

## **DECLARATION OF CONFORMITY EC**

### No. 50/D/EN/3

MANUFACTURER REH4MAT

**PRODUCT** TORSO SUPPORT

LIST OF ITEMS IN APPENDIX NO.1

marked with the CE sign is Class I medical device, of rule 1, consistent with the requirements of the **Council Directive 93/42/EEC of 14 June 1993 on medical devices** and the **Law of 20 May 2010 on medical devices** as amended. Conformity assessment was carried out on the basis of the **VII Council Directive 93/42/EEC**.

The product meets the requirements of the harmonized standards

**PN-EN 1041+A1:2013-12** Information supplied by the manufacturer of medical devices

#### PN-EN 12182:2012

Assistive products for persons with disability. General requirements and test methods

#### PN-EN ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

#### PN-EN ISO 14971:2012

Medical devices. Application of risk management to medical device

#### PN - EN ISO 15223-1:2017-02

Medical devices Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY OF THE MANUFACTURER REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, Poland





Głogów Małopolski 27.09.2019



# **APPENDIX NO. 1**

To declaration of conformity no. 50/D/EN/3

#### **PRODUCT:** TORSO SUPPORT

#### **MODELS:**

TORSO SUPPORT AM-PCS TORSO SUPPORT MS-T-01 TORSO SUPPORT MS-T-02 AM-TX-09 TORSO SUPPORT AM-TX-03 TORSO SUPPORT AM-TX-02 TORSO SUPPORT AM-TX-01 TORSO SUPPORT AM-DPZ TORSO SUPPORT AM-DPB TORSO SUPPORT AM-GJ-03 TORSO SUPPORT AM-GJ-02 TORSO SUPPORT EB-LK-03 TORSO SUPPORT AM-DOL TORSO SUPPORT AM-PES-04 TORSO SUPPORT AM-PZM TORSO SUPPORT AM-PZD TORSO SUPPORT AM-PTM TORSO SUPPORT AM-PTD TORSO SUPPORT AM-OPBW TORSO SUPPORT AM-OPBN TORSO SUPPORT AM-ZPBW TORSO SUPPORT AM-ZPBN TORSO SUPPORT AM-APBW TORSO SUPPORT AM-APBN TORSO SUPPORT AM-PC TORSO SUPPORT AM-PP TORSO SUPPORT AM-1PP TORSO SUPPORT AM-2PP TORSO SUPPORT AM-PPB TORSO SUPPORT AM-PLBW TORSO SUPPORT AM-PLBN TORSO SUPPORT AM-WSK TORSO SUPPORT AM-WSP-08



TORSO SUPPORT EB-LK-02 TORSO SUPPORT AM-GI-01 TORSO SUPPORT AM-OK. TORSO SUPPORT AM-OM TORSO SUPPORT AM-PES-05 TORSO SUPPORT AM-PES-06 **TORSO SUPPORT AM-PES-07 TORSO SUPPORT AM-PES-08** TORSO SUPPORT AM-PES-09 **TORSO SUPPORT OT-08 TORSO SUPPORT OT-09 TORSO SUPPORT OT-10** TORSO SUPPORT AM-PPB-01 **TORSO SUPPORT AM-PPB-02** TORSO SUPPORT AM-PC-02 TORSO SUPPORT AM-PCS-01 TORSO SUPPORT AM-PCS-02 TORSO SUPPORT AM-PZM-02 TORSO SUPPORT AM-PZM-01 TORSO SUPPORT STRADA TORSO SUPPORT EB-LK/TLSO TORSO SUPPORT EB-LK-01/TLSO TORSO SUPPORT AM-WSP-01/TLSO TORSO SUPPORT AM-WSP-03/TLSO TORSO SUPPORT AM-WSP-04/TLSO TORSO SUPPORT AM-WSP-07/TLSO TORSO SUPPORT OT-01 **TORSO SUPPORT OT-02 TORSO SUPPORT OT-03 TORSO SUPPORT OT-04 TORSO SUPPORT OT-05 TORSO SUPPORT OT-06 TORSO SUPPORT OT-07** 



Głogów Małopolski 27.09.2019



# **APPENDIX NO. 1**

To declaration of conformity no. 50/D/EN/3

## PRODUCT:

### TORSO SUPPORT

#### MODELS:

TORSO SUPPORT ENDURO-01 **TORSO SUPPORT ENDURO-02** TORSO SUPPORT AM-PC-01 AM-PES-03 AR-SO-01 AR-SO-01 AR-SO-02 AR-SO-03 EB-LK EB-LK-01 U-LK AS-LK-02 AR-WSP-01 AR-WSP-01/A AR-WSP-02 AR-WSP-02/B AR-WSP-03 TORSO SUPPORT AM-TX-04 TORSO SUPPORT AM-TX-05 TORSO SUPPORT AM-TX-06 TORSO SUPPORT AM-TX-07 TORSO SUPPORT AM-TX-08 TORSO SUPPORT AM-TX-09 TORSO SUPPORT AM-TX-10 TORSO SUPPORT AM-SO-07 TORSO SUPPORT AM-SO-08 TORSO SUPPORT AM-SO-09 TORSO SUPPORT AM-SO-10 **TORSO SUPPORT AM-SO-11** TORSO SUPPORT AM-SO-12 TORSO SUPPORT AM-SO-13

SO ISO 13485

TORSO SUPPORT AM-WSP-08 TORSO SUPPORT AM-WSP-09 TORSO SUPPORT AM-WSP-10 TORSO SUPPORT AM-WSP-11 TORSO SUPPORT AM-WSP-12 TORSO SUPPORT AM-WSP-13 TORSO SUPPORT AM-WSP-14 TORSO SUPPORT 4ARMY-TX-01 TORSO SUPPORT 4ARMY-TX-02 TORSO SUPPORT 4ARMY-TX-03 TORSO SUPPORT 4ARMY-TX-04 TORSO SUPPORT 4ARMY-TX-05 FIX-T-01

FIX-T-02 FIX-T-03 FIX-T-04 FIX-T-05 FIX-T-06 FIX-T-07 FIX-T-08 FIX-T-09 FIX-T-09 FIX-T-10



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