

DECLARATION

OF EC CONFORMITY

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

of intended use: provides stabilization and relief of upper limb. It is used in case of painful syndrome and/or injuries of upper extremity.

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 - UPPER EXTREMITY SUPPORT
MODELS:

UPPER - EXTREMITY SUPPORT EB-L-01	(Basic UDI-DI 59009497EB-L-0189),
UPPER - EXTREMITY SUPPORT EB-L-02	(Basic UDI-DI 59009497EB-L-028B),
UPPER - EXTREMITY SUPPORT AS-L/F	(Basic UDI-DI59009497AS-L/FHY),
AS-L/A	(Basic UDI-DI59009497AS-L/AHN),
UPPER - EXTREMITY SUPPORT AM-TL-01	(Basic UDI-DI59009497AM-TL-01P5),
U-SL	(Basic UDI-DI59009497U-SLSN),
EB-L	(Basic UDI-DI59009497EB-LNT),
UPPER - EXTREMITY SUPPORT AM-SOB-01	(Basic UDI-DI59009497AM-SOB-012X),
UPPER - EXTREMITY SUPPORT AM-AO-KG-01	(Basic UDI-DI59009497AM-AO-KG-01PX),
UPPER - EXTREMITY SUPPORT AM-AO-KG-02	(Basic UDI-DI59009497AM-AO-KG-02PZ),
UPPER - EXTREMITY SUPPORT AM-SOB-04	(Basic UDI-DI59009497AM-SOB-0435),
UPPER - EXTREMITY SUPPORT AM-SOB-05	(Basic UDI-DI59009497AM-SOB-0537),
UPPER - EXTREMITY SUPPORT AM-SOB-06	(Basic UDI-DI59009497AM-SOB-0639),
UPPER - EXTREMITY SUPPORT AM-SOB-07	(Basic UDI-DI59009497AM-SOB-073B),
UPPER - EXTREMITY SUPPORT AM-BX-01	(Basic UDI-DI59009497AM-BX-01KK),
UPPER - EXTREMITY SUPPORT AM-BX-02	(Basic UDI-DI59009497AM-BX-02KM),
UPPER - EXTREMITY SUPPORT AM-BX-03	(Basic UDI-DI59009497AM-BX-03KP),
UPPER - EXTREMITY SUPPORT MASTER-01	(Basic UDI-DI59009497MASTER-01QK),
UPPER - EXTREMITY SUPPORT MASTER-02	(Basic UDI-DI59009497MASTER-02QM),
UPPER - EXTREMITY SUPPORT MASTER-03	(Basic UDI-DI59009497MASTER-03QP),
UPPER - EXTREMITY SUPPORT MASTER-04	(Basic UDI-DI59009497MASTER-04QR),
UPPER - EXTREMITY SUPPORT OKG-01	(Basic UDI-DI59009497OKG-01LJ),
UPPER - EXTREMITY SUPPORT OKG-02	(Basic UDI-DI59009497OKG-02LL),
UPPER - EXTREMITY SUPPORT OKG-03	(Basic UDI-DI59009497OKG-03LN),
UPPER - EXTREMITY SUPPORT OKG-04	(Basic UDI-DI59009497OKG-04LQ),
UPPER - EXTREMITY SUPPORT OKG-05	(Basic UDI-DI59009497OKG-05LS),
AM-SOB	(Basic UDI-DI59009497AM-SOBKN),
AM-SOB-02	(Basic UDI-DI59009497AM-SOB-022Z),
AM-KOB	(Basic UDI-DI59009497AM-KOBJE),
AS-B	(Basic UDI-DI59009497AS-BPY),
AM-SOB-03	(Basic UDI-DI59009497AM-SOB-0333),
AM-SOB-03 CZ	(Basic UDI-DI59009497AM-SOB-03CZZ4),
AM-SOB-03 PO	(Basic UDI-DI59009497AM-SOB-03POZM),
AM-SOB-03 NI	(Basic UDI-DI59009497AM-SOB-03NIZ3),
AM-AO-KG	(Basic UDI-DI59009497AM-AO-KGLZ),
AM-KG-AM/1RE	(Basic UDI-DI59009497AM-KG-AM/1REC4),



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Sławomir Wroński

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COUNTRY OF ORIGIN: POLAND, SRN: PL-MF-000009271

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TO DECLARATION OF CONFORMITY

PRODUCT - UPPER EXTREMITY SUPPORT
MODELS:

