

# Decleration OF CONFORMiTY

*Armo Line*

**EC Decleration of Conformity:** MEDiCAL DEViCES DiRECTiVES (93/42/EEC)  
APPENDiX-Vii

**Manufacturer:** MEDiMPORT SAĐLIK ÜRÜNLERi  
SAN.TiC.LTD.ĐTi.

**Manufacturer's address:** Oruç Reis Mah. Giyimkent Sitesi 3.Sok. No:87/A  
Esenler / İSTANBUL

**Device/s:** ORTHOPEDiC SUPPORT PRODUCTS

**Description:** MEDiCAL DEViCE(S) THAT SUPPORT(S) THE  
HUMAN BODY EXTERNALLY.

**EC Product Class:** CLASS 1

**MEDiCAL DEViCES DiRECTiVES (93/42/EEC) - APPENDiX Vii**

**STANDARDS:**

- EN 980: 2008: Graphical symbols for use in the labelling of medical devices.
- EN ISO 14971: 2012 Medical devices. Application of risk management to medical devices
- EN 1041: 2008 + A1: 2013 information supplied by the manufacturer of medical devices.
- EN 14971: 2004: The risk analysis for medical devices.



## **Decleration OF CONFORMiTY**

**HEGELi ORTHOPEDiCS** declares that the medical device(s) listed on the attached Appendix A conform(s) to the relevant provisions of the **MDD 93/42/EEC MEDiCAL WRITTEN DECREE COUNCiL** conditions.

**HEGELi ORTHOPEDiCS** confirms that no other application has been lodged with another notified body fort he same device related **QUALiTY MANAGEMENT SYSTEM iSO 9001:2008 and iSO 13485:2003**.

**HEGELi ORTHOPEDiCS** agrees to develop, implement and maintain a formally-recognised Quality Management System to ensure continued adequacy and efficacy.

**HEGELi ORTHOPEDiCS** agrees to inform the appointed Notified Body of any planned and unplanned substantial change to the Quality Management System.

**HEGELi ORTHOPEDiCS** agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Appendix A, including significant design change to the devices.

**Signed by the designated representative;**

**Name: Mr NURİ SADIK ERDEM**

**Title: GENERAL MANAGER**

**medimport**  
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No:87/A Esehler / İSTANBUL  
Atışalanı V.D. 613 072 4316

