



Warsaw, 27.09.2024

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:

ELECTRIC WHEELCHAIR: AT52332, AT52333

The Basic UDI-DI: 59015714AT523324G, 59015714AT523334J

have been classified as medical device class I, rule 13.

Intended purpose: Electric wheelchair is a vehicle structurally designed for the mobility of a disabled person. It is powered by a motor, the design of which limits the speed to walking pace.

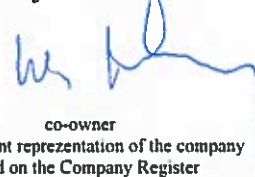
We herein declare that the medical devices are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. The assessment of conformity has been proceeded in compliance with the requirements of the above Regulation.

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

