



EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding section 4

Certificate No.:
DGM – 879

Reference:
aur2a1902v140f833

Date of issue:
2019-03-01

Valid Until:
2024-03-01

Initial date of issue:
2016-04-21

This is to certify that the quality system of:

KEN HYGIENE SYSTEMS A/S
Bøgebjergvej 60
5672 Broby
Denmark

has been audited under the requirements of:

Annex II, Full quality assurance system, excluding section 4, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex II.

The certificate covers the following devices:

Design, manufacture and final inspection of bedpan washers and washer disinfectors in class IIa and IIb

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. This EC certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the MDD, Annex II, section 5.

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

Bent Buus
Authorized person
For Presafe Denmark A/S



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The following product families in class IIa are covered by the certificate:

Bedpan Washers

The following product families in class IIb are covered by the certificate:

Washer Disinfectors

Product List

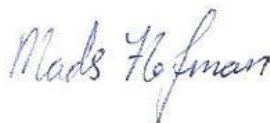
The following products are covered by DGM – 879:

Product	Class	Date for placing on the market (with CE Mark)	Product family on DGM – 879 covering the device
BWD 731	Ila	2005-12-30	Bedpan Washers
BWD 733	Ila	2001-03-10	Bedpan Washers
BWD 736	Ila	2001-12-07	Bedpan Washers
BWD 738	Ila	2003-02-17	Bedpan Washers
IWD 2211	Ilb	2005-03-29	Washer Disinfectors
IWD 2311	Ilb	2004-11-22	Washer Disinfectors
IWD 2314/MAT LD2314	Ilb	2005-04-05	Washer Disinfectors
IWD 521/MAT LD521	Ilb	2001-01-29	Washer Disinfectors
2211-LAB	Ilb	2004-11-25	Washer Disinfectors
2311-LAB	Ilb	2004-11-25	Washer Disinfectors
521-LAB	Ilb	2001-12-20	Washer Disinfectors
IWD 521XLS/MAT LD521XLS	Ilb	2012-02-13	Washer Disinfectors
CWD 5000	Ilb	2014-02-20	Washer Disinfectors
IQ5/MAT LD500	Ilb	2017-06-09	Washer Disinfectors
IQ6/MAT LD1000	Ilb	2017-10-13	Washer Disinfectors
IQ4/MAT LD100	Ilb	2019-01-25	Washer Disinfectors

"The products on this list have been accepted by Presafe Denmark A/S"

Date: 2019-01-25

Name and signature: Mads Hofman



Title: Lead Auditor