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Warsaw, 23.10.2023

EU DECLARATION OF CONFORMITY MEDICAL DEVICE

Irena Groniecka - Tarnkowska, Andrzej Tarnkowski „ANTAR" Spółka Jawna
ul. Zawiślańska 43
03-068 Warszawa

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:

ROLLATOR: AT51043, AT51044, AT51045, AT51046, AT51047

The Basic UDI-DI: 59015714AT510433X, 59015714AT510443Z, 59015714AT5104543, 59015714AT5104645, 59015714AT5104747

have been classifed as medical device class I, 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

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 reprezentation of the company
based on the Company Register

CE