer 4.0 mm, Conical Washer Couple, Wire Fixation Bolt Slotted, Wire Fixation Bolt Cannulated, Wire Fixation Buckle, Pin Fixation Bolt for 4, 5, 6 mm Pins, Rancho Cube for Half Pins 1 Hole, Rancho Cube for Half Pins 2 Hole, Rancho Cube for Half Pins 3 Holes, Rancho Cube for Half Pins 4 Holes, Rancho Cube for Half Pins 5 Holes, Universal Joint, Single Pin Fixation Bolt, Rotational Translation Device, Oblique Support
Combo Screw Driver Set	Screw Removal 4.5 A/FX 125 mm, Screw Removal 3.5 A/FX 125 mm, Cannulated Screw Driver Shank 3.5mm A/FX 125 mm, Cannulated Screw Driver, Shank 3.5 mm A/FX 125 mm, Cannulated Screw Driver Shank 2.5 mm A/FX 150 mm, Hex Screw Driver Shank 2.5 mm A/FX 125 mm, Hex Screw Driver Shank, 3.0 mm A/FX 125 mm, Hex Screw Driver Shank 4.0 mm A/FX 125 mm, Hollow Mill, Shank 6.5 mm x 8.5 mm 125, Philips Screw Driver Shank 4.0 mm A/FX 125 mm, Philips Screw Driver Shank 6.0 mm A/FX 125 mm, Hollow Mill Shank 8.5 mm x 10.5 mm x 125 mm, Flat Screw Driver Size 6.0 mm A/FX 125 mm, Hex Screw Driver, Shank 4.7 mm A/FX 225 mm, Hex Screw Driver 5.0 mm A/FX 125 mm, Hex, Screw Driver Shank 1.5 mm A/FX 125 mm, Hollow Mill Shank 5.5 mm x 125mm, Cannulated Screw Driver Shank 3.5 mm A/FX 200 mm, Trocar Shank 6.9 mm x 125 mm, Hex Screw Driver Shank 3.5 mm A/FX 225 mm



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