DECLARATION OF CONFORMITY
No. 53/D/EN/2

COMPANY
REH4MAT Sławomir Wroński
DECLARIES
that product:

UPPER-EXTREMITY SUPPORT

LIST OF ITEMS IN APPENDIX NO.1


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 COMPANY
REH4MAT Sławomir Wroński, 36-060 Głogów Małopolski, ul. Piaski 47, POLAND

Country of origin: POLAND

Company owner
Sławomir Wroński

Głogów Małopolski., 04.03.2019
APPENDIX NO. 1

TO DECLARATION OF CONFORMITY NO. 53/D/EN/2

PRODUCT:

UPPER-EXTREMITY SUPPORT

MODEL:

- 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-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
- 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 4ARMY-SN-01

Company owner:

Sławomir Wróński

Głogów Małopolski., 04.03.2019
APPENDIX NO. 1
TO DECLARATION OF CONFORMITY NO. 53/D/EN/2

PRODUCT:
UPPER-EXTREMITY SUPPORT

MODEL:
- UPPER-EXTREMITY SUPPORT OKG-07
- UPPER-EXTREMITY SUPPORT OKG-08
- UPPER-EXTREMITY SUPPORT OKG-09
- UPPER-EXTREMITY SUPPORT OKG-10
- UPPER-EXTREMITY SUPPORT OKG-11
- 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
- FIX-KG-11
- FIX-KG-12
- FIX-KG-13

Company owner
Sławomir Wroński
Głogów Małopolski, 04.03.2019