

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: SPINAL ORTHOSIS
LIST OF ITEMS IN APPENDIX NO. 1

of intended use: stabilizes and off loads the thoraco-lumbo-sacral spine. It is used in case of lower back pain and orthopaedic neurological and rheumatologic conditions.

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.

The above product to which this declaration applies complies with Regulation (EU) 2017/745 of the European Parliament and of the Council.

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 ISO 20417:2021-10

Medical devices -- Information to be supplied by the manufacturer.

PN-EN ISO 21856:2023-01

Assistive products -- General requirements and test methods.

PN-EN ISO 15223-1:2022-01

Medical devices -- Symbols to be used with information to be supplied by the manufacturer
-- Part 1: General requirements.

PN-EN ISO 13485:2016-04

Medical devices -- Quality management systems -- Requirements for regulatory purposes.

PN-EN ISO 14971:2020-05

Medical devices -- Application of risk management to medical devices.



President of the board

Sławomir Wroński

THE ABOVE CERTIFICATE WAS ISSUED ON SOLE RESPONSIBILITY OF
REH4MAT LTD., 35-301 RZESZÓW, UL. ZENITOWA 5A,
COUNTRY OF ORIGIN: POLAND, SRN: PL-MF-000009271

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APPENDIX NO. 1

TO DECLARATION OF CONFORMITY

PRODUCT - SPINAL ORTHOSIS
MODELS:

AM-WSP-01
AM-WSP-02
AM-WSP-03
AM-WSP-04
AM-WSP-05
AM-WSP-06
AM-WSP-07

(Basic UDI-DI 59009497AM-WSP-018Z),
(Basic UDI-DI 59009497AM-WSP-0293),
(Basic UDI-DI 59009497AM-WSP-0395),
(Basic UDI-DI 59009497AM-WSP-0497),
(Basic UDI-DI 59009497AM-WSP-0599),
(Basic UDI-DI 59009497AM-WSP-069B),
(Basic UDI-DI 59009497AM-WSP-079D).



President of the board

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