



Warsaw, 17.08.2023

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:

KNEE ORTHOSIS: AT53063

The Basic UDI-DI: 59015714AT530634K

have been classified 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

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

