

Warsaw, 25.05.2021

## EU DECLARATION OF CONFORMITY MEDICAL DEVICE

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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:

### ORTHOPAEDIC PILLOW: AT03016, AT03017

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.

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Andrzej Tarnkowski



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

