

**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)

**Body Belts & Braces, Cervical Aids, Fracture Aids, Ankle Supports, Knee Supports, Wrist & Fore Arm Products, Finger Splints, Traction Kits, Allied Products, Compression Garments, Neoprene Products, Silicon Products/ Foot Care Products, OAC Products, Walking Aids & Paediatric Range**

(For Detailed Specifications Refer to Annexure of this Certificate, Pages 06)

Manufactured by Company

**TYNOR ORTHOTICS PVT. LTD.**

**D-111, INDUSTRIAL AREA, PHASE - 7, MOHALI - 160 055, PUNJAB, 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**



*Authorized Signature*

**Certificate No. : ET/MDD/2015/998**

**Issued On : May 25, 2015**

**Valid Up To : May 24, 2020**

**Eurotech Assessment and Certification Services Pvt. Ltd.**

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## Annexure to Certificate

No. ET/MDD/2015/998

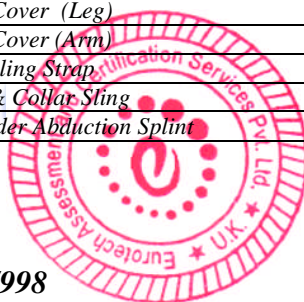
Issued for the Company:

**TYNOR ORTHOTICS PVT. LTD.**

**D-111, INDUSTRIAL AREA, PHASE - 7, MOHALI - 160 055, PUNJAB, INDIA**

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

<b>Product Group 1 – Body Belts &amp; Braces</b>	
<b>Product</b>	<b>Type of Model</b>
Body Belts & Braces	Abdominal Support 9"
	Tummy Trimmer/ Abdominal Belt 8"
	LS Belt Lumbopore
	Lumbo Sacral Belt
	Contoured L.S. Support
	Rib Belt
	Chest Binder
	Ash Brace (Hyper Extension Brace)
	Taylor's Brace Short / Long
	Lumbo Support Uni
	Hernia Belt
	Lumbo Lacepull Brace
	Pregnancy Back Support
Lumbo Flexi Pore	
<b>Product Group 2 – Cervical Aids</b>	
Cervical Aids	Collar Soft (Firm Density)
	Cervical Collar Soft with Support
	Cervical Collar Hard Adjustable
	Cervical Orthosis (Philadelphia) Ethafoam
	Cervical Collar Soft
	Cervical Pillow Regular
	Cervical Orthosis (Philadelphia) Plastazote
	Contoured Cervical Pillow
Cervical Collar Hard With Chin	
<b>Product Group 3 – Fracture Aids</b>	
Fracture Aids	Pouch Arm Sling (Tropical)
	Universal Shoulder Immobilizer
	Elastic Shoulder Immobilizer
	Clavicle Brace with Buckle
	Clavicle Brace with Velcro
	Pouch Arm Sling (Baggy)
	Cast Shoe
	Cast Cover (Leg)
	Cast Cover (Arm)
	Arm Sling Strap
	Cuff & Collar Sling
Shoulder Abduction Splint	



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List of the Medical Devices covered by the EC Certificate:

<b>Product Group 4 – Ankle Supports</b>	
<b>Product</b>	<b>Type of Model</b>
Ankle Supports	Ankle Binder
	Ankle Brace
	Anklet (Pair)
	F. Drop Splint Right/Left
	Anklet Comfeel (Single)
	Ankle Splint Air Pad
	Walker Boot
	PF Night Splint De-rotation
	F. Drop Splint with Liner Right/ Left
	Dennis Brown Splint
Ankle Splint	
<b>Product Group 5 – Knee Supports</b>	
Knee Supports	Knee Cap (Pair)
	Knee Cap (with Rigid Hinge)
	Knee Cap with Patellar Ring
	Elastic Knee Support
	Functional Knee Support
	R.O.M. Knee Brace
	Knee Immobilizer
	Thigh Support
	Patellar Support
	Knee Cap Comfeel (Single)
	Offloader Knee Brace
	Knee Immobilizer 3 Panel
	Bunion Splint



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

<b>Product Group 6 – Wrist &amp; Fore Arm Products</b>	
<b>Product</b>	<b>Type of Model</b>
Wrist & Fore Arm Products	Wrist Splint (Ambidextrous)
	Wrist & Forearm Splint Right/ Left
	Wrist Brace with Double Lock
	Wrist Brace with Thumb
	Tennis Elbow Support
	Elbow Support
	Hand Resting Splint
	Forearm Splint
	Wrist Splint with Thumb
	Carpal Tunnel Splint
	Lunar Splint
	Solar Splint
Protector Glove	
<b>Product Group 7 – Finger Splints</b>	
Finger Splints	Finger Cot
	Finger Extension Splint
	Frog Splint
	Mallet Finger Splint
	Thumb Spica Splint
<b>Product Group 8 – Traction Kits</b>	
Traction Kits	Skin Traction Set (PUF Liner)
	Leg Traction Brace
	Pelvic Traction Belt
	Cervical Traction Head Halter
	Cervical Traction Spreader Bar
	Traction Pulley Bracket
	Traction Weight Bag
	Pelvic Traction Kit with Weight Bag
	Cervical Traction Kit (Sitting) with Weight Bag
	Cervical Traction Kit (Sleeping) with Weight Bag
Pelvic Traction Spreader Bar	



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<b>Product Group 9 – Allied Products</b>	
<b>Product</b>	<b>Type of Model</b>
Allied Products	Weight Cuff
	Exercising Ball
	Ortho Stockinete 10 Mt.
	Hot & Cold Pack
	Back Rest
	Scrotal Support
	Restrainer
Commode Chair	
<b>Product Group 10 – Compression Garments</b>	
Compression Garments	Compression Stocking Mid-Thigh
	Compression Stocking below Knee
	Tubular Elastic Bandage
	Medical Compression Stocking below Knee Class 1
	Medical Compression Stocking below Knee Class 2
	Medical Compression Stocking below Knee Class 3
	Medical Compression Stocking Mid-Thigh Class 1
Medical Compression Stocking Mid-Thigh Class 2	
Medical Compression Stocking Mid-Thigh Class 3	
<b>Product Group 11 – Neoprene Products</b>	
Neoprene Products	Knee Support Hinged (Neoprene)
	Wrist Brace with Thumb (Neoprene)
	Wrist Wrap (Neoprene)
	Knee Wrap (Neoprene)
	ABS Wrap (Neoprene)
	OA Knee Support (Neoprene)
	Knee Support Sportif (Neoprene)
	Ankle Support (Neoprene)
	Shoulder Support (Neoprene)
Knee Wrap Hinged (Neoprene)	



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<b>Product Group 12 – Silicon Products/ Foot Care Products</b>	
<b>Product</b>	<b>Type of Model</b>
Silicon Products/ Foot Care Products	Insole Full Silicon
	Heel Cushion Silicon
	Toe Separator Silicon
	Metatarsal Pad Silicon
	Heel Cup Silicon
	Medial Arch Orthosis
	Massage Gel Insole
	Insole Omni Silicon
	Arch Support (Pair)
<b>Product Group 13 – OAC Products</b>	
OAC Products	Contoured L.S. Belt (OAC)
	Lumbo Sacral Belt (OAC)
	Abdominal Belt (OAC)
	Pouch Arm Sling Oxy-pore (OAC)
	Anklet (OAC)
	Knee Cap (OAC)
Elbow Support OAC	
<b>Product Group 14 – Walking Aids</b>	
Walking Aids	Walking Stick (Soft Top Handle)
	Walking Stick (L Type)
	Walking Stick Pod (Pyramid ) (19mm)
	Crutch Pod (Goose Neck) (22 mm)
	Quadripod (Goose Neck) (15 mm)
	Walking Stick Quadripod
	Elbow Crutch
	Auxiliary Crutch
	Walker Invalid's Reciprocating - All Pods - AL
	Walker Invalid's - Front Wheels - AL
	Walking Stick Tripod
	Pod Walker
	Walker Invalid's Heavy Duty - All Pods



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

<b>Product Group 15 – Paediatric Range</b>	
<b>Product</b>	<b>Type of Model</b>
Paediatric Range	Clavicle Brace with Buckle
	Clavicle Brace with Velcro
	Pouch Arm Sling
	Collar Soft (Firm Density)
	Ankle Brace
	Wrist & Forearm Splint
	Medial Arch Orthosis
Skin Traction Set	



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