

DECLARATION OF CONFORMITY EC

No. 45/D/EN/6

THE REH4MAT MANUFACTURER DECLARES THAT

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 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Conformity assessment was carried out in accordance with the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council.

In order to demonstrate the safety and effectiveness of the medical device, the following standards were used to assess conformity:

PN-EN 1041+A1:2013-12

Information provided by the producer together with the medical product.

PN-EN 12182:2012

Assistive products for persons with disability - General requirements and research methods.

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.

PN-EN ISO 13485:2016

Medical products - Quality management systems - Requirements for law regulations aims.

PN-EN ISO 14971:2020

Medical devices - Application of risk management to medical devices.

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY
OF THE MANUFACTURER

REH4MAT, 36-060 Głogów Małopolski, ul. Piaski 47, Poland

SINGLE REGISTRATION NUMBER (SRN): PL-MF-000009271

reh4mat  COMPANY OWNER
Sławomir Wroński

APPENDIX NO. 1

To declaration of conformity no. 45/D/EN/6

PRODUCT: WRIST ORTHOSIS

MODELS:

WRIST ORTHOSIS AM-DON-01 (Basic UDI-DI 590128913AM-DON-01PJ);
WRIST ORTHOSIS AS-N-02 (Basic UDI-DI 590128913AS-N-0249);
WRIST ORTHOSIS AM-OSN-U-03 (Basic UDI-DI 590128913AM-OSN-U-033G);
WRIST ORTHOSIS AM-OSN-U-04 (Basic UDI-DI 590128913AM-OSN-U-043J);
WRIST ORTHOSIS AM-OSN-U-05 (Basic UDI-DI 590128913AM-OSN-U-053L);
WRIST ORTHOSIS AM-SN-LM (Basic UDI-DI 590128913AM-SN-LMKL);
WRIST ORTHOSIS AM-OSN-L-03 (Basic UDI-DI 590128913AM-OSN-L-03ZE);
WRIST ORTHOSIS AM-OSN-L-04 (Basic UDI-DI 590128913AM-OSN-L-04ZG);
WRIST ORTHOSIS AM-SN-02 (Basic UDI-DI 590128913AM-SN-02FF);
WRIST ORTHOSIS AS-NX-01 (Basic UDI-DI 590128913AS-NX-01K2);
WRIST ORTHOSIS AS-NX-02 (Basic UDI-DI 590128913AS-NX-02K4);
WRIST ORTHOSIS MS-N-01 (Basic UDI-DI 590128913MS-N-01AK);
WRIST ORTHOSIS MS-N-02 (Basic UDI-DI 590128913MS-N-02AM);
EB-N (Basic UDI-DI 590128913EB-N9S);
EB-N-01 (Basic UDI-DI 590128913EB-N-01XB);
EB-N-02 (Basic UDI-DI 590128913EB-N-02XD);
U-SN (Basic UDI-DI 590128913U-SNDM);
AM-OSN-U-01 (Basic UDI-DI 590743912AM-OSN-U-0198);
AM-OSN-U-02 (Basic UDI-DI 590743912AM-OSN-U-029A);
AM-OSN-L-01 (Basic UDI-DI 590743912AM-OSN-L-0179);
AM-OSN-L-02 (Basic UDI-DI 590743912AM-OSN-L-027B);
AM-SDP-K-01 (Basic UDI-DI 590743912AM-SDP-K-0129);
AM-SDP-K-02 (Basic UDI-DI 590743912AM-SDP-K-022B);
AM-SN-01 (Basic UDI-DI 590743912AM-SN-01KH);
AS-N (Basic UDI-DI 590128913AS-NBK);
AS-N-01 (Basic UDI-DI 590128913AS-N-0147);
WRIST ORTHOSIS AM-OSN-U-06 (Basic UDI-DI 590128913AM-OSN-U-063N);
WRIST ORTHOSIS AM-OSN-U-07 (Basic UDI-DI 590128913AM-OSN-U-073Q);
WRIST ORTHOSIS AM-OSN-U-08 (Basic UDI-DI 590128913AM-OSN-U-083S);
WRIST ORTHOSIS AM-OSN-U-09 (Basic UDI-DI 590128913AM-OSN-U-093U);
WRIST ORTHOSIS AM-OSN-U-10 (Basic UDI-DI 590128913AM-OSN-U-103D);
WRIST ORTHOSIS AM-OSN-U-11 (Basic UDI-DI 590128913AM-OSN-U-113F);
WRIST ORTHOSIS AM-OSN-U-12 (Basic UDI-DI 590128913AM-OSN-U-123H);
WRIST ORTHOSIS AM-OSN-U-13 (Basic UDI-DI 590128913AM-OSN-U-133K);
WRIST ORTHOSIS AM-OSN-U-14 (Basic UDI-DI 590128913AM-OSN-U-143M);

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To declaration of conformity no. 45/D/EN/6

PRODUCT: WRIST ORTHOSIS

MODELS:

WRIST ORTHOSIS AM-OSN-U-15 (Basic UDI-DI 590128913AM-OSN-U-153P);
WRIST ORTHOSIS AM-OSN-L-05 (Basic UDI-DI 590128913AM-OSN-L-05ZJ);
WRIST ORTHOSIS AM-OSN-L-06 (Basic UDI-DI 590128913AM-OSN-L-06ZL);
WRIST ORTHOSIS AM-OSN-L-07 (Basic UDI-DI 590128913AM-OSN-L-07ZN);
WRIST ORTHOSIS AM-OSN-L-08 (Basic UDI-DI 590128913AM-OSN-L-08ZQ);
WRIST ORTHOSIS AM-OSN-L-09 (Basic UDI-DI 590128913AM-OSN-L-09ZS);
WRIST ORTHOSIS AM-OSN-L-10 (Basic UDI-DI 590128913AM-OSN-L-10ZB).



reh4mat

COMPANY OWNER

Sławomir Wroński