

Declaration of Conformity

Valid from: 2021-04-01

Manufacturer: TR Equipment AB

Rundelgatan 2 573 35 Tranås Sweden

SRN: SE-MF-000027486

Notified body: N/A

Statement: This declaration of conformity is issued under the sole responsibility of

TR Equipment AB

Basic UDI-DI: 7350016060206C

Product: TR Comfortline – bathing system

Product variants: TR Comfortline II, TR Ecoline II Fixed height

Presumption of compliance SS-EN 1717, SS-EN 60601-1:2005

Classification: MDR Class I

MDR Annex: VIII

We hereby declare that above mentioned devices comply with the European Medical Device Regulations MDR 2017/745, Swedish law 1993:584 regarding Medical devices, Regulation 1993:876 regarding Medical devices and regulation LVFS 2003:11 from the Swedish Medical Products Agency.

Tranås 2024-01-11

TR Equipment AB

Mico Olsen, CEO

