

Warsaw, 28.02.2022

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:

ELECTRIC WHEELCHAIR: AT52320, AT52321

The Basic UDI-DI: 59015714AT5232049, 59015714AT523214B

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

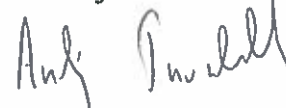
PN-EN ISO 14971: 2020

PN-EN ISO 10993-1: 2021

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

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



Zarejestrowana pod numerem KRS 0000086895 w Sądzie Rejonowym dla m. st. Warszawy w Warszawie,
XIII Wydział Gospodarczy Krajowego Rejestru Sądowego
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