

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:

### SITTING PILLOW „HEDGEHOG” TYPE WITH REMOVABLE INNER PART-FOAM: AT03010

The Basic UDI-DI: not issued

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

Intended purpose: sitting pillow prevents bedsores when patient must seat for long time, for example using a wheelchair. It is helpful during rehabilitation.

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.

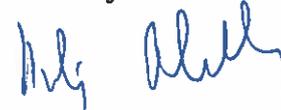
Applied standards:

- 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

