

DECLARATION OF CONFORMITY EC

No. 45/D/EN/4

MANUFACTURER

REH4MAT

PRODUCT

WRIST ORTHOSIS

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



rehamat **COMPANY OWNER**

Sławomir Wronski

APPENDIX NO. 1

To declaration of conformity no. 45/D/4

PRODUCT:

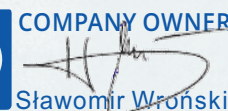
WRIST ORTHOSIS

MODELS:

WRIST ORTHOSIS AM-DON-01
WRIST ORTHOSIS AS-N-02
WRIST ORTHOSIS AM-OSN-U-03
WRIST ORTHOSIS AM-OSN-U-04
WRIST ORTHOSIS AM-OSN-U-05
WRIST ORTHOSIS AM-SN-LM
WRIST ORTHOSIS AM-OSN-L-03
WRIST ORTHOSIS AM-OSN-L-04
WRIST ORTHOSIS AM-SN-02
WRIST ORTHOSIS AS-NX-01
WRIST ORTHOSIS AS-NX-02
WRIST ORTHOSIS MS-N-01
WRIST ORTHOSIS MS-N-02
EB-N
EB-N-01
EB-N-02
U-SN
AM-OSN-U-01
AM-OSN-U-02
AM-OSN-L-01
AM-OSN-L-02
AM-SDP-K-01
AM-SDP-K-02
AM-SN-01
AS-N
AS-N-01

WRIST ORTHOSIS AM-OSN-U-06
WRIST ORTHOSIS AM-OSN-U-07
WRIST ORTHOSIS AM-OSN-U-08
WRIST ORTHOSIS AM-OSN-U-09
WRIST ORTHOSIS AM-OSN-U-10
WRIST ORTHOSIS AM-OSN-U-11
WRIST ORTHOSIS AM-OSN-U-12
WRIST ORTHOSIS AM-OSN-U-13
WRIST ORTHOSIS AM-OSN-U-14
WRIST ORTHOSIS AM-OSN-U-15
WRIST ORTHOSIS AM-OSN-L-05
WRIST ORTHOSIS AM-OSN-L-06
WRIST ORTHOSIS AM-OSN-L-07
WRIST ORTHOSIS AM-OSN-L-08
WRIST ORTHOSIS AM-OSN-L-09
WRIST ORTHOSIS AM-OSN-L-10



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