

Quality System Certificate

Certificate No.:
DGM – 878

Reference:
aur2a1811v110f833

Date of issue:
2018-12-11

Valid Until:
2020-06-13

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

fulfills the requirements in:

EN ISO 13485:2016

The certificate covers the following activities:

Development and production of washer disinfectors. Sales and service of washer disinfectors, ultrasonic cleaners and sterilizers.

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001:2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Presafe Denmark A/S

Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

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Additional site(s) covered by the certificate:

KEN HYGIENE SYSTEM AS
Verkseier Furulunds Vei 21, Alnabru
0668 Oslo
Norway

KEN HYGIENE SYSTEMS s.r.o.
Južná trieