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Warsaw, 20.03.2023

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:

LUMBO-SACRAL ORTHOSIS: AT53056_AT53057_AT53058

The Basic UDI-DI: 59015714AT530564N, 59015714AT530574Q, 59015714AT530584S

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

Intended purpose: The spine brace is designed for maximum limitation and/or complete immobilization of the lumbar and sacral spine.

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.

Andrzej Tarnkowski

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

CE