

DECLARATION OF CONFORMITY EC

No. 50/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

PRODUCT: TORSO 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 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


COMPANY OWNER
Sławomir Wroński

APPENDIX NO. 1

To declaration of conformity no. 50/D/EN/5

PRODUCT: TORSO SUPPORT

MODELS:

TORSO SUPPORT AM-PCS (Basic UDI-DI 59009497AM-PCSK5);
TORSO SUPPORT MS-T-01 (Basic UDI-DI 59009497MS-T-01M6);
TORSO SUPPORT MS-T-02 (Basic UDI-DI 59009497MS-T-02M8);
AM-TX-09 (Basic UDI-DI 59009497AM-TX-09S9);
TORSO SUPPORT AM-TX-03 (Basic UDI-DI 59009497AM-TX-03RV);
TORSO SUPPORT AM-TX-02 (Basic UDI-DI 59009497AM-TX-02RT);
TORSO SUPPORT AM-TX-01 (Basic UDI-DI 59009497AM-TX-01RR);
TORSO SUPPORT AM-DPZ (Basic UDI-DI 59009497AM-DPZJW);
TORSO SUPPORT AM-DPB (Basic UDI-DI 59009497AM-DPBHE);
TORSO SUPPORT AM-GJ-03 (Basic UDI-DI 59009497AM-GJ-03JC);
TORSO SUPPORT AM-GJ-02 (Basic UDI-DI 59009497AM-GJ-02JA);
TORSO SUPPORT EB-LK-03 (Basic UDI-DI 59009497EB-LK-03GT);
TORSO SUPPORT AM-DOL (Basic UDI-DI 59009497AM-DOLHX);
TORSO SUPPORT AM-PES-04 (Basic UDI-DI 59009497AM-PES-0427);
TORSO SUPPORT AM-PZM (Basic UDI-DI 59009497AM-PZMLW);
TORSO SUPPORT AM-PZD (Basic UDI-DI 59009497AM-PZDLC);
TORSO SUPPORT AM-PTM (Basic UDI-DI 59009497AM-PTMLC);
TORSO SUPPORT AM-PTD (Basic UDI-DI 59009497AM-PTDKS);
TORSO SUPPORT AM-OPBW (Basic UDI-DI 59009497AM-OPBWLK);
TORSO SUPPORT AM-OPBN (Basic UDI-DI 59009497AM-OPBNKW);
TORSO SUPPORT AM-ZPBW (Basic UDI-DI 59009497AM-ZPBWNV);
TORSO SUPPORT AM-ZPBN (Basic UDI-DI 59009497AM-ZPBNNB);
TORSO SUPPORT AM-APBW (Basic UDI-DI 59009497AM-APBWHE);
TORSO SUPPORT AM-APBN (Basic UDI-DI 59009497AM-APBNGU);
TORSO SUPPORT AM-PC (Basic UDI-DI 59009497AM-PCKK);
TORSO SUPPORT AM-PP (Basic UDI-DI 59009497AM-PPLD);
TORSO SUPPORT AM-1PP (Basic UDI-DI 59009497AM-1PPFG);
TORSO SUPPORT AM-2PP (Basic UDI-DI 59009497AM-2PPFM);
TORSO SUPPORT AM-PPB (Basic UDI-DI 59009497AM-PPBKA);
TORSO SUPPORT AM-PLBW (Basic UDI-DI 59009497AM-PLBWL3);
TORSO SUPPORT AM-PLBN (Basic UDI-DI 59009497AM-PLBNKH);
TORSO SUPPORT AM-WSK (Basic UDI-DI 59009497AM-WSKM8);
TORSO SUPPORT AM-WSP-08 (Basic UDI-DI 59009497AM-WSP-089F);

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PRODUCT: TORSO SUPPORT

MODELS:

