

**eu**roTECH

# 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 Medical Furniture, Hospital Hollowware, OT Equipments, Medical Disposables, Medical and Surgical Rubber Goods, Diagnostic Equipments and Products, Miscellaneous Surgical Medical Products, Rehabilitation Aids & Orthopaedic Instruments**

(For Detailed Specifications, Refer to Annexure of this Certificate, Pages 07)

Manufactured by Company

**NARANG MEDICAL LIMITED**

**46, COMMUNITY CENTRE, NARAINA PHASE-I, NEW DELHI – 110 028, DELHI, 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 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**



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Issued On : December 09, 2017

Valid Up To : December 08, 2022

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## Annexure to Certificate

No. ET/MDD/2017/1124

Issued for the Company:

### **NARANG MEDICAL LIMITED**

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*List of the Medical Devices covered by the EC Certificate:*

<b>Product Group 1– Hospital Medical Furniture</b>	
<b>Product</b>	<b>Models/ Variants</b>
<b>Hospital Beds</b>	ICU Bed Electric/Mechanical Fowler Bed, Semi Fowler Bed General /Standard Bed, Attendant Bed, Orthopaedic Bed Paediatric Bed Infant Bed/Cot/Cribs Examination Bed/Table
<b>Delivery Beds / Gynaecological Beds</b>	Delivery Bed / Gynecological Bed
<b>Ward Furniture</b>	Saline Stand Examination Lamp/ Angle Poise Lamp, Swaddling Bed/Table, Blood Donor Chair
<b>Stretchers</b>	Single Fold, Double Fold, Two Fold, Three Fold, Four Fold, with wheels, without wheels, Salvage Stretchers, Spine Board Ambulance Stretcher, Stretcher Chairs, Stretcher Trolleys
<b>Mobility Aids</b>	Wheel Chairs, Walker / Walker Rollators, Walking Sticks/Crutches, Commode Chair, Shower chair
<b>Product Group 2– Hospital Hollowware</b>	
<b>Hospital Hollowware</b>	Urinals (Male & Female)
	Spittoons /Sputum Mugs (Stainless Steel / Plastic)
	Douche Cans (Stainless Steel / Plastic)
	Bed Pans (Stainless Steel / Plastic)
	Buckets (Stainless Steel / Plastic)
	Bowls & Basins (Stainless Steel / Plastic)
	Instrument Trays (Stainless Steel / Plastic)
	Kidney Trays (Stainless Steel / Plastic)
	Dressing Drums (Stainless Steel)
	Vomit Bag



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List of the Medical Devices covered by the EC Certificate:

<b>Product Group 3– OT Equipments</b>	
<b>Product</b>	<b>Models/ Variants</b>
<b>OT Tables</b>	Operation Theatre Table- Electrometric, Hydraulic, Mechanical & Electro Mechanical
<b>OT Lights</b>	Operation Theatre Light Mobile, Ceiling & Wall Mounted
<b>Product Group 4– Medical Disposables</b>	
<b>Umbilical Clamp Cord</b>	-
<b>Urine Bag</b>	-
<b>Tongue Depressor Disposable Wooden</b>	-
<b>Disposable Non-Woven</b>	Surgical gown, Nurse gown, Scrub suit, Lab Coat, Face Mask, Cap & Apron
<b>Reusable</b>	Surgical gown, Nurse gown, Scrub suit, Lab Coat, Face Mask, Cap, Disposable PE Apron/Reusable PVC apron
<b>Examination Gloves</b>	Examination Gloves Latex, Non Sterile, Disposable



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<b>Product Group 5– Medical and Surgical Rubber Goods</b>	
<b>Product</b>	<b>Models/ Variants</b>
<b>Hot Water Bottle</b>	-
<b>Invalid Rings /Air Cushion</b>	-
<b>Tourniquet Latex &amp; Latex Free</b>	-
<b>Rubber Sheeting/ Mackintosh Sheeting</b>	-
<b>Breast Pump</b>	Breast Pump, Manual
<b>Surgical Rubber Tubing</b>	Surgical Rubber Tubing Large, Surgical Rubber Tubing Medium & Surgical Rubber Tubing Small
<b>Chloroform Bellow</b>	Chloroform Bellow
<b>Atomizer Bulb</b>	Atomizer Bulb with Metal Valve Oval, Black / Ash Colour Atomizer Bulb with Metal Valve & Rubber Tube black/ ash colour Atomizer Bulbs with Long tube (single bellow) in orange colour
<b>Ice Bag</b>	Round- Sizes available 2 Oz. (50 ml) & 4 Oz. (100 ml). Oval- Sizes available 2 Oz. (50 ml) & 4 Oz. (100 ml). Throat- Sizes available 2 Oz. (50 ml) & 4 Oz. (100 ml).

