EU Declaration of Conformity

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

MANUFACTURER

SRN	NL-MF-000010807
Official company name	Economic Holland B.V.
Full address	Het Lentfert 38 7547 SR Enschede
Country	The Netherlands

MEDICAL DEVICE IDENTIFICATION

Product name	Toilet- and shower lift	
Trade name	Aerolet®	
Basic UDI-DI	87193276956AEROLET19985M	
Product models	**Product model:**	**GTIN - UDI-DI**
	BI-ST	8719327695609
	BI-BA	8719327695616
	BI-SM	8719327695623
	VE-DO	8719327695630
	CL-BA	8719327695647
	CL-ST	8719327695654
	GEME-ST	8719327695661
	GEME-BA	8719327695678
	VE-UNI-ST	8720299854567
	VE-UNI-SM	8719327695685
	VE-UNI-BA	8719327695692
	JHC-ST	8719327695708
	UNI-ST	8719327695715
	UNI-SM	8719327695722
	UNI-BA	8719327695739
	VA-ST	8719327695753
	VA-BA	8719327695760
	VE-BI-ST	8719327695777
	VE-BI-LA	8719327695784
	VE-BI-BA	8719327695791
	VE-BI-SM	8720299854505
	VE-CL-BA	8720299854512
	VE-CL-ST	8720299854529
	VE-GEME-ST	8720299854536
	VE-GEME-BA	8720299854543
	VE-JHC-ST	8720299854550
	VE-VA-BA	8720299854574
	VE-VA-ST	8719327695746
Intended purpose	A device to enable independent use of the toilet for individuals with reduced muscle strength and/or limited flexibility.	
Risk class	Class I, Rule I	

The device described above is in accordance with the following harmonization legislation of the European Union and meets the provision of the:

- **Medical Devices Regulation (EU) MDR 2017/745 relating to medical devices**
- **Directive 2014/35/EU relating to electrical equipment designed for use within certain voltage limits (Low Voltage Directive – LVD)**
- **Machinery Regulation EU 2023/1230**

These standards have been applied to demonstrate compliance with the applicable essential requirements of Regulation (EU) 2017/745, Directive 2014/35/EU, and Directive 2023/1230."

- **EN-ISO 13485:2016** – Medical devices – Quality management systems – Requirements for regulatory purposes
- **ISO 21856:2022** – Assistive products for persons with disability – General requirements and test methods
- **ISO 14971:2019/A11:2021** – Application of risk management to medical devices
- **ISO 20417:2021 (cor. 2022-04)** – Medical devices – Information to be supplied by the manufacturer
- **ISO 3746:2010** – Acoustics – Determination of sound power levels of noise sources
- **IEC 60601-1:2006 + A1:2013 + A2:2021** – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2:2021** – Medical electrical equipment – Part 1-2: Electromagnetic disturbances – Requirements and tests

Place of issue:	Enschede The Netherlands	**Identity:** **Position:**	Ewout Tiemersma *CEO*
Date of issue :	01 June 2025	**Signature:**