

DECLARATION

OF EC CONFORMITY

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

of intended use: to stabilize fingers. It is used when tendons and joints of fingers are damaged, malformed or while chronic joints instability, after surgical interventions or after removing a cast.

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
A handwritten signature in black ink, appearing to read 'Sławomir Wroński'.
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 - FINGER SPLINT
MODELS:

FINGER SPLINT AM-D-01
FINGER SPLINT AM-D-02
FINGER SPLINT AM-D-03
FINGER SPLINT AM-D-04
FINGER SPLINT AM-D-05
FINGER SPLINT AM-SP-01
FINGER SPLINT AM-SP-02
FINGER SPLINT AM-SP-03
FINGER SPLINT AM-SP-04
FINGER SPLINT AM-SP-05

(Basic UDI-DI 590128913AM-D-01XG),
(Basic UDI-DI 590128913AM-D-02XJ),
(Basic UDI-DI 590128913AM-D-03XL),
(Basic UDI-DI 590128913AM-D-04XN),
(Basic UDI-DI 590128913AM-D-05XQ),
(Basic UDI-DI 590128913AM-SP-01FT),
(Basic UDI-DI 590128913AM-SP-02FV),
(Basic UDI-DI 590128913AM-SP-03FX),
(Basic UDI-DI 590128913AM-SP-04F Z),
(Basic UDI-DI 590128913AM-SP-05G3).



President of the board
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Sławomir Wroński

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