

# EU Declaration of Conformity



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

## MANUFACTURER

<b>SRN</b>	NL-MF-000010807
<b>Official company name</b>	Economic Holland B.V.
<b>Full address</b>	Hanzestraat 12-B 7622 AX BORNE
<b>Country</b>	The Netherlands

## MEDICAL DEVICE IDENTIFICATION

<b>Basic UDI-DI</b>	<b>87193276956</b> AEROLET1998 <b>5M</b>
<b>Product name</b>	Toilet/shower lift
<b>Trade name</b>	Aerolet
<b>Product code</b>	20181998
<b>Product models</b>	ST, BA, CL-ST, GE-8000, GE-ME, SM, DO, CL-BA VE-ST, VE-CL, VE-GE-8000, VE-GE-ME, VE-SM, VE-DO, VE-CL-BA
<b>Intended purpose</b>	The device is a toilet/shower lift for easy standing up and sitting down on existing toilet/shower seat and is used as an aid to daily living
<b>Identification marking</b>	Version 01-2014NL
<b>Risk class</b>	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 relating to medical devices and carry the required CE Mark**

*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 60601-1-2:2015; NEN-EN 12182:2012;  
EN-ISO 14971:2019; EN 1041:2008+A1:2013;  
ISO 3746:2010; GLP-ISO 17025;  
EN-ISO 13485:2016;

*Signed for and on behalf of*

<b>Place of issue:</b>	Borne The Netherlands	<b>Identity:</b>	Ewout Tiemersma
		<b>Position:</b>	Management
<b>Date of issue :</b>	01 March 2024	<b>Signature:</b>	