UPPER - EXTREMITY SUPPORT 4ARMY-SN-01	(Basic UDI-DI 590094974ARMY-SN-01C5),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-02	(Basic UDI-DI 590094974ARMY-SN-02C7),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-03	(Basic UDI-DI 590094974ARMY-SN-03C9),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-04	(Basic UDI-DI 590094974ARMY-SN-04CB),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-05	(Basic UDI-DI 590094974ARMY-SN-05CD),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-06	(Basic UDI-DI 590094974ARMY-SN-06CF),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-07	(Basic UDI-DI 590094974ARMY-SN-07CH),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-08	(Basic UDI-DI 590094974ARMY-SN-08CK),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-09	(Basic UDI-DI 590094974ARMY-SN-09CM),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-10	(Basic UDI-DI 590094974ARMY-SN-10C6),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-11	(Basic UDI-DI 590094974ARMY-SN-11C8),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-12	(Basic UDI-DI 590094974ARMY-SN-12CA),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-13	(Basic UDI-DI 590094974ARMY-SN-13CC),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-14	(Basic UDI-DI 590094974ARMY-SN-14CE),
UPPER - EXTREMITY SUPPORT 4ARMY-SN-15	(Basic UDI-DI 590094974ARMY-SN-15CG),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-01	(Basic UDI-DI 590094974ARMY-SL-01BP),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-02	(Basic UDI-DI 590094974ARMY-SL-02BR),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-03	(Basic UDI-DI 590094974ARMY-SL-03BT),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-04	(Basic UDI-DI 590094974ARMY-SL-04BV),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-05	(Basic UDI-DI 590094974ARMY-SL-05BX),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-06	(Basic UDI-DI 590094974ARMY-SL-06BZ),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-07	(Basic UDI-DI 590094974ARMY-SL-07C3),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-08	(Basic UDI-DI 590094974ARMY-SL-08C5),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-09	(Basic UDI-DI 590094974ARMY-SL-09C7),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-10	(Basic UDI-DI 590094974ARMY-SL-10BQ),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-11	(Basic UDI-DI 590094974ARMY-SL-11BS),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-12	(Basic UDI-DI 590094974ARMY-SL-12BU),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-13	(Basic UDI-DI 590094974ARMY-SL-13BW),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-14	(Basic UDI-DI 590094974ARMY-SL-14BY),
UPPER - EXTREMITY SUPPORT 4ARMY-SL-15	(Basic UDI-DI 590094974ARMY-SL-15C2),
UPPER - EXTREMITY SUPPORT 4ARMY-B-01	(Basic UDI-DI 590094974ARMY-B-01F6),
UPPER - EXTREMITY SUPPORT 4ARMY-B-02	(Basic UDI-DI 590094974ARMY-B-02F8),
UPPER - EXTREMITY SUPPORT 4ARMY-B-03	(Basic UDI-DI 590094974ARMY-B-03FA),
UPPER - EXTREMITY SUPPORT 4ARMY-B-04	(Basic UDI-DI 590094974ARMY-B-04FC),
UPPER - EXTREMITY SUPPORT 4ARMY-B-05	(Basic UDI-DI 590094974ARMY-B-05FE),
UPPER - EXTREMITY SUPPORT 4ARMY-B-06	(Basic UDI-DI 590094974ARMY-B-06FG),
UPPER - EXTREMITY SUPPORT 4ARMY-B-07	(Basic UDI-DI 590094974ARMY-B-07FJ),
UPPER - EXTREMITY SUPPORT 4ARMY-B-08	(Basic UDI-DI 590094974ARMY-B-08FL),



President of the board

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MODELS:

UPPER - EXTREMITY SUPPORT 4ARMY-B-09	(Basic UDI-DI 590094974ARMY-B-09FN),
UPPER - EXTREMITY SUPPORT 4ARMY-B-10	(Basic UDI-DI 590094974ARMY-B-10F7),
UPPER - EXTREMITY SUPPORT 4ARMY-B-11	(Basic UDI-DI 590094974ARMY-B-11F9),
UPPER - EXTREMITY SUPPORT 4ARMY-B-12	(Basic UDI-DI 590094974ARMY-B-12FB),
UPPER - EXTREMITY SUPPORT 4ARMY-B-13	(Basic UDI-DI 590094974ARMY-B-13FD),
UPPER - EXTREMITY SUPPORT 4ARMY-B-14	(Basic UDI-DI 590094974ARMY-B-14FF),
UPPER - EXTREMITY SUPPORT 4ARMY-B-15	(Basic UDI-DI 590094974ARMY-B-15FH),
UPPER - EXTREMITY SUPPORT OKG-06	(Basic UDI-DI 59009497OKG-06LU),
UPPER - EXTREMITY SUPPORT OKG-07	(Basic UDI-DI 59009497OKG-07LW),
UPPER - EXTREMITY SUPPORT OKG-08	(Basic UDI-DI 59009497OKG-08LY),
UPPER - EXTREMITY SUPPORT OKG-09	(Basic UDI-DI 59009497OKG-09M2),
UPPER - EXTREMITY SUPPORT OKG-10	(Basic UDI-DI 59009497OKG-10LK),
UPPER - EXTREMITY SUPPORT OKG-11	(Basic UDI-DI 59009497OKG-11LM),
UPPER - EXTREMITY SUPPORT OKG-12	(Basic UDI-DI 59009497OKG-12LP),
UPPER - EXTREMITY SUPPORT OKG-13	(Basic UDI-DI 59009497OKG-13LR),
UPPER - EXTREMITY SUPPORT OKG-14	(Basic UDI-DI 59009497OKG-14LT),
UPPER - EXTREMITY SUPPORT OKG-15	(Basic UDI-DI 59009497OKG-15LV),
UPPER - EXTREMITY SUPPORT OKG-16	(Basic UDI-DI 59009497OKG-16LX),
UPPER - EXTREMITY SUPPORT AM-OSN-U-16	(Basic UDI-DI 59009497AM-OSN-U-168Y),
UPPER - EXTREMITY SUPPORT AM-OSN-U-17	(Basic UDI-DI 59009497AM-OSN-U-1792),
UPPER - EXTREMITY SUPPORT AM-OSN-U-18	(Basic UDI-DI 59009497AM-OSN-U-1894),
UPPER - EXTREMITY SUPPORT AM-OSN-U-19	(Basic UDI-DI 59009497AM-OSN-U-1996),
UPPER - EXTREMITY SUPPORT AM-OSN-U-20	(Basic UDI-DI 59009497AM-OSN-U-208P),
UPPER - EXTREMITY SUPPORT AM-OSN-U-21	(Basic UDI-DI 59009497AM-OSN-U-218R),
UPPER - EXTREMITY SUPPORT AM-OSN-U-22	(Basic UDI-DI 59009497AM-OSN-U-228T),
UPPER - EXTREMITY SUPPORT AM-OSN-U-23	(Basic UDI-DI 59009497AM-OSN-U-238V),
UPPER - EXTREMITY SUPPORT AM-OSN-U-24	(Basic UDI-DI 59009497AM-OSN-U-248X),
UPPER - EXTREMITY SUPPORT AM-OSN-U-25	(Basic UDI-DI 59009497AM-OSN-U-258Z),
UPPER - EXTREMITY SUPPORT AM-OSN-L-11	(Basic UDI-DI 59009497AM-OSN-L-116P),
UPPER - EXTREMITY SUPPORT AM-OSN-L-12	(Basic UDI-DI 59009497AM-OSN-L-126R),
UPPER - EXTREMITY SUPPORT AM-OSN-L-13	(Basic UDI-DI 59009497AM-OSN-L-136T),
UPPER - EXTREMITY SUPPORT AM-OSN-L-14	(Basic UDI-DI 59009497AM-OSN-L-146V),
UPPER - EXTREMITY SUPPORT AM-OSN-L-15	(Basic UDI-DI 59009497AM-OSN-L-156X),



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PRODUCT - UPPER EXTREMITY SUPPORT
MODELS:

FIX-KG-01	(Basic UDI-DI 59009497FIX-KG-01B6),
FIX-KG-02	(Basic UDI-DI 59009497FIX-KG-02B8),
FIX-KG-03	(Basic UDI-DI 59009497FIX-KG-03BA),
FIX-KG-04	(Basic UDI-DI 59009497FIX-KG-04BC),
FIX-KG-05	(Basic UDI-DI 59009497FIX-KG-05BE),
FIX-KG-06	(Basic UDI-DI 59009497FIX-KG-06BG),
FIX-KG-07	(Basic UDI-DI 59009497FIX-KG-07BJ),
FIX-KG-08	(Basic UDI-DI 59009497FIX-KG-08BL),
FIX-KG-09	(Basic UDI-DI 59009497FIX-KG-09BN),
FIX-KG-10	(Basic UDI-DI 59009497FIX-KG-10B7),
FIX-KG-11	(Basic UDI-DI 59009497FIX-KG-11B9),
FIX-KG-12	(Basic UDI-DI 59009497FIX-KG-12BB),
FIX-KG-13	(Basic UDI-DI 59009497FIX-KG-13BD),
FIX-KG-14	(Basic UDI-DI 59009497FIX-KG-14BF),
FIX-KG-15	(Basic UDI-DI 59009497FIX-KG-15BH),
FIX-KG-16	(Basic UDI-DI 59009497FIX-KG-16BK),
FIX-KG-17	(Basic UDI-DI 59009497FIX-KG-17BM),
FIX-KG-18	(Basic UDI-DI 59009497FIX-KG-18BP),
FIX-KG-19	(Basic UDI-DI 59009497FIX-KG-19BR),
FIX-KG-20	(Basic UDI-DI 59009497FIX-KG-20BA).



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