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EU DECLARATION OF CONFORMITY

Irena Groniecka-Tarnkowska, Andrzej Tarnkowski "ANTAR" General Partnership
ul. Zawisłańska 43; 03-068 Warsaw, Poland
SRN: PL-MF-000001583

We hereby declare, under our sole responsibility, that the product covered by this declaration of conformity complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 [MDR].

Medical Device:

ELECTRIC WHEELCHAIR AT52325 The Basic UDI-DI: 59015714AT523254K
ELECTRIC WHEELCHAIR AT52326 The Basic UDI-DI: 59015714AT523264M
ELECTRIC WHEELCHAIR AT52327 The Basic UDI-DI: 59015714AT523274P
ELECTRIC WHEELCHAIR AT52328 The Basic UDI-DI: 59015714AT523284R
ELECTRIC WHEELCHAIR AT52329 The Basic UDI-DI: 59015714AT523294T

The device has been classified in accordance with Annex VIII of MDR as Class I, Rule 13.

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.

The conformity assessment was carried out according to Annex II + III of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, with the application of the following standards:

PN-EN ISO 15223-1:2022

PN-EN ISO 13485:2016

PN-EN 20417:2021

PN-EN ISO 10993-1:2021

PN-EN ISO 14971:2020

PN-EN 62366-1:2015-07/A1:2021

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

(Signature)
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