

EU Declaration of Conformity

according to Medical Device Regulation 2017/745/EU

(Translation of original declaration)

Manufacturer / Distributor:

Kyburz-Switzerland AG, Solarweg, 8427 Freienstein, Switzerland

Authorised representative:

Kyburz GmbH, Turmstrasse 11, 78467 Konstanz, Germany

The manufacturer hereby declares under its sole responsibility that the electric tricycle

Kyburz MaXX2

UDI-DI: 111752880504

Product name: Kyburz MaXX2

Maximum speed: 15 km/h

Make: KYBURZ

Serial number: TCK7167D......

for use as a wheelchair class C with a maximum speed of 15 km/h

complies with all relevant provisions of the above-mentioned Regulation as Medical Device Class I.

The following harmonized standards were applied:

EN 12184:2014 Power wheelchairs and mobility scooters and associated charging equipment - Requirements and test methods (EN 12184:2014)

ISO 7176-14:2008 Propulsion and control systems for power wheelchairs and scooters (ISO 7176-14:2008)

ISO 7176-21:2009 Electromagnetic compatibility requirements and tests for power wheelchairs and mobility scooters (ISO 7176-21:2009)

EN 1021-2:2014 Furniture - Assessment of flammability of upholstered furniture (EN 1021-2:2014)

EN ISO 10993-5:2009 Biological evaluation of medical devices (ISO 10993-5:2009)

Freienstein, 21 May 2021

Martin Kyburz, Director