

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	Hanzestraat 12-B 7622 AX BORNE
Country	The Netherlands

MEDICAL DEVICE IDENTIFICATION

Basic UDI-DI	87193276956 AEROLET1998 5M
Product name	Toilet/shower lift
Trade name	Aerolet
Product code	20181998
Product models	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
Intended purpose	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
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 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

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