

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 & ForeArm 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 07)

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 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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Certificate No. : ET/MDD/2015/998
Issued On : May 25, 2015
Re Issued On : August 13, 2019
Valid Up To : May 24, 2020

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Deliberate misuse of certificate will result in cancellation without notification. To check current validity of certificate, log on to

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Annexure to Certificate

No. ET/MDD/2015/998

Issued for the Company:

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

List of the Medical Devices covered by the EC Certificate:

Product Group 1 – Body Belts & Braces	
Product	Type of Model
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
	Lacepull L.S Belt
	L S Belt Urbane
Posture Corrector	
Taylor's Brace Urbane Short/Long	
Product Group 2 – Cervical Aids	
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
Nelson Collar	
Product Group 3 – Fracture Aids	
Fracture Aids	Pouch Arm Sling (Tropical)
	Universal Shoulder Immobilizer
	Elastic Shoulder Immobilizer
	Clavicle Brace with Buckle
	Clavicle Brace with Velcro
	Pouch Arm Sling (Baggy)

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Product	Type of Model
Product Group 3 – Fracture Aids	
Fracture Aids	Cast Shoe (Rocker Sole)
	Cast Cover (Leg)
	Cast Cover (Arm)
	Cast Cover (Tapered Sole)
	Arm Sling Strap
	Cuff & Collar Sling
	Shoulder Abduction Splint
	Pouch Arm Sling with Abduction Pillow
	Cuff & C Sling 6 Mtr x 75 mm x 1
	Cuff & C Sling 6 Mtr x 50 mm x 2
	Pouch Arm Sling Urbane
Shoulder Abduction Pillow	
Product Group 4 – Ankle Supports	
Ankle Supports	Ankle Binder
	Ankle Brace
	Anklet (Pair)
	F. Drop Splint Right/Left
	F. Drop Splint Right/Left w/o Acc.
	Anklet Comfeel (Single)
	Ankle Splint Air Pad
	Walker Boot / Walker Boot - short
	PF Night Splint De-rotation
	F. Drop Splint with Liner Right/ Left
	Dennis Brown Splint
	Ankle Splint
	Ankle Support Urbane
	Foot Raiser
	Ankle Stabilizer Kinezio
Walker Boot Air	
Product Group 5 – Knee Supports	
Knee Supports	Knee Cap (Pair)
	Knee Cap (with Rigid Hinge)
	Knee Cap with Patellar Ring
	Knee Cap Open Patella

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List of the Medical Devices covered by the EC Certificate:

Product Group 5 – Knee Supports	
Product	Type of Model
Knee Supports	Elastic Knee Support
	Functional Knee Support
	R.O.M. Knee Brace
	Knee Immobilizer 19”
	Knee Immobilizer 14”
	Knee Immobilizer 22”
	Thigh Support
	Patellar Support
	Knee Cap Comfeel (Pair)
	Offloader Knee Brace
	Knee Immobilizer Adjustable
	Bunion Splint
	Knee Protector
	Knee Support Urbane
R.O.M. Knee Brace 22"/56cm	
Knee Stabilizer Kinezio	
Product Group 6 – Wrist & Fore Arm Products	
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
	Elastic Wrist Splint Right/Left
	ROM Elbow Brace
	Elbow Protector
Wrist Support Urbane	
Elbow Support Urbane	
Elbow Stabilizer Kinezio	

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List of the Medical Devices covered by the EC Certificate:

Product	Type of Model
Product Group 7 – Finger Splints	
Finger Splints	Finger Cot
	Finger Extension Splint
	Frog Splint
	Mallet Finger Splint
	Thumb Spica Splint
Product Group 8 – Traction Kits	
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	
Product Group 9 – Allied Products	
Allied Products	Weight Cuff
	Exercising Ball
	Exercising Gel Ball
	Tyrobond
	Cool Pack
	Cool Pack Knee Wrap
	Seat Raiser 4"
	Coccyx Cushion Seat
	Ortho Stockinete 10 Mt.
	Hot & Cold Pack
	Back Rest
	Scrotal Support
	Restrainer
	Heating Pad Ortho
	Breast Prosthesis
	Breast Prosthesis Lite

