



TIMO d.o.o. Ajdovščina
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DDV ID: SI79828612
MŠ: 5545935000
BIC: KBMASI2X
IBAN: SI56 0475 1000 0200 307

EU DECLARATION OF CONFORMITY

No. 155000-8

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 – hydraulic
Model: **155000, 155010**
basic UDI-DI: 383007646TI155000HYD0004G
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 1 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 60601-2-52:2010/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