

Certificate of Approval

This is to certify that the Management System of:

Antonio Matachana, S.A.

Almogavares, 174-176, 08018 Barcelona, Spain

has been approved by Lloyd's Register to the following standards:

ISO 9001:2015

Approval number(s): ISO 9001 – 0036999

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design and manufacture of sterilizers, disinfection devices and treatment equipment for medical devices, food, associated research, industry, medical waste and pharmaceutical laboratories. Distribution of communities, surgical, sterilisation, disinfection and mortuary equipment. Technical and validation service at customer's premises (sterilizers, washer-disinfectors and sealing machines).



Daniel Oliva Marcilio de Souza

Area Operations Manager - South Europe

Issued by: Lloyd's Register Quality Assurance España, S.L.U.

for and on behalf of: Lloyd's Register Quality Assurance Limited



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
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

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



Manufacturer: KEN HYGIENE SYSTEMS A/S
Adresse: 5672 Broby, Bøgebjerg vej 60, Denmark
Tel: +45 62 63 10 91
Fax: +45 62 63 16 07

Hereby declares that:

According to Annex II to Council Directive 93/42/EEC of June 14, 1993

KEN HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEM
EN **KEN Washer-disinfector, type: MAT LD 1000 Machine No.:** SYSTEMS A/S KEN
HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S

GMDN Term: Surgical utensil washer/decontaminator. GMDN Code: 35424

Is produced in accordance with - and meets the requirements of:

Council Directive 93/42 EEC with supplement 2007/47/EC (Directive for Medical Device Class IIb products)

and complies with the following international standards and legislation:

Title:	Subject:
MDR 2017/745	Medical devices Regulation (Transitional provisions)
EN ISO 13485:2016 +A11:2021	Medical devices - Quality management system
EN ISO 14971:2019 +A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used
EN ISO 15883-1:2009 +A11:2014	Washer disinfectors Part 1
EN ISO 15883-2:2009	Washer disinfectors Part 2
EN ISO 15883-5:2021	Washer disinfectors Part 5
EN 60601-1-2:2015	Electromagnetic disturbances - Requirements and tests (EMC)
EN 62304:2006 + A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015 +A1:2020	Application of usability engineering to medical devices
EN 61010-1:2010 +A1:2019	Safety requirements Part 1
EN 61010-2-040:2021	Safety requirements Part 2

We declare compliance of the above medical device with the requirements of the Council Directive 93/42/EEC of June 14, 1993, the Norwegian Implementation of the same directive, and their amendments. Any modification of the medical device not authorized by us will invalidate this declaration.

The Route to Compliance: 93/42/EEC Medical devices directive, Annex II excluding section 4

EU Certificate: 10000379653-PA-NA-DNK Rev 0.0

Certified by: DNV Product Assurance AS

Number: 2460

KEN Brobyværk date:2022-04-29 KEN HYGIENE SYST **KEN HYGIENE SYSTEMS A/S** ENETEMS A/S KEN HYGIENE SYSTEM A/S KEN HYGIENE SYSTEMS A/S KEN
HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S
ENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S
HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S KEN HYGIENE SYSTEMS A/S
John Veje Olesen
Managing Director 2460