

DECLARATION OF CONFORMITY EC

No. 71/D/EN/5

THE REH4MAT MANUFACTURER DECLARES THAT

PRODUCT: LOWER BACK BRACE

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

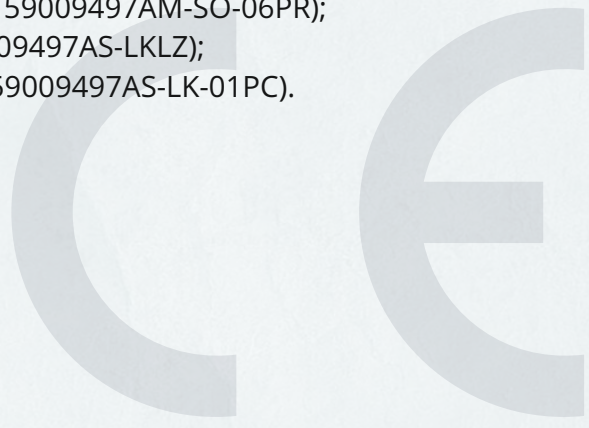
APPENDIX NO. 1

To declaration of conformity no. 71/D/EN/5

PRODUCT: LOWER BACK BRACE

MODELS:

AM-SO-01 (Basic UDI-DI 59009497AM-SO-01PF);
AM-SO-02 (Basic UDI-DI 59009497AM-SO-02PH);
AM-SO-03 (Basic UDI-DI 59009497AM-SO-03PK);
AM-SO-04 (Basic UDI-DI 59009497AM-SO-04PM);
AM-SO-05 (Basic UDI-DI 59009497AM-SO-05PP);
AM-SO-06 (Basic UDI-DI 59009497AM-SO-06PR);
AS-LK (Basic UDI-DI 59009497AS-LKLZ);
AS-LK-01 (Basic UDI-DI 59009497AS-LK-01PC).



reimat  COMPANY OWNER

Sławomir Wroński