

DECLARATION OF CONFORMITY EC

No. 53/D/EN/4

MANUFACTURER

REH4MAT

PRODUCT

UPPER-EXTREMITY 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



re:mat **COMPANY OWNER**
Sławomir Wroński

APPENDIX NO. 1

To declaration of conformity no. 53/D/EN/4

PRODUCT:

UPPER-EXTREMITY SUPPORT

MODELS:

UPPER-EXTREMITY SUPPORT EB-L-01

UPPER-EXTREMITY SUPPORT EB-L-02

UPPER-EXTREMITY SUPPORT AS-L/F

AS-L/A

UPPER-EXTREMITY SUPPORT AM-TL-01

U-SL

EB-L

UPPER-EXTREMITY SUPPORT AM-SOB-01

UPPER-EXTREMITY SUPPORT AM-AO-KG-01

UPPER-EXTREMITY SUPPORT AM-AO-KG-02

UPPER-EXTREMITY SUPPORT AM-SOB-04

UPPER-EXTREMITY SUPPORT AM-SOB-05

UPPER-EXTREMITY SUPPORT AM-SOB-06

UPPER-EXTREMITY SUPPORT AM-SOB-07

UPPER-EXTREMITY SUPPORT AM-BX-01

UPPER-EXTREMITY SUPPORT AM-BX-02

UPPER-EXTREMITY SUPPORT AM-BX-03

UPPER-EXTREMITY SUPPORT MASTER-01

UPPER-EXTREMITY SUPPORT MASTER-02

UPPER-EXTREMITY SUPPORT MASTER-03

UPPER-EXTREMITY SUPPORT MASTER-04

UPPER-EXTREMITY SUPPORT OKG-01

UPPER-EXTREMITY SUPPORT OKG-02

UPPER-EXTREMITY SUPPORT OKG-03

UPPER-EXTREMITY SUPPORT OKG-04

UPPER-EXTREMITY SUPPORT OKG-05

AM-SOB

AM-SOB-02

AM-KOB

AS-B

AM-SOB-03

AM-SOB-03 NI

AM-SOB-03 PO

AM-SOB-03 CZ

AM-AO-KG

AM-KG-AM/1RE

UPPER-EXTREMITY SUPPORT 4ARMY-SN-01

UPPER-EXTREMITY SUPPORT 4ARMY-SN-02

UPPER-EXTREMITY SUPPORT 4ARMY-SN-03

UPPER-EXTREMITY SUPPORT 4ARMY-SN-04

UPPER-EXTREMITY SUPPORT 4ARMY-SN-05

UPPER-EXTREMITY SUPPORT 4ARMY-SN-06

UPPER-EXTREMITY SUPPORT 4ARMY-SN-07

UPPER-EXTREMITY SUPPORT 4ARMY-SN-08

UPPER-EXTREMITY SUPPORT 4ARMY-SN-09

UPPER-EXTREMITY SUPPORT 4ARMY-SN-10

UPPER-EXTREMITY SUPPORT 4ARMY-SN-11

UPPER-EXTREMITY SUPPORT 4ARMY-SN-12

UPPER-EXTREMITY SUPPORT 4ARMY-SN-13

UPPER-EXTREMITY SUPPORT 4ARMY-SN-14

UPPER-EXTREMITY SUPPORT 4ARMY-SN-15

UPPER-EXTREMITY SUPPORT 4ARMY-SL-01

UPPER-EXTREMITY SUPPORT 4ARMY-SL-02

UPPER-EXTREMITY SUPPORT 4ARMY-SL-03

UPPER-EXTREMITY SUPPORT 4ARMY-SL-04

UPPER-EXTREMITY SUPPORT 4ARMY-SL-05

UPPER-EXTREMITY SUPPORT 4ARMY-SL-06

UPPER-EXTREMITY SUPPORT 4ARMY-SL-07

UPPER-EXTREMITY SUPPORT 4ARMY-SL-08

UPPER-EXTREMITY SUPPORT 4ARMY-SL-09

UPPER-EXTREMITY SUPPORT 4ARMY-SL-10

UPPER-EXTREMITY SUPPORT 4ARMY-SL-11

UPPER-EXTREMITY SUPPORT 4ARMY-SL-12

UPPER-EXTREMITY SUPPORT 4ARMY-SL-13

UPPER-EXTREMITY SUPPORT 4ARMY-SL-14

UPPER-EXTREMITY SUPPORT 4ARMY-SL-15



APPENDIX NO. 1

To declaration of conformity no. 53/D/EN/4

PRODUCT:

UPPER-EXTREMITY SUPPORT

MODELS:

UPPER-EXTREMITY SUPPORT 4ARMY-B-01
UPPER-EXTREMITY SUPPORT 4ARMY-B-02
UPPER-EXTREMITY SUPPORT 4ARMY-B-03
UPPER-EXTREMITY SUPPORT 4ARMY-B-04
UPPER-EXTREMITY SUPPORT 4ARMY-B-05
UPPER-EXTREMITY SUPPORT 4ARMY-B-06
UPPER-EXTREMITY SUPPORT 4ARMY-B-07
UPPER-EXTREMITY SUPPORT 4ARMY-B-08
UPPER-EXTREMITY SUPPORT 4ARMY-B-09
UPPER-EXTREMITY SUPPORT 4ARMY-B-10
UPPER-EXTREMITY SUPPORT 4ARMY-B-11
UPPER-EXTREMITY SUPPORT 4ARMY-B-12
UPPER-EXTREMITY SUPPORT 4ARMY-B-13
UPPER-EXTREMITY SUPPORT 4ARMY-B-14
UPPER-EXTREMITY SUPPORT 4ARMY-B-15
UPPER-EXTREMITY SUPPORT OKG-06
UPPER-EXTREMITY SUPPORT OKG-07
UPPER-EXTREMITY SUPPORT OKG-08
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UPPER-EXTREMITY SUPPORT OKG-12
UPPER-EXTREMITY SUPPORT OKG-13
UPPER-EXTREMITY SUPPORT OKG-14
UPPER-EXTREMITY SUPPORT OKG-15
UPPER-EXTREMITY SUPPORT OKG-16
UPPER-EXTREMITY SUPPORT AM-OSN-U-16
UPPER-EXTREMITY SUPPORT AM-OSN-U-17
UPPER-EXTREMITY SUPPORT AM-OSN-U-18
UPPER-EXTREMITY SUPPORT AM-OSN-U-19
UPPER-EXTREMITY SUPPORT AM-OSN-U-20
UPPER-EXTREMITY SUPPORT AM-OSN-U-21
UPPER-EXTREMITY SUPPORT AM-OSN-U-22

UPPER-EXTREMITY SUPPORT AM-OSN-U-23
UPPER-EXTREMITY SUPPORT AM-OSN-U-24
UPPER-EXTREMITY SUPPORT AM-OSN-U-25
UPPER-EXTREMITY SUPPORT AM-OSN-L-11
UPPER-EXTREMITY SUPPORT AM-OSN-L-12
UPPER-EXTREMITY SUPPORT AM-OSN-L-13
UPPER-EXTREMITY SUPPORT AM-OSN-L-14
UPPER-EXTREMITY SUPPORT AM-OSN-L-15
FIX-KG-01
FIX-KG-02
FIX-KG-03
FIX-KG-04
FIX-KG-05
FIX-KG-06
FIX-KG-07
FIX-KG-08
FIX-KG-09
FIX-KG-10
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FIX-KG-19
FIX-KG-20



rehamat **COMPANY OWNER**
Sławomir Wroński