

DECLARATION OF CONFORMITY EC

No. 98/D/EN/2

THE REH4MAT MANUFACTURER DECLARES THAT

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 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


COMPANY OWNER
Sławomir Wroński

APPENDIX NO. 1

To declaration of conformity no. 98/D/EN/2

PRODUCT: LOWER-EXTREMITY SUPPORT

MODELS:

FIX-KD-21	(Basic UDI-DI 59009497FIX-KD-21AP);
FIX-KD-22	(Basic UDI-DI 59009497FIX-KD-22AR);
FIX-KD-23	(Basic UDI-DI 59009497FIX-KD-23AT);
FIX-KD-24	(Basic UDI-DI 59009497FIX-KD-24AV);
FIX-KD-25	(Basic UDI-DI 59009497FIX-KD-25AX);
FIX-KD-26	(Basic UDI-DI 59009497FIX-KD-26AZ);
FIX-KD-27	(Basic UDI-DI 59009497FIX-KD-27B3);
FIX-KD-28	(Basic UDI-DI 59009497FIX-KD-28B5);
FIX-KD-29	(Basic UDI-DI 59009497FIX-KD-29B7);
FIX-KD-30	(Basic UDI-DI 59009497FIX-KD-30AQ);
FIX-KD-31	(Basic UDI-DI 59009497FIX-KD-31AS);
FIX-KD-32	(Basic UDI-DI 59009497FIX-KD-32AU);
FIX-KD-33	(Basic UDI-DI 59009497FIX-KD-33AW);
FIX-KD-34	(Basic UDI-DI 59009497FIX-KD-34AY);
FIX-KD-35	(Basic UDI-DI 59009497FIX-KD-35B2);
FIX-KD-36	(Basic UDI-DI 59009497FIX-KD-36B4);
FIX-KD-37	(Basic UDI-DI 59009497FIX-KD-37B6);
FIX-KD-38	(Basic UDI-DI 59009497FIX-KD-38B8);
FIX-KD-39	(Basic UDI-DI 59009497FIX-KD-39BA);
FIX-KD-40	(Basic UDI-DI 59009497FIX-KD-40AT);
FIX-KD-41	(Basic UDI-DI 59009497FIX-KD-41AV);
FIX-KD-42	(Basic UDI-DI 59009497FIX-KD-42AX);
FIX-KD-43	(Basic UDI-DI 59009497FIX-KD-43AZ);
FIX-KD-44	(Basic UDI-DI 59009497FIX-KD-44B3);
FIX-KD-45	(Basic UDI-DI 59009497FIX-KD-45B5);
FIX-KD-46	(Basic UDI-DI 59009497FIX-KD-46B7);
FIX-KD-47	(Basic UDI-DI 59009497FIX-KD-47B9);
FIX-KD-48	(Basic UDI-DI 59009497FIX-KD-48BB);
FIX-KD-49	(Basic UDI-DI 59009497FIX-KD-49BD);
FIX-KD-50	(Basic UDI-DI 59009497FIX-KD-50AW);


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