

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:

10000379653-PA-NA-DNK Rev 0.0

Project No.:

PRJN-191773-2020-PA-DNK

Valid Until:

01 March 2024

This is to certify that the quality system of:

KEN HYGIENE SYSTEMS A/S

Bøgebjergvej 60, 5672 Broby, Denmark

For design, production and final product inspection/testing of:

BEDPAN WASHERS AND WASHER DISINFECTORS

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:

Høvik, 06 May 2021

For the issuing office:

Notified Body 2460
DNV Product Assurance AS



Eugenie Winger Husebye
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM -879 to DNV Product Assurance (NB 2460)	06 May 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Washer Disinfectors	IQ3/MAT LD100BM	IIb
	IQ4/MAT LD100	
	IQ5/MAT LD500	
	IQ5-M/Mat LD500M	
	IQ6/MAT LD1000	
	IQ10	
Bedpan Washers	BWD 731	IIa
	BWD 733	
	BWD 736	
	BWD 738	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
KEN HYGIENE SYSTEMS A/S	Bøgebjergvej 60, 5672 Broby, Denmark

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10000379653-PA-NA-DNK Rev 0.0

Valid Until:
01 March 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
KEN HYGIENE SYSTEMS A/S

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and/or audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A device already covered by the certification is placed on the market under an additional name or Identifier.

Products covered by this Certificate (replaces information on certificate):		
Product Description	Product Name	Class
Washer Disinfectors	IQ3/MAT LD100BM	IIb
	IQ4/MAT LD100	
	IQ5/MAT LD500	
	IQ5-M/Mat LD500M	
	IQ6/MAT LD1000	
	IQ10	
Bedpan Washers	BWD 731/MAT LC10	IIa
	BWD 733/MAT LC20	
	BWD 736/MAT LC30	
	BWD 738	

Place and date:
Høvik, 09 July 2021



For the issuing office:
DNV Product Assurance AS - Notified Body
2460
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer



DNV

Appendix to Certificate no.: 10000379653-PA-NA-DNK Rev 0.0
Place and date: Høvik, 09 July 2021

Appendix History

Revision	Description	Issued Date
0.0	Correction of Product brands according to latest product list approved by Presafe Denmark A/S	09 July 2021

