EU DECLARATION OF CONFORMITY

GTM MOBIL

Manufacturer: **GTM-Mobil M-T T. Walisiewicz Spółka Komandytowa**

Manufacturer's address: 03-195 Warszawa, ul. Dorodna 16, Poland

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

Intended use of the medical device: for individual transport of disabled people with spinal injury, cerebral palsy, limb damage.

Name of the medical device:

Manual wheelchair for active rehabilitation GTM MUSTANG

BASIC UDI-DI: 5904422167011

A class I medical device according to rule 1 complies with Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5 2017 on medical devices, and the conformity assessment of the device was carried out in accordance with Annexes I, II and III of this Regulation.

Harmonized standards:

PN-EN 12183:2014-07 - Manual wheelchairs - Requirements and test methods

PN-EN 1041:2010- Information provided by the manufacturer of medical device.

PN-EN ISO 14971:2020-05 - Medical devices - Application of risk management to medical devices Part 1: General requirements

PN-EN ISO 15223-1:2022-01 - Medical devices—Symbols to be used with information provided by the manufacturer - Part 1: General requirements

PN-EN ISO 9001:2015 - Quality management systems – Requirements

CE

Certificate AC 137QMS

Warsaw, 05.03.2023 r.

GTM-MOBIL M-T
T. Walisiewicz Sp. Komandytowa
ul. Dorodna 16, 03-195 Warszawa
REGON: 147177279, NIP: 524-27-68-598

.....
(Tomasz Walisiewicz – general partner)