TORSO SUPPORT EB-LK-02 (Basic UDI-DI 59009497EB-LK-02GR);
TORSO SUPPORT AM-GJ-01 (Basic UDI-DI 59009497AM-GJ-01J8);
TORSO SUPPORT AM-OK (Basic UDI-DI 59009497AM-OKKY);
TORSO SUPPORT AM-OM (Basic UDI-DI 59009497AM-OML4);
TORSO SUPPORT AM-PES-05 (Basic UDI-DI 59009497AM-PES-0529);
TORSO SUPPORT AM-PES-06 (Basic UDI-DI 59009497AM-PES-062B);
TORSO SUPPORT AM-PES-07 (Basic UDI-DI 59009497AM-PES-072D);
TORSO SUPPORT AM-PES-08 (Basic UDI-DI 59009497AM-PES-082F);
TORSO SUPPORT AM-PES-09 (Basic UDI-DI 59009497AM-PES-092H);
TORSO SUPPORT OT-08 (Basic UDI-DI 59009497OT-08ND);
TORSO SUPPORT OT-09 (Basic UDI-DI 59009497OT-09NF);
TORSO SUPPORT OT-10 (Basic UDI-DI 59009497OT-10MY);
TORSO SUPPORT AM-PPB-01 (Basic UDI-DI 59009497AM-PPB-0123);
TORSO SUPPORT AM-PPB-02 (Basic UDI-DI 59009497AM-PPB-0225);
TORSO SUPPORT AM-PC-02 (Basic UDI-DI 59009497AM-PC-02KU);
TORSO SUPPORT AM-PCS-01 (Basic UDI-DI 59009497AM-PCS-01Z8);
TORSO SUPPORT AM-PCS-02 (Basic UDI-DI 59009497AM-PCS-02ZA);
TORSO SUPPORT AM-PZM-02 (Basic UDI-DI 59009497AM-PZM-027Y);
TORSO SUPPORT AM-PZM-01 (Basic UDI-DI 59009497AM-PZM-017W);
TORSO SUPPORT STRADA (Basic UDI-DI 59009497STRADAZC);
TORSO SUPPORT EB-LK/TLSO (Basic UDI-DI 59009497EB-LK/TLSOH4);
TORSO SUPPORT EB-LK-01/TLSO (Basic UDI-DI 59009497EB-LK-01/TLSONK);
TORSO SUPPORT AM-WSP-01/TLSO (Basic UDI-DI 59009497AM-WSP-01/TLSONL);
TORSO SUPPORT AM-WSP-03/TLSO (Basic UDI-DI 59009497AM-WSP-03/TLSOPE);
TORSO SUPPORT AM-WSP-04/TLSO (Basic UDI-DI 59009497AM-WSP-04/TLSOPT);
TORSO SUPPORT AM-WSP-07/TLSO (Basic UDI-DI 59009497AM-WSP-07/TLSOR2);
TORSO SUPPORT OT-01 (Basic UDI-DI 59009497OT-01X);
TORSO SUPPORT OT-02 (Basic UDI-DI 59009497OT-02MZ);
TORSO SUPPORT OT-03 (Basic UDI-DI 59009497OT-03N3);
TORSO SUPPORT OT-04 (Basic UDI-DI 59009497OT-04N5);
TORSO SUPPORT OT-05 (Basic UDI-DI 59009497OT-05N7);
TORSO SUPPORT OT-06 (Basic UDI-DI 59009497OT-06N9);
TORSO SUPPORT OT-07 (Basic UDI-DI 59009497OT-07NB);

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PRODUCT: TORSO SUPPORT

MODELS:

TORSO SUPPORT ENDURO-01 (Basic UDI-DI 59009497ENDURO-01NS);
TORSO SUPPORT ENDURO-02 (Basic UDI-DI 59009497ENDURO-02NU);
TORSO SUPPORT AM-PC-01 (Basic UDI-DI 59009497AM-PC-01KS);
AM-PES-03 (Basic UDI-DI 59009497AM-PES-0325);
AR-SO-01 (Basic UDI-DI 59009497AR-SO-01S4);
AR-SO-02 (Basic UDI-DI 59009497AR-SO-02S6);
AR-SO-03 (Basic UDI-DI 59009497AR-SO-03S8);
EB-LK (Basic UDI-DI 59009497EB-LKJN);
EB-LK-01 (Basic UDI-DI 59009497EB-LK-01GP);
U-LK (Basic UDI-DI 59009497U-LKRX);
AS-LK-02 (Basic UDI-DI 59009497AS-LK-02PE);
AR-WSP-01 (Basic UDI-DI 59009497AR-WSP-01BY);
AR-WSP-01/A (Basic UDI-DI 59009497AR-WSP-01/AC9);
AR-WSP-02 (Basic UDI-DI 59009497AR-WSP-02C2);
AR-WSP-02/B (Basic UDI-DI 59009497AR-WSP-02/BCG);
AR-WSP-03 (Basic UDI-DI 59009497AR-WSP-03C4);
TORSO SUPPORT AM-TX-04 (Basic UDI-DI 59009497AM-TX-04RX);
TORSO SUPPORT AM-TX-05 (Basic UDI-DI 59009497AM-TX-05RZ);
TORSO SUPPORT AM-TX-06 (Basic UDI-DI 59009497AM-TX-06S3);
TORSO SUPPORT AM-TX-07 (Basic UDI-DI 59009497AM-TX-07S5);
TORSO SUPPORT AM-TX-08 (Basic UDI-DI 59009497AM-TX-08S7);
TORSO SUPPORT AM-TX-09 (Basic UDI-DI 59009497AM-TX-09S9);
TORSO SUPPORT AM-TX-10 (Basic UDI-DI 59009497AM-TX-10RS);
TORSO SUPPORT AM-SO-07 (Basic UDI-DI 59009497AM-SO-07PT);
TORSO SUPPORT AM-SO-08 (Basic UDI-DI 59009497AM-SO-08PV);
TORSO SUPPORT AM-SO-09 (Basic UDI-DI 59009497AM-SO-09PX);
TORSO SUPPORT AM-SO-10 (Basic UDI-DI 59009497AM-SO-10PG);
TORSO SUPPORT AM-SO-11 (Basic UDI-DI 59009497AM-SO-11PJ);
TORSO SUPPORT AM-SO-12 (Basic UDI-DI 59009497AM-SO-12PL);
TORSO SUPPORT AM-SO-13 (Basic UDI-DI 59009497AM-SO-13PN);
TORSO SUPPORT AM-WSP-08 (Basic UDI-DI 59009497AM-WSP-089F);
TORSO SUPPORT AM-WSP-09 (Basic UDI-DI 59009497AM-WSP-099H);
TORSO SUPPORT AM-WSP-10 (Basic UDI-DI 59009497AM-WSP-1092);
TORSO SUPPORT AM-WSP-11 (Basic UDI-DI 59009497AM-WSP-1194);

