



Warsaw, 08.11.2024

## 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:

### **ABDOMINAL BELT: AT04608**

The Basic UDI-DI: 59015714AT046083R

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

Intended purpose: The abdominal belt is an orthopedic product that provides effective support for the abdominal area, back, and lumbar muscles. It can be used preventively to promote proper posture and protect the spine from excessive strain. The Velcro fastening allows for adjustable fitting. It is most commonly recommended for abdominal hernia, weakened abdominal muscles, post-partum recovery, after abdominal surgeries, and post-surgical procedures.

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: 2015

PN-EN ISO 13485: 2016

PN-EN ISO 15223-1: 2021

PN-EN ISO 14971: 2020

PN-EN ISO 10993-1: 2021

The EU declaration of conformity is issued under the sole responsibility of the Manufacturer.

Andrzej Tarnkowski

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

