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Warsaw, 20.10.2023

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:

THUMB ORTHOSIS: AT53065

The Basic UDI-DI: 59015714AT530654P

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

Intended purpose: Thumb brace, ensuring immobilization and abduction of the thumb and stiffening of the wrist. Made of light, soft, breathable material. Reduces pain associated with joint overload, rheumatism, degeneration and shock. Recommended as a means of protecting and soothing the effects of injuries and degenerations in the case of thumb cracks. The orthosis also reduces rheumatic pain.

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: 2015
PN-EN ISO 13485: 2016
PN-EN ISO 15223-1: 2021
PN-EN ISO 14971: 2020
PN-EN ISO 10993-1: 2021

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

Andrzej Tarnkowski

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

CE