

To: KEN Hygiene Systems A/S Bøgebjergvej 60 5672 Broby Denmark

and to whom it may concern.

DNV Business Assurance A/S Medical, DK Tuborg Parkvej 8 2900 Hellerup Denmark

Phone +45 39454999

Date: Our reference:

2021-06-16 DNV EC Certification,

certificate no.

10000379653-PA-NA-DNK

Rev 0.0

## Clarification of products to be covered by the KEN HYGIENE SYSTEMS A/S, DNV EC Certificate.

In relation to transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM -879 with related separate product list to DNV Product Assurance (NB 2460) EC Certificate which includes a product list on page 2 with headline "Products covered by this Certificate". The following clarification of this products list on the DNV Product Assurance EC Certificate page 2 is made below.

The KEN Hygiene Systems A/S device are distributed under two brand names, but legal manufacture is for both Brands KEN Hygiene Systems A/S and is labelled as such. The below clarifies the device identification in relation to Brand names on the devices (two product brand names for the same type device).

Product Description	Product Name		Class
	KEN Hygiene System A/S Brand	Matachana Brand	
Bedpan Washers	BWD 731	MAT LC10	lla
	BWD 733	MAT LC20	lla
	BWD 736	MAT LC30	lla
	BWD 738	NA, not distributed as Matachana Brand	lla
Washer Disinfectors	IQ3	MAT LD100BM	Ilb
	IQ4	MAT LD100	Ilb
	IQ5	MAT LD500	Ilb
	IQ5-M	MAT LD500M	Ilb
	IQ6	MAT LD1000	Ilb
	IQ10	NA, not distributed as Matachana Brand	Ilb

If any further clarification of which products is covered by the DNV Product Assurance EC Certification, certificate no. 10000379653-PA-NA-DNK Rev 0.0 is needed please contact the DNV Business Assurance A/S, Tuborg Parkvej 8, 2900 Hellerup, Denmark.



## Page 2 of 2

Sincerely for Presafe Denmark A/S

Mads Hofman

Mads Hofman Lead Auditor Presafe Denmark A/S