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PRODUCT: TORSO SUPPORT

MODELS:

TORSO SUPPORT AM-WSP-12 (Basic UDI-DI 59009497AM-WSP-1296);
TORSO SUPPORT AM-WSP-13 (Basic UDI-DI 59009497AM-WSP-1398);
TORSO SUPPORT AM-WSP-14 (Basic UDI-DI 59009497AM-WSP-149A);
TORSO SUPPORT 4ARMY-TX-01 (Basic UDI-DI 590094974ARMY-TX-01EN);
TORSO SUPPORT 4ARMY-TX-02 (Basic UDI-DI 590094974ARMY-TX-02EQ);
TORSO SUPPORT 4ARMY-TX-03 (Basic UDI-DI 590094974ARMY-TX-03ES);
TORSO SUPPORT 4ARMY-TX-04 (Basic UDI-DI 590094974ARMY-TX-04EU);
TORSO SUPPORT 4ARMY-TX-05 (Basic UDI-DI 590094974ARMY-TX-05EW);
FIX-T-01 (Basic UDI-DI 59009497FIX-T-01VQ);
FIX-T-02 (Basic UDI-DI 59009497FIX-T-02VS);
FIX-T-03 (Basic UDI-DI 59009497FIX-T-03VU);
FIX-T-04 (Basic UDI-DI 59009497FIX-T-04VW);
FIX-T-05 (Basic UDI-DI 59009497FIX-T-05VY);
FIX-T-06 (Basic UDI-DI 59009497FIX-T-06W2);
FIX-T-07 (Basic UDI-DI 59009497FIX-T-07W4);
FIX-T-08 (Basic UDI-DI 59009497FIX-T-08W6);
FIX-T-09 (Basic UDI-DI 59009497FIX-T-09W8);
FIX-T-10 (Basic UDI-DI 59009497FIX-T-10VR);
MS-T-01/LSO (Basic UDI-DI 59009497MS-T-01/LSOY2);
MS-T-02/LSO (Basic UDI-DI 59009497MS-T-02/LSOYD);
AM-OK/CCA (Basic UDI-DI 59009497AM-WSP-089F);
AS-LK-02/CCA (Basic UDI-DI 59009497AS-LK-02/CCA6K);
AR-SO-01/BEŹ (Basic UDI-DI 59009497AR-SO-01/BEZE9);
MS-T-01/LSO PLUS (Basic UDI-DI 59009497MS-T-01/LSO+JD);
MS-T-01/TLSO PLUS (Basic UDI-DI 59009497MS-T-01/TLSO+HM);
MS-T-02/TLSO PLUS (Basic UDI-DI 59009497MS-T-02/TLSO+J6);
MS-T-01/TLSO (Basic UDI-DI 59009497MS-T-01/TLSOML);
MS-T-02/TLSO (Basic UDI-DI 59009497MS-T-02/TLSOZ);
AM-PZM-02/M (Basic UDI-DI 59009497AM-PZM-02/M6Y);