



Warsaw, 22.06.2022

## EU DECLARATION OF CONFORMITY MEDICAL DEVICE

*Irena Groniecka - Tarnowska, Andrzej Tarnowski „ANTAR” Spółka Jawna  
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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: AT52323**

The Basic UDI-DI: 59015714AT523234F

have been classified as medical device 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.

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.

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Andrzej Tarnowski

co-owner  
independent representation of the company  
based on the Company Register

