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Warsaw, 25.05.2021

EU DECLARATION OF CONFORMITY MEDICAL DEVICE

Irena Groniecka - Tarnkowska, Andrzej Tarnkowski „ANTAR" Spółka Jawna
ul. Zawiślańska 43
03-068 Warszawa

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:

ANKLE ORTHOSIS: AT04201

The Basic UDI-DI: 59015714AT042012P

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

Intended purpose: orthosis is used to stiffen the ankle. It allows you to move the foot. The interior is covered with a soft cloth. Is used in sprains ankle, instability and during postoperative rehabilitation

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.

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Andrzej Tarnkowski

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

CE