**Date: 01/04/2017**



## CORSETS

LUMBOSTAD CORSET-MP-525

LUMBOSTAD CORSET-MP-523

LUMBOSACRAL CORSET-MP-535

LUMBOSACRAL CORSET-MP-533

DORSOLOMBAR CORSET-MP-537

ABDOMINAL CORSET-MP-553

STERNUM CORSET – MP-555

POSTUREX CORSET-MP-557

PREGNANCY CORSET-MP-559

THORACIC – LUMBO – SACRAL – ORTHOSIS - TLSO – MP-545

## HANDWRIST SUPPORTS

BASIC THUMB SPLINT-WITH AN ALUMINUM THUMB SUPPORT- MP-623

THUMB SPLINT-WITH VELCRO ADJUSTMENT- MP-623

HAND SPLINT-SHORT-MP-625

HAND SPLINT-LONG-MP-627

THUMB AND HAND SPLINT-WITH ALUMINUM SUPPORT ADJUSTMENT-MP-629

## ARMSLINGS

ARMSLING WITH EXTRA BELT-GABARDINE-BASIC-MP-325

ARMSLING WITH EXTRA BELT-LUXURY-MP-323

CLAVICULA BANDAGE-MP-343

VELPAU BANDAGE-MP-329

PADDED ARMSLING-30 DEGREES-MP-3333

PADDED ARMSLING-45&60 DEGREES-MP-335

ARMSLING-BASIC-MESH FABRIC-MP-327

## NEOPRENE GROUP

KNEE SUPPORT-PATELLAR SUPPORT-NP-322

KNEE SUPPORT-PATELLAR SUPPORT-NP-324

KNEE SUPPORT-PATELLAR&LIGAMENT SUPPORT-SHORT-NP-326

KNEE SUPPORT-PATELLAR&LIGAMENT SUPPORT-LONG-NP-328

KNEE SUPPORT-PATELLAR&LIGAMENT HINGED SUPPORT-NP-332

KNEE SUPPORT-PATELLAR&LIGAMENT HINGED SUPPORT-OPEN UPPER PART-NP-334

KNEE SUPPORT-PATELLAR&LIGAMENT HINGED SUPPORT-FULL OPEN FRONT – NP-330

KNEE SUPPORT-PATELLAR&LIGAMENT HINGED SUPPORT-FULL OPEN FRONT – NP-334

KNEE SUPPORT-PADDED PATELLAR PROTECTION – NP-338

KNEE SUPPORT-CRUCIAL LIGAMENT SUPPORT – NP-340

PATELLAR TENDON BANDAGE-NP-342

PATELLAR TENDON SUPPORT-NP-344

ANKLE SUPPORT-BASIC-WITH VELCRO CLOSURE-NP-622

ANKLE SUPPORT-MALLEOLAR PAD PROTECTION-WITH VELCRO CLOSURE-NP-624

ANKLE STABILIZER-WITH VELCRO CLOSURE-NP-626

FIGURE OF 8 BANDAGE-NP-628

TENNIS PLAYER'S ELBOW SUPPORT-NP-522

PADDED ELBOW SUPPORT-NP-524

EPICONDYLITIS BANDAGE-NP-526



SIMPLE NEOPRENE WRIST SUPPORT-NP-822
NEOPRENE WRIST SUPPORT-NP-936
NEOPRENE BANDAGE WRIST SUPPORT-NP-826
NEOPRENE THUMB SUPPORT-NP-938
NEOPRENE THUMB AND WRIST SUPPORT -ARH2605
NEOPRENE LUMBOSACRAL CORSET-ARC2201
NEOPRENE LUMBOSACRAL CORSET WITH BELT-ARC2202
NEOPRENE ABDOMINAL CORSET-NP-422
NEOPRENE SHOULDER SUPPORT-NP-928
NEOPRENE THIGH SUPPORT-NP-722
NEOPRENE CALF SUPPORT-NP-724
NEOPRENE HIP SUPPORT-NP-750
NEOPRENE SPORTMAN'S SHORTS-NP-900
<b>THERMOPLASTIC GROUP</b>
THERMOPLASTIC THUMB SPLINT-OP-303
THERMOPLASTIC ANTISPASTICITY SPLINT-OP-306
THERMOPLASTIC WRIST SPLINT-OP-304
THERMOPLASTIC THUMB AND WRIST SPLINT-OP-305
THERMOPLASTIC DYNAMIC HAND SPLINT-OP-307
THERMOPLASTIC AFO-REFLEX-OP-302
THERMOPLASTIC AFO-RESTING-OP-301
<b>CERVICAL COLLARS</b>
BASIC NECK COLLAR-SPONGE-WITH AN ADDITIONAL COVER-OP-102
CLASSICAL NELSON COLLAR-PLASTIZOTE-OP-101
CLASSICAL PHILADELPHIA COLLAR-OP-103
CLASSICAL PHILEDELPHIA COLLAR-WITH A TRACHEAL HOLE-OP-104
THERMOPLASTIC RIGID CERVICAL COLLAR - WITH A COVER-OP-107
WIRE-FRAME CERVICAL COLLAR-OP-109
<b>OTHER PRODUCTS</b>
PLASTIC ANKLE SUPPORT-AIRCAST-MP-853
PLASTIC ANKLE SUPPORT-SPONGE PADDED-MP-855
FREJKA PILLOW-OP-192
ANGLE ADJUSTABLE KNEE ORTHOSIS-MP-723
ANGLE ADJUSTABLE KNEE ORTHOSIS-NEOPRENE-NP-346
ROM WALKER- ACHILLES TENTON ORTHOSIS-MP-863
ROM WALKER-ANGLE ADJUSTABLE ANKLE ORTHOSIS-MP-865
BUTONIER SPLINT-OP-705
BASEBALL SPLINT-OP-702
SILICONE METATARSAL PAD-OP-171
HALLUX VALGUS NIGHT SPLINT-MP-653
HALLUX VALGUS DAY SPLINT-MP-654
JEWETT HYPEREXTENSION CORSET-MP-543
ANGLE ADJUSTABLE ELBOW CONTACTURE SPLINT-SOFT-MP-113
HERNIA SUPPORT-SINGLE-MP-923
HERNIA SUPPORT-DOUBLE-MP-925



ARM"ALL"- ONE SIZE KNEE SUPPORT - HINGED KNEE SUPPORT -NP-934
ARM"ALL"- ONE SIZE UNIVERSAL WRIST SUPPORT-NP-936
ARM"ALL"- ONE SIZE UNIVERSAL THUMB SUPPORT-MP-623
ARM"ALL"- ONE SIZE UNIVERSAL WRIST AND THUMB SUPPORT-NP-938
ARM"ALL"- ONE SIZE ANKLE SUPPORT - NP-644
ARM"ALL"- ONE SIZE ANKLE SUPPORT-SILICONE SUPPORT- NP-642
ARM"ALL"- ONE SIZE ANKLE SUPPORT -LIGAMENT SUPPORT - NP-646
<b>ARM'O KNIT-KNITTED BANDAGES</b>
ARM'O KNIT - KNITTED PATELLAR SUPPORT-OP-611
ARM'O KNIT - KNITTED PATELLA AND LIGAMENT SUPPORT SUPPORT-OP-601
<b>ARMAID-WALKING AIDS</b>
ELBOW CRUTCHES-ALUMUNUM-PAIR-OP-902
CRUTCHES-ALUMINUM-PAIR-OP-921
WALKER-ALUMINUM-OP-901A
REVERSE WALKER-IRON PIPE-OP-903
WALKING STICK-CANE-ALUMINUM-OP-923
TRIPOD WALKING STICK-IRON PIPE-OP-911
QUADRIPOD WALKING STICK-IRON PIPE-OP-912
<b>ARM'OMODE-TOILET COMMODE CHAIRS</b>
COMMODE CHAIR-EKO-OP-931

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