

DECLARATION

OF EC CONFORMITY

MANUFACTURER REH4MAT LTD. DECLARE, THAT
PRODUCT: UPPER - EXTREMITY SUPPORT
MODELS: AM-AO-KG-02 CLEVER 2 ROTATOR (Basic UDI-DI 59009497AM-AO-KG-01C2RM4),
AM-AO-KG-02 CLEVER 2 ABDUCTOR (Basic UDI-DI 59009497AM-AO-KG-01C2AL2),
AM-OSN-U-01/CCA (Basic UDI-DI 59009497AM-OSN-U-01/CCAF6),
AM-SOB-03/AIR (Basic UDI-DI 59009497AM-SOB-03/AIR8D),

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

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

Rzeszów, 27.03.2024 No. 95/D/EN/6