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Product	Type of Model
Product Group 9 – Allied Products	
Immobiliser Allied Products	Ortho Heating Gel Bag (Electric)
	Mastectomy Bra
	Ortho Cushion Seat
	Tourniquet
	Lumbo-Back Rest
Product Group 10 – Compression Garments	
Compression Garments	Compression Stocking Mid-Thigh
	Compression Stocking Below Knee
	Tubular Elastic Bandage
	Anti Embolism Stockings (D.V.T.) Knee High Class 1
	Medical Compression Stocking below Knee High Class 1
	Medical Compression Stocking below Knee High Class 2
	Medical Compression Stocking below Knee High Class 3
	Anti Embolism Stockings (D.V.T.) Thigh High Class 1
	Medical Compression Stocking Mid-Thigh Class 1
	Medical Compression Stocking Mid-Thigh Class 2
	Medical Compression Stocking Mid-Thigh Class 3
	Medical Compression Stocking Thigh High Class 2
	Medical Compression Stocking Thigh High Class 3
	Compression Garment Arm Sleeve
	Compression Garment Arm Sleeve + Mitten (with Thumb)
	Compression Garment Arm Sleeve with Shoulder Cover
	Compression Garment Hand Glove- Pair
	Compression Garment Leg Mid Thigh (Open Toe)
	Compression Garment Leg Mid Thigh (Closed Toe)
	Compression Garment Leg Below Knee (Open Toe)
	Compression Garment Leg Below Knee (Closed Toe)
	Compression Garment Thigh & Panty (2" above Knee)
	Compression Garment Foot Glove with Toe Separator
Compression Garment Vest (Sleeveless)	
Compression Garment Abdominal Girdle	
Compression Garment Face Open Hood	
Penguin Cancer Cap (Set of 3)	
Comp. Gar. Vest Zipper (Sleeveless)	

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List of the Medical Devices covered by the EC Certificate:

Product	Type of Model
Product Group 11 – Neoprene Products	
Neoprene Products	<i>Knee Support Hinged (Neoprene)</i>
	<i>Wrist Brace with Thumb (Neoprene)</i>
	<i>Wrist Wrap (Neoprene)</i>
	<i>Knee Wrap (Neoprene)</i>
	<i>ABS Wrap (Neoprene)</i>
	<i>OA Knee Support (Neoprene)</i>
	<i>Knee Support Sportif (Neoprene)</i>
	<i>Ankle Support (Neoprene)</i>
	<i>Shoulder Support (Neoprene)</i>
	<i>Knee Wrap Hinged (Neoprene)</i>
<i>Ankle Wrap (Neoprene)</i>	
Product Group 12 – Silicon Products/ Foot Care Products	
Silicon Products/ Foot Care Products	<i>Insole Full Silicon</i>
	<i>Heel Cushion Silicon</i>
	<i>Toe Separator Silicon</i>
	<i>Metatarsal Pad Silicon</i>
	<i>Heel Cup Silicon</i>
	<i>Medial Arch Orthosis (Adult / Child)</i>
	<i>Massage Gel Insole</i>
	<i>Insole Omni Silicon</i>
	<i>Bunion Splint</i>
	<i>Arch Support (Pair)</i>
	<i>Insole Gel Female (Pair)</i>
	<i>Heel Protector (Pair)</i>
	<i>OA Wedge Insoles</i>
Product Group 13 – OAC Products	
OAC Products	<i>Contoured L.S. Belt</i>
	<i>Lumbo Sacral Belt</i>
	<i>Abdominal Belt</i>
	<i>Pouch Arm Sling (Oxypore)</i>
	<i>Anklet (OAC)</i>
	<i>Knee Cap (OAC)</i>
	<i>Elbow Support OAC</i>
	<i>Heating Pad Ortho</i>
<i>Knee Immobiliser 19"/48cm</i>	

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Product	Type of Model
Product Group 14 – Walking Aids	
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 Adjustable
	Auxiliary Crutch
	Walker Invalid's Reciprocating - All Pods - AL
	Walker Invalid's - Front Wheels - AL
	Walker Invalid's - Front Wheels - HD
	Walking Stick Tripod
	Pod Walker
	Walker Invalid's Heavy Duty - All Pods
	Commode Chair
	Commode Chair Ergo
	Walking Stick Trio
Walking Stick Tetra	
Pod Trio (19mm)	
Pod Tetra (19mm)	
Product Group 15 – Paediatric Range	
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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