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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: AT52325, AT52326, AT52327, AT52328, AT52329

The Basic UDI-DI: 59015714AT523254K, 59015714AT523264M, 59015714AT523274P, 59015714AT523284R, 59015714AT523294T

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

Intended purpose: Power wheelchair - a vehicle designed for the mobility of a disabled person. Powered by engine whose design limits the speed of movement to the speed of the pedestrian.

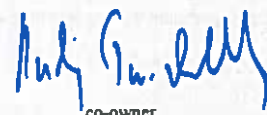
We herein declare that the medical devices are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. The assessment of conformity has been proceeded in compliance with the requirements of the above Regulation.

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

