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Warsaw, 25.05.2021

EU DECLARATION OF CONFORMITY MEDICAL DEVICE

Irena Groniecka - Tarnkowska, Andrzej Tarnkowski „ANTAR" Spółka Jawna
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acting as Manufacturer registered in Eudamed, SRN number: PL-MF-000001583, according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, herein declare that medical devices:

ROM ELBOW ORTHOSIS: AT53009

The Basic UDI-DI: 59015714AT530094D

have been classifed as medical device class I, rule 1.

Intended purpose: the brace provides superior stabilization of the elbow joint. Adjusting the angle of flexion and extension provides control movement of the joint, with adjustable range of flexion and extension. Recommended for the treatment of sprains, fractures and after treatment with the gypsum
We herein declare that the medical devices are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. The assessment of conformity has been proceeded in compliance with the requirements of the above Regulation.

Applied standards:
PN-EN ISO 9001 (current edition)
PN-EN ISO 13485 (current edition)
PN-EN ISO 15223 (current edition)
PN-EN ISO 14971 (current edition)
PN-EN ISO 10993 (current edition)

The EU declaration of conformity is issued under the sole responsibility of the Manufacturer.

Andrzej Tarnkowski

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co-owner
independent reprezentation of the company
based on the Company Register

CE