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Warsaw, 25.05.2021

# 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:

**ROM KNEE ORTHOSIS: AT53034**

The Basic UDI-DI: not issued

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

Intended purpose: knee brace with adjustable range of motion stabilizes the knee joint and the whole limb. It provides optimum, controlled the operation of the joint. Recommended for diseases of the meniscus, ligaments, instability of the knee joint sprains

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