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EU DECLARATION OF CONFORMITY

No. 155030-6

Name and address of the manufacturer

TIMO d.o.o. Ajdovščina
Vipavska cesta 4i, 5270 Ajdovščina, Slovenia

We declare with all and sole responsibility that medical devices:

Shower trolley – electric

Model: 155030, 155030G, 155030C

basic UDI-DI: 383007646TI155030EL0000UB

serial number and year of manufacture are on the label of the device

is in conformity with Regulation 2017/745 on medical devices.

Medical device is classified as class I, classification rule 13 in accordance with Annex VIII of Regulation 2017/745 on medical devices. Conformity assessment was done according to Annex II and Annex III of Regulation 2017/745 on medical devices.

The following harmonized standards were used in the design and manufacture:

- **SIST EN ISO 14971:2012** - Medical devices - Application of risk management to medical devices
- **SIST EN 60601-1:2007** - Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- **SIST EN 60601-1-2:2015** - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- **SIST EN 60601-2-52:2010** - Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds
- **SIST EN ISO 10993-1:2010** - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Ajdovščina, 17.6.2020

Mojca Gruntar, director

Podjetje je vpisano v sodni register pri okrožnem sodišču v Novi Gorici, št. reg. Vpisa 1/01977/00, osnovni kapital 219.496,00 EUR