DECLARATION

OF EC CONFORMITY

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

of intended use: provides stabilization and relieving the trunk and spine. The support provides compression and stabilization of thoracic, lumbar and sacral spine. It is used in case of rheumatic, neurological and orthopedic disorders and injuries.

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.

REH4MAT
MANUFACTURER OF MODERN ORTHOPAEDIC BRACES

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

APPENDIX NO. 1
TO DECLARATION OF CONFORMITY

PRODUCT - TORSO SUPPORT
MODELS:

AM-PES-10	(Basic UDI-DI 59009497AM-PES-1022),
AM-PES-11	(Basic UDI-DI 59009497AM-PES-1124),
AM-PES-12	(Basic UDI-DI 59009497AM-PES-1226),
AM-PES-13	(Basic UDI-DI 59009497AM-PES-1328),
AM-PES-14	(Basic UDI-DI 59009497AM-PES-142A),
AM-PES-15	(Basic UDI-DI 59009497AM-PES-152C),
AM-SO-14	(Basic UDI-DI 59009497AM-SO-14PQ),
AM-SO-15	(Basic UDI-DI 59009497AM-SO-15PS),
AM-SO-16	(Basic UDI-DI 59009497AM-SO-16PU),
AM-SO-17	(Basic UDI-DI 59009497AM-SO-17PW),
AM-SO-18	(Basic UDI-DI 59009497AM-SO-18PY),
AM-SO-19	(Basic UDI-DI 59009497AM-SO-19Q2),
AM-SO-20	(Basic UDI-DI 59009497AM-SO-20PK),
AM-WSP-15	(Basic UDI DI 59009497AM-WSP-159C),
AM-WSP-16	(Basic UDI DI 59009497AM-WSP-169E),
AM-WSP-17	(Basic UDI DI 59009497AM-WSP-179G),
AM-WSP-18	(Basic UDI DI 59009497AM-WSP-189J),
AM-WSP-19	(Basic UDI DI 59009497AM-WSP-199L),
AM-WSP-20	(Basic UDI DI 59009497AM-WSP-2095).

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