EU DECLARATION OF CONFORMITY

Nr 01/05/2021

BLUMIL

Manufacturer's name: **BLUMIL Miłosz Krawczyk**

Manufacturer's address: **01-211 Warsaw, ul. Giełdowa 4B lok. 11**

We hereby declare that the EU declaration of conformity was issued under the sole responsibility of the manufacturer.

Product name:

Electric drive for wheelchairs

BLUMIL GO

Basic UDI-DI: 59044221686BLUMILGO7T

A class I medical device according to rule 13 in accordance with Annex VIII (point 6.5) of the Regulation of the European Parliament and of the Council (EU) 2017/745 of April 5, 2017 is compliant with this Regulation and the product conformity assessment was carried out in accordance with Annexes I, II and III of this Regulation.

Harmonized standards :

EN 1041 + A12013-12 - Information supplied by the manufacturer of medical device.
EN ISO 14971: 2012 - Medical devices - Application of risk management to medical devices
EN ISO 15223-1: 2017-02 - Medical devices-Symbols to be used with medical device labels, labelling and information provided with them - Part 1: General requirements

CE

Warsaw, 30.03.2021

M Krawczyk

(Owner Miłosz Krawczyk)