

Warsaw, 25.05.2021

## EU DECLARATION OF CONFORMITY MEDICAL DEVICE

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

**TOILET STOOL: AT51117** 

The Basic UDI-DI: not issued

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

Intended purpose: shower toilet stool is designed for disabled people or people with reduced possibility to enable or help people to take shower in a safe and comfortable way

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 Zawlślańska 43. 03-068 Warszav

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 26 99

Andrzei Tarnkowski

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





