

Warsaw, 25.05.2021

EU DECLARATION OF CONFORMITY MEDICAL DEVICE

Irena Groniecka - Tarnkowska, Andrzej Tarnkowski "ANTAR" Spólka 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:

WHEELCHAIR: AT52302, AT52303

The Basic UDI-DI: not issued

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

Intended purpose: wheelchair - a vehicle designed for the mobility of a disabled person. Powered by muscle power, 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 (current edition)

PN-EN ISO 13485 (current edition)

PN-EN ISO 15223 (current edition)

PN-EN ISO 14971 (current edition)

PN-EN ISO 10993 (current edition)

The EU declaration of conformity is issued under the sole responsibility of the Manufacturer.

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

NIP: 524-21-23-915, REGON 012853911 Fax: 22 518 36 30, 22 518 36 31 Tel: 22 518 35 90

co-owner

independent reprezentation of the company based on the Company Register

Andrzej Tarnkowski

CE



