

Warsaw, 25.05.2021

EU DECLARATION OF CONFORMITY MEDICAL DEVICE

*Irena Groniecka - Tarnkowska, Andrzej Tarnkowski „ANTAR” Spółka Jawna
ul. Zawisłańska 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:

ORTHOPAEDIC PILLOW: AT03007

The Basic UDI-DI: not issued

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

Intended purpose: orthopaedic pillow increases the comfort of sleeping and prevents the morning pain of head, neck and shoulders. The appropriate shape provides optimal support for head and neck, and as result relax muscles is possible, besides the back bone is in the appropriate anatomical shape.

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
Irena Groniecka-Tarnkowska
Andrzej Tarnkowski
ul. Zawisłańska 43, 03-068 Warszawa
NIP: 524-21-23-915, REGON 012853911
Fax: 22 518 36 30, 22 518 36 31
Tel.: 22 518 36 00

Andrzej Tarnkowski



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