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List of the Medical Devices covered by the EC Certificate:

<b>Product Group 6– Diagnostic Equipments and Products</b>	
<b>Product</b>	<b>Models/ Variants</b>
<b>Tuning Forks</b>	-
<b>Bung IV White</b>	-
<b>Otoscope and Ophthalmoscope Diagnostic Set</b>	Battery operated Otoscope (Auroscope Set)
	Otoscope (Pin Connection System) Battery Operated
	Ophthalmoscope, Battery Operated
	Ophthalmoscope with Otoscope, Battery Operated
	Diagnostic set (Pin Contacting Fitting) 2.5V Standard illumination for use with 2 batteries type
	Professional Otoscope, Battery operated
	Professional Ophthalmoscope, Battery Operated
	Professional Ophthalmoscope
	Diagnostic Series, Battery operated
	Otoscope Cum Ophthalmoscope Set, Battery Operated
<b>Stethoscopes and Spare Parts</b>	Stethoscopes Dual Headed Regular
	Stethoscopes Dual Headed Microfon
	Stethoscopes Dual Headed Regular Brass
	Stethoscopes Dual Headed Pediatric Brass
	Stethoscopes Dual Headed, Diamond
	Stethoscopes Dual Headed, Deluxe
	Stethoscopes Dual Headed, Cardio
	Stethoscopes Single Headed Nurse Scope
	Stethoscopes Foetal
	Stethoscopes Cardio
	Stethoscope Single Head for Adults
	Stethoscope Deluxe Single Head for Adults
	Sprague Rappaport Type Stethoscope
	Deluxe Doctor's Single Head Stethoscope
	Stethoscope for Adults Cardio Type
Stethoscope Deluxe for Adults	
Stethoscope Tubes	

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<b>Product Group 6– Diagnostic Equipments and Products</b>	
<b>Product</b>	<b>Models/ Variants</b>
<b>Armlet Bag</b>	Velcro cuff for sphygmomanometer, complete with rubber bladder with two tubes for new born, (5.7 x 30.5cm).
	Velcro cuff for sphygmomanometer, complete with rubber bladder with two tubes for 1 - 3 years, (7 x 30.5cm)
	Velcro cuff for sphygmomanometer, complete with rubber bladder with two tubes for 3 - 7 years, (8.3 x 35cm)
	Velcro cuff for sphygmomanometer, complete with rubber bladder with two tubes for 7 - 10 years, (9.5 x 38cm)
	Velcro cuff for sphygmomanometer, complete with rubber bladder with two tubes for adult, (14.5 x 51.5)
	Velcro cuff for sphygmomanometer, complete with rubber bladder with two tubes for obese (17.5 x 63cm)
	Velcro cuff for sphygmomanometer, complete with rubber bladder with two tubes for thigh (21 x 83cm)
<b>Product Group 7 – Miscellaneous Surgical Medical Products</b>	
<b>Needle Syringe Destroyer</b>	Needle Syringe Destroyer Electrical & Manual
<b>Blanket Emergency</b>	-
<b>Product Group 8 – Rehabilitation Products &amp; Aids</b>	
<b>Bandages</b>	W.O.W Bandages, B. P
	Bandage Skin Traction
	Orthopaedic Bandage / Padding
	Elastic Adhesive Bandage, B. P
	Cotton Crepe Bandage, B.P.
	Triangular Bandage Cotton
	Plaster of Paris Bandages, BP

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List of the Medical Devices covered by the EC Certificate:

<b>Product Group 9 – Orthopaedic Instruments</b>	
<b>Product</b>	<b>Models/ Variants</b>
<b>Orthopaedic Instruments</b>	Instruments Set for Perfect Tibial Nails
	Instruments Set for Perfect Femoral Nails
	Instruments Set for Multi-Fix Tibial & Femoral Nails
	Instruments Set for Multi-Fix Tibial & Femoral Nails with Distal Jig
	Instruments Set for Easy Universal Nails
	Instruments Set for Gaam Nails
	Instruments set for Humeral Nails Cannulated
	Instruments set for Humeral Nails Unreamed
	Instruments Set for Tens Nails
	Kuntscher Nails Instruments Set
	Instruments for Ender Nails
	Instruments for Rush Nails
	Pins & Wire Instruments
	Small Fragment Instruments Set combo with standard instruments & locking instruments
	Small Fragment Safety Lock Instruments Set
	Small Fragment Instruments Set
	Damaged / Broken Screws Removal Instruments Set
	Large Fragment Instruments Set – Combo with Standard Instruments & Locking instruments
	Large Fragment Instruments Set
	Instruments set for 4.0mm Cannulated Cancellous screws
	Instruments set for 4.5mm Cortex Cannulated screws
	Instruments set for 7.0mm Cancellous Cannulated screws
	Instruments set for 6.5mm Cancellous Cannulated screws
Mini Fragment Instruments Set	
Bone Holding Forceps Set	
Instruments Set for Condylar Plate	

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<b>Product Group 9 – Orthopaedic Instruments</b>	
<b>Product</b>	<b>Models/ Variants</b>
<b>Orthopaedic Instruments</b>	Instruments Set for Angled Blade Plate
	Paediatric DHS/DCS Instruments Set
	DHS/DCS Plate Instruments Set
	Instruments for Jewett Nails Plates
	Femoral Head Instruments Set
	Instruments set for Modular Bipolar and Total Hip Replacement Set
	Instruments for Universal External Fixator – 4.0 mm
	Instruments for Universal External Fixator – 8.0 mm
	Instruments for Distal Radius External Fixator
	Instruments for Dynamic External Fixator
	Instruments for the Rail Fixation System
	Instruments for Paediatric Rail System
	Instruments for Posterior Thoracolumbar
	Instruments for Paediatric Thoracolumbar
	Instruments for Minimal Invasive Screw System
Instruments for Interbody Fusion Cage System	
Instruments for Dual Tap Self-Centering Screw System	

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