



Warsaw, 27.06.2022

## 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:

### CONTROLLER FOR A WHEELCHAIR ASSISTANT AT52304

The Basic UDI-DI: 59015714STEROWNIKASYTEN27

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

Intended purpose: The controller is intended for an assistant, guardian of a person using an electric wheelchair. It is intended for use in an emergency when the user of the wheelchair is not able to operate the wheelchair with its own controller. The assistant can use the controller to set the wheelchair in motion without force.

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

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

