

## **EU Declaration of Conformity**

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

## **MANUFACTURER**

SRN	APP000014048	
Official company name	Economic Holland B.V.	
Full address	Frankfurtstraat 37 1175 RH LUNDEN	
Country	The Netherlands	

## MEDICAL DEVICE IDENTIFICATION

Basic UDI-DI	Registration not yet implemented
Product name	Toilet lift
Trade name	Aerolet
Product code	20181998
Intended purpose	The device is a toilet lift for easy standing up and sitting down on existing toiloet and is used as an aid to daily living
Identification marking	Version 01-2014NL
Risk class	Class I

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

Medical Devices Regulation (EU) MDR 2017/745

Whereby the following relevant (harmonised) standards and/or Common specifications (GS) have been applied

EN 60601-1:2006;

MEDDEV 2.71/1 (rev.4)-2016;

EN-ISO 14971:2019;

NEN-EN 12182:2012;

ISO 3746:2010;

EN 1041:2008+A1:2013;

EN-ISO 13485:2016;

GLP-ISO 17025

Signed for and on behalf of

Place of issue:

Lijnden

Identity:

Gerard Huijerman

The Netherlands

Position:

Management

Datum van afgifte:

27 July 2021

Signature:

Lijnden, 28 November 2021 – the Aerolet Toilet lift – version 1.4 – Dir. G. Huijerman – agreed