



EU DECLARATION OF CONFORMITY

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We hereby declare, under our sole responsibility, that the medical device covered by this declaration of conformity complies with all applicable requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

MEDICAL DEVICES:

AT05007 Waterproof Bedding Set – Basic UDI-DI : 59015714AT050072Y
AT05008 Waterproof Pillowcase – Basic UDI-DI : 59015714AT0500832
AT05009 Waterproof Duvet Cover – Basic UDI-DI : 59015714AT0500934
AT05010 Waterproof Bed Sheet – Basic UDI-DI : 59015714AT050102M

These products have been classified in accordance with Annex VIII of the MDR as a **Class I medical device, Rule 1**

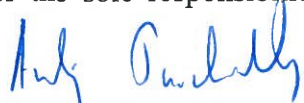
Intended purpose: Reusable medical devices intended to protect contact surfaces (pillows, duvets, mattresses) in healthcare settings. They serve as a physical barrier against liquids and contaminants, helping to reduce the risk of cross-contamination and infection.

The conformity assessment was carried out according to Annex II and III of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, with the application of the following standards:

PN-EN ISO 15223-1:2022
PN-EN 20417:2021
PN-EN ISO 14971:2020

PN-EN ISO 13485:2016
PN-EN ISO 10993-1:2021
PN-EN 62366-1:2015-07/A1:2021

The EU Declaration of Conformity has been issued under the sole responsibility of the manufacturer.


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

Warsaw, 30.10.2025



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