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Warsaw, 27.06.2022

EU DECLARATION OF CONFORMITY MEDICAL DEVICE

Irena Groniecka - Tarnkowska, Andrzej Tarnkowski „ANTAR" Spółka Jawna
ul. Zawiślańska 43
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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:

KNEE ORTHOSIS: AT53051

The Basic UDI-DI: 59015714AT530514C

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

Intended purpose: Knee brace is designed for use in the event of instability of the knee joint, allowing for faster treatment of injuries, relieving the patella and preventing its movements.

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

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

CE