

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	Aerolet – 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	Easylet®	
Basic UDI-DI	87193276956AEROLET19985M	
Product models	Product model: EAS-ST	GTIN - UDI-DI 8720299854581
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 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: Ewout Tiemersma
Position: CEO

Date of issue : 01 July 2025

Signature:

