

DECLARATION OF CONFORMITY EC

No. 81/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. 81/D/EN/5

PRODUCT: TORSO SUPPORT

MODELS:

- | | |
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| OT-11 (Basic UDI-DI 59009497OT-11N2); | OT-44 (Basic UDI-DI 59009497OT-44NH); |
| OT-12 (Basic UDI-DI 59009497OT-12N4); | OT-45 (Basic UDI-DI 59009497OT-45NK); |
| OT-13 (Basic UDI-DI 59009497OT-13N6); | OT-46 (Basic UDI-DI 59009497OT-46NM); |
| OT-14 (Basic UDI-DI 59009497OT-14N8); | OT-47 (Basic UDI-DI 59009497OT-47NP); |
| OT-15 (Basic UDI-DI 59009497OT-15NA); | OT-48 (Basic UDI-DI 59009497OT-48NR); |
| OT-16 (Basic UDI-DI 59009497OT-16NC); | OT-49 (Basic UDI-DI 59009497OT-49NT); |
| OT-17 (Basic UDI-DI 59009497OT-17NE); | OT-50 (Basic UDI-DI 59009497OT-50NC); |
| OT-18 (Basic UDI-DI 59009497OT-18NG); | OT-51 (Basic UDI-DI 59009497OT-51NE); |
| OT-19 (Basic UDI-DI 59009497OT-19NJ); | OT-52 (Basic UDI-DI 59009497OT-52NG); |
| OT-20 (Basic UDI-DI 59009497OT-20N3); | OT-53 (Basic UDI-DI 59009497OT-53NJ); |
| OT-21 (Basic UDI-DI 59009497OT-21N5); | OT-54 (Basic UDI-DI 59009497OT-54NL); |
| OT-22 (Basic UDI-DI 59009497OT-22N7); | OT-55 (Basic UDI-DI 59009497OT-55NN); |
| OT-23 (Basic UDI-DI 59009497OT-23N9); | OT-56 (Basic UDI-DI 59009497OT-56NQ); |
| OT-24 (Basic UDI-DI 59009497OT-24NB); | OT-57 (Basic UDI-DI 59009497OT-57NS); |
| OT-25 (Basic UDI-DI 59009497OT-25ND); | OT-58 (Basic UDI-DI 59009497OT-58NU); |
| OT-26 (Basic UDI-DI 59009497OT-26NF); | OT-59 (Basic UDI-DI 59009497OT-59NW); |
| OT-27 (Basic UDI-DI 59009497OT-27NH); | OT-60 (Basic UDI-DI 59009497OT-60NF); |
| OT-28 (Basic UDI-DI 59009497OT-28NK); | OT-61 (Basic UDI-DI 59009497OT-61NH); |
| OT-29 (Basic UDI-DI 59009497OT-29NM); | OT-62 (Basic UDI-DI 59009497OT-62NK); |
| OT-30 (Basic UDI-DI 59009497OT-30N6); | OT-63 (Basic UDI-DI 59009497OT-63NM); |
| OT-31 (Basic UDI-DI 59009497OT-31N8); | OT-64 (Basic UDI-DI 59009497OT-64NP); |
| OT-32 (Basic UDI-DI 59009497OT-32NA); | OT-65 (Basic UDI-DI 59009497OT-65NR); |
| OT-33 (Basic UDI-DI 59009497OT-33NC); | OT-66 (Basic UDI-DI 59009497OT-66NT); |
| OT-34 (Basic UDI-DI 59009497OT-34NE); | OT-67 (Basic UDI-DI 59009497OT-67NV); |
| OT-35 (Basic UDI-DI 59009497OT-35NG); | OT-68 (Basic UDI-DI 59009497OT-68NX); |
| OT-36 (Basic UDI-DI 59009497OT-36NJ); | OT-69 (Basic UDI-DI 59009497OT-69NZ); |
| OT-37 (Basic UDI-DI 59009497OT-37NL); | OT-70 (Basic UDI-DI 59009497OT-70NJ); |
| OT-38 (Basic UDI-DI 59009497OT-38NN); | OT-71 (Basic UDI-DI 59009497OT-71NL); |
| OT-39 (Basic UDI-DI 59009497OT-39NQ); | OT-72 (Basic UDI-DI 59009497OT-72NN); |
| OT-40 (Basic UDI-DI 59009497OT-40N9); | OT-73 (Basic UDI-DI 59009497OT-73NQ); |
| OT-41 (Basic UDI-DI 59009497OT-41NB); | OT-74 (Basic UDI-DI 59009497OT-74NS); |
| OT-42 (Basic UDI-DI 59009497OT-42ND); | OT-75 (Basic UDI-DI 59009497OT-75NU); |
| OT-43 (Basic UDI-DI 59009497OT-43NF); | |


COMPANY OWNER
Sławomir Wroński

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PRODUCT: TORSO SUPPORT

MODELS:

- OT-76 (Basic UDI-DI 59009497OT-76NW);
- OT-77 (Basic UDI-DI 59009497OT-77NY);
- OT-78 (Basic UDI-DI 59009497OT-78P2);
- OT-79 (Basic UDI-DI 59009497OT-79P4);
- OT-80 (Basic UDI-DI 59009497OT-80NM);
- OT-81 (Basic UDI-DI 59009497OT-81NP);
- OT-82 (Basic UDI-DI 59009497OT-82NR);
- OT-83 (Basic UDI-DI 59009497OT-83NT);
- OT-84 (Basic UDI-DI 59009497OT-84NV);
- OT-85 (Basic UDI-DI 59009497OT-85NX);
- OT-86 (Basic UDI-DI 59009497OT-86NZ);
- OT-87 (Basic UDI-DI 59009497OT-87P3);
- OT-88 (Basic UDI-DI 59009497OT-88P5);
- OT-89 (Basic UDI-DI 59009497OT-89P7);
- OT-90 (Basic UDI-DI 59009497OT-90NQ).


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