



TIMO d.o.o. Ajdovščina  
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MŠ: 5545935000  
BIC: KBMASI2X  
IBAN: SI56 0475 1000 0200 307

## EU DECLARATION OF CONFORMITY

No. 155030-8

### Name and address of the manufacturer

TIMO d.o.o. Ajdovščina  
Pod letališčem 5, 5270 Ajdovščina, Slovenia  
Single registration number: SI-MF-000029515

We declare with all and sole responsibility that medical devices:

**Shower trolley – electric**  
Model: **155030, 155030G, 155030C**  
basic UDI-DI: 383007646TI155030EL0000UB  
EMDN: Y093312

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 14971:2020/A11:2022** - Medical devices - Application of risk management to medical devices (EN ISO 14971:2019/A11:2021)
- **SIST EN 60601-1:2007/A2:2021** - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **SIST EN 60601-1-2:2015/A2:2021** - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- **SIST EN 60601-2-52:2010/A1:2015** - Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
- **SIST EN ISO 10993-1:2021** - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (EN ISO 10993-1:2018)

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

Ajdovščina, 22.May.2023

Mojca Gruntar, director