

EU DECLARATION OF CONFORMITY

Conforms to the original

The manufacturer:

Company: VAIMAS SRL

SRN: IT-MF-000018121

Address: Via Volpato, 39 - 36035 Marano Vicentino (VI) - Italy

Declares, under its own and exclusive responsibility, that the device

Code	Model	ID BD/RDM	Basic UDI-DI
90750010	SEDILVASCA GIREVOLE	2480247/R	805411742AUSILIBAGNOVR

Intended use:

The device is designed to be placed on the edge of a bathtub in order to facilitate adult patients with mobility difficulties in cleaning operations for personal hygiene.

Environment of use: The device is intended for use in hospital, care and home environments. The device may not be used in potentially explosive or flammable atmospheres.

People intended for use of the device: patient, caregivers, health care personnel and caregivers.

Risk class: Class I (in accordance with Regulation 1, Annex VIII of Regulation (EU) (2017/745)

It complies with the following Union acts:

(EU) 2017/745 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

It complies with the following harmonised standards/technical standards and/or common specifications:

UNI EN ISO 21856:2022 - Technical aids for disabled people General requirements and test methods

The device is subject to the conformity assessment procedure provided for in Article 52, point 7 of Regulation (EU) 2017/745

Marano Vicentino, 22 September 2023

The legal representative,

De Pretto Benedetto


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