

DECLARATION OF CONFORMITY EC

No. 52/D/EN/5

MANUFACTURER

REH4MAT

PRODUCT

LOWER-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



reh:mat **COMPANY OWNER**
Sławomir Wronski

APPENDIX NO. 1

To declaration of conformity no. 52/D/EN/5

PRODUCT:

LOWER-EXTREMITY SUPPORT

MODELS:

LOWER-EXTREMITY SUPPORT AM-KDX-01
LOWER-EXTREMITY SUPPORT AM-KDX-02
LOWER-EXTREMITY SUPPORT AM-KDX-03
LOWER-EXTREMITY SUPPORT IB-SK/A
LOWER-EXTREMITY SUPPORT IB-SK/2
LOWER-EXTREMITY SUPPORT EB-SK/P
LOWER-EXTREMITY SUPPORT IB-SK/2RA
LOWER-EXTREMITY SUPPORT IB-SK/1R
LOWER-EXTREMITY SUPPORT IB-SKL/2RA
LOWER-EXTREMITY SUPPORT IB-SKL/1R
LOWER-EXTREMITY SUPPORT IB-SKL/3
LOWER-EXTREMITY SUPPORT ATTACK 1R
LOWER-EXTREMITY SUPPORT ATTACK 2RA
LOWER-EXTREMITY SUPPORT ZEUS
LOWER-EXTREMITY SUPPORT AM-TUD-KD-03
LOWER-EXTREMITY SUPPORT OKD-04
LOWER-EXTREMITY SUPPORT OKD-05
LOWER-EXTREMITY SUPPORT OKD-06
LOWER-EXTREMITY SUPPORT OKD-07
LOWER-EXTREMITY SUPPORT OKD-08
LOWER-EXTREMITY SUPPORT OKD-09
LOWER-EXTREMITY SUPPORT EB-SK/F
LOWER-EXTREMITY SUPPORT SPARTAN
LOWER-EXTREMITY SUPPORT OKD-Z/F
LOWER-EXTREMITY SUPPORT RAPTOR
LOWER-EXTREMITY SUPPORT ATOM
LOWER-EXTREMITY SUPPORT AM-OSK-O/1R-01
LOWER-EXTREMITY SUPPORT AM-OSK-Z/1R-01
LOWER-EXTREMITY SUPPORT AM-OSK-ZL/1R-01
LOWER-EXTREMITY SUPPORT AM-OSK-OL/1R-01
LOWER-EXTREMITY SUPPORT AM-KD-AM/1R-01
LOWER-EXTREMITY SUPPORT OKD-01
LOWER-EXTREMITY SUPPORT OKD-02
LOWER-EXTREMITY SUPPORT OKD-03
LOWER-EXTREMITY SUPPORT OKD-03/10
LOWER-EXTREMITY SUPPORT OKD-03/20
AM-OSK-ZL/3
AM-TUD-KD
AM-TUD-KD-02
AM-OSK-OL/3
EB-SK/A
AM-OSK-Z/S-A
AM-OSK-Z/J3
EB-SK/1R
EB-SKL/3
EB-SKL/2RA
EB-SKL/2RA-ACL
AM-KD-AM/1RE
AM-KD-AM/1RE-03
AM-KD-AM/2RA-03
AM-KD-AM/1RE-02
AM-KDS-AM/1RE
AS-SK/A
EB-SK/2
EB-SK/2RA
AM-OSK-Z/2RA-OR
AM-KD-AM/3-03
EB-SKL/1R
AM-OSK-ZL/2RA-ACL
AM-KD-AM/1RE-ACL
AM-KD-AM/2R-03
AM-KDS-AM/1RE-02
AM-KD-DAM/1R
AM-KD-AJ/2R
AM-KDS-AJ/2R
AM-KD-AM/1R



APPENDIX NO. 1

To declaration of conformity no. 52/D/EN/5

PRODUCT:

LOWER-EXTREMITY SUPPORT

MODELS:

AM-KD-AM/2R
AM-KD-AM/2R-02
AM-KDS-AM/2R
AM-KDS-AM/2R-02
AM-OSK-O/2R
AM-OSK-ZJ/2R
AM-OSK-Z/1
AM-OSK-O/1
AM-OSK-Z/2
AM-OSK-Z/2-02
AM-OSK-O/2
AM-OSK-ZJ/2
AM-OSK-ZL/1R
AM-OSK-OL/1R
AM-OSK-ZL/2R
AM-OSK-ZL/2R-02
AM-OSK-OL/2R
AM-OSK-ZL/2
AM-OSK-ZL/2-02
AM-OSK-OL/2
AM-OSK-Z/2RA
AM-OSK-Z/2RA-02
AM-OSK-O/2RA
AM-OSK-ZJ/2RA
AS-SKL/F
AM-OSK-ZL/2RA
AM-OSK-ZL/2RA-02
AM-OSK-OL/2RA
AM-OSK-OL/1
AM-OSK-ZL/1
LOWER-EXTREMITY SUPPORT AM-OP-03
LOWER-EXTREMITY SUPPORT AM-OP-04
LOWER-EXTREMITY SUPPORT AM-OP-05

LOWER-EXTREMITY SUPPORT AM-SB/1R
LOWER-EXTREMITY SUPPORT 4ARMY-SK-01
LOWER-EXTREMITY SUPPORT 4ARMY-SK-02
LOWER-EXTREMITY SUPPORT 4ARMY-SK-03
LOWER-EXTREMITY SUPPORT 4ARMY-SK-04
LOWER-EXTREMITY SUPPORT 4ARMY-SK-05
LOWER-EXTREMITY SUPPORT 4ARMY-SK-06
LOWER-EXTREMITY SUPPORT 4ARMY-SK-07
LOWER-EXTREMITY SUPPORT 4ARMY-SK-08
LOWER-EXTREMITY SUPPORT 4ARMY-SK-09
LOWER-EXTREMITY SUPPORT 4ARMY-SK-10
LOWER-EXTREMITY SUPPORT 4ARMY-SK-11
LOWER-EXTREMITY SUPPORT 4ARMY-SK-12
LOWER-EXTREMITY SUPPORT 4ARMY-SK-13
LOWER-EXTREMITY SUPPORT 4ARMY-SK-14
LOWER-EXTREMITY SUPPORT 4ARMY-SK-15
LOWER-EXTREMITY SUPPORT 4ARMY-SB-01
LOWER-EXTREMITY SUPPORT 4ARMY-SB-02
LOWER-EXTREMITY SUPPORT 4ARMY-SB-03
LOWER-EXTREMITY SUPPORT 4ARMY-SB-04
LOWER-EXTREMITY SUPPORT 4ARMY-SB-05
LOWER-EXTREMITY SUPPORT 4ARMY-U-01
LOWER-EXTREMITY SUPPORT 4ARMY-U-02
LOWER-EXTREMITY SUPPORT 4ARMY-U-03
LOWER-EXTREMITY SUPPORT 4ARMY-U-04
LOWER-EXTREMITY SUPPORT 4ARMY-U-05
LOWER-EXTREMITY SUPPORT 4ARMY-PU-01
LOWER-EXTREMITY SUPPORT 4ARMY-PU-02
LOWER-EXTREMITY SUPPORT 4ARMY-PU-03
LOWER-EXTREMITY SUPPORT 4ARMY-PU-04
LOWER-EXTREMITY SUPPORT 4ARMY-PU-05
LOWER-EXTREMITY SUPPORT 4ARMY-SS-01
LOWER-EXTREMITY SUPPORT 4ARMY-SS-02



APPENDIX NO. 1

To declaration of conformity no. 52/D/EN/5

PRODUCT:

LOWER-EXTREMITY SUPPORT

MODELS:

LOWER-EXTREMITY SUPPORT 4ARMY-SS-03
LOWER-EXTREMITY SUPPORT 4ARMY-SS-04
LOWER-EXTREMITY SUPPORT 4ARMY-SS-05
LOWER-EXTREMITY SUPPORT 4ARMY-SS-06
LOWER-EXTREMITY SUPPORT 4ARMY-SS-07
LOWER-EXTREMITY SUPPORT 4ARMY-SS-08
LOWER-EXTREMITY SUPPORT 4ARMY-SS-09
LOWER-EXTREMITY SUPPORT 4ARMY-SS-10
LOWER-EXTREMITY SUPPORT 4ARMY-SS-11
LOWER-EXTREMITY SUPPORT 4ARMY-SS-12
LOWER-EXTREMITY SUPPORT 4ARMY-SS-13
LOWER-EXTREMITY SUPPORT 4ARMY-SS-14
LOWER-EXTREMITY SUPPORT 4ARMY-SS-15
LOWER-EXTREMITY SUPPORT OKD-10
LOWER-EXTREMITY SUPPORT OKD-11
LOWER-EXTREMITY SUPPORT OKD-12
LOWER-EXTREMITY SUPPORT OKD-13
LOWER-EXTREMITY SUPPORT OKD-14
LOWER-EXTREMITY SUPPORT OKD-15
LOWER-EXTREMITY SUPPORT OKD-16
LOWER-EXTREMITY SUPPORT OKD-17
LOWER-EXTREMITY SUPPORT OKD-18
LOWER-EXTREMITY SUPPORT OKD-19
LOWER-EXTREMITY SUPPORT OKD-20
LOWER-EXTREMITY SUPPORT OKD-21
LOWER-EXTREMITY SUPPORT OKD-22
LOWER-EXTREMITY SUPPORT OKD-23
LOWER-EXTREMITY SUPPORT OKD-24
LOWER-EXTREMITY SUPPORT OKD-25
LOWER-EXTREMITY SUPPORT OKD-26
LOWER-EXTREMITY SUPPORT OKD-27
LOWER-EXTREMITY SUPPORT OKD-28
LOWER-EXTREMITY SUPPORT OKD-29

LOWER-EXTREMITY SUPPORT OKD-30
LOWER-EXTREMITY SUPPORT AM-OSS-21
LOWER-EXTREMITY SUPPORT AM-OSS-22
LOWER-EXTREMITY SUPPORT AM-OSS-23
LOWER-EXTREMITY SUPPORT AM-OSS-24
LOWER-EXTREMITY SUPPORT AM-OSS-25
LOWER-EXTREMITY SUPPORT AM-OSS-26
LOWER-EXTREMITY SUPPORT AM-OSS-27
LOWER-EXTREMITY SUPPORT AM-OSS-28
LOWER-EXTREMITY SUPPORT AM-OSS-29
LOWER-EXTREMITY SUPPORT AM-OSS-30
LOWER-EXTREMITY SUPPORT AM-SB-06
LOWER-EXTREMITY SUPPORT AM-SB-07
LOWER-EXTREMITY SUPPORT AM-SB-08
LOWER-EXTREMITY SUPPORT AM-SB-09
LOWER-EXTREMITY SUPPORT AM-SB-10
LOWER-EXTREMITY SUPPORT AS-PU-02
LOWER-EXTREMITY SUPPORT AS-PU-03
LOWER-EXTREMITY SUPPORT AS-PU-04
LOWER-EXTREMITY SUPPORT AS-PU-05
LOWER-EXTREMITY SUPPORT AS-PU-06
LOWER-EXTREMITY SUPPORT AS-U-01
LOWER-EXTREMITY SUPPORT AS-U-02
LOWER-EXTREMITY SUPPORT AS-U-03
LOWER-EXTREMITY SUPPORT AS-U-04
LOWER-EXTREMITY SUPPORT AS-U-05
LOWER-EXTREMITY SUPPORT AS-U-06
KNEE BRACE UNDERSLEEVE RW-ProFit
KNEE BRACE UNDERSLEEVE RW-Sport
KNEE BRACE UNDERSLEEVE RW-PowerFit
KNEE BRACE UNDERSLEEVE RW-01
KNEE BRACE UNDERSLEEVE RW-02
KNEE BRACE UNDERSLEEVE RW-03



APPENDIX NO. 1

To declaration of conformity no. 52/D/EN/5

PRODUCT:

LOWER-EXTREMITY SUPPORT

MODELS:

- FIX-KD-01
- FIX-KD-02
- FIX-KD-03
- FIX-KD-04
- FIX-KD-05
- FIX-KD-06
- FIX-KD-07
- FIX-KD-08
- FIX-KD-09
- FIX-KD-10
- FIX-KD-11
- FIX-KD-12
- FIX-KD-13
- FIX-KD-14
- FIX-KD-15
- FIX-KD-16
- FIX-KD-17
- FIX-KD-18
- FIX-KD-19
- FIX-KD-20

