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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:

RIGID SHIN/ANKLE ORTHOSIS: AT53005, AT53006

The Basic UDI-DI: not issued

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

Intended purpose: stiff and plastic knee-ankle orthosis is designed to treat bone fractures, soft tissue, Achilles tendonitis and ankle sprains. The orthosis provides optimal and controlled operation of the ankle.

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.

„ANTAR" Sp. Jawna
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Andrzej Tarnkowski

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

CE