

EU DECLARATION OF CONFORMITY

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SRN: PL-MF-000001583*

We hereby declare, under our sole responsibility, that this declaration of conformity has been issued in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR), and that the relevant requirements of the Regulation have been fulfilled.

Medical Device:

BATHTUB BENCH: AT51053 Basic UDI-DI: 59015714AT5105342

The device has been classified in accordance with Annex VIII of the MDR as Class I, based on Rule 1.

Intended use: The bathtub bench is intended for individuals with disabilities or limited mobility to assist them in performing activities such as bathing in a safe and comfortable manner.

Conformity assessment has been carried out according to Annex II and III of Regulation (EU) 2017/745.

The following standards have been applied to demonstrate compliance:

PN-EN ISO 15223-1:2022
PN-EN 20417:2021
PN-EN ISO 14971:2020
PN-EN ISO 13485:2016

PN-EN ISO 10993-1:2021
PN-EN ISO 10993-5:2009
PN-EN ISO 10993-10:2015
PN-EN 62366-1:2015-07/A1:2021



version 1_04.2025


Andrzej Tarnkowski
co-owner
independent representation of the company
based on the Company Register

Warsaw, 24.04.2025