

Warsaw, 18.10.2021

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:

REHABILITATION PILLOW: AT51413, AT51414, AT51429

The Basic UDI-DI: 59015714AT514134A, 59015714AT514144C, 59015714AT514294R

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

Intended purpose: pillow is designed for exercise and sitting. It is used during exercise of muscles, tendons and joints, especially during the rehabilitation period, as well as for forcing the appropriate sitting position.

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 commany

based on the Company Register

CE



