ANTAR MEDICAL Spółka z ograniczoną odpowiedzialnością
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EU DECLARATION OF CONFORMITY

ANTAR MEDICAL Limited Liability Company
ul. Zawiślańska 43; 03-068 Warsaw, Poland
SRN: PL-MF-000001583

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 DEVICE: ROLLATOR: AT51003, AT51004, AT51005, AT51006

AT51003: Basic UDI-DI: 59015714AT510033K
AT51004: Basic UDI-DI: 59015714AT510043M
AT51005: Basic UDI-DI: 59015714AT510053P
AT51006: Basic UDI-DI: 59015714AT510063R

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

Intended purpose: rollators are designed for disable people, to enable them to move. User rests on the rollator, makes a step forward and then pushes the rollator.

The conformity assessment procedure has been carried out in accordance with Article 52(7) of Regulation (EU) 2017/745. The technical documentation has been drawn up in accordance with Annex II and Annex III of the Regulation, 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 11199-2:2005
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
President of the Management Board

Warsaw, 03.03.2026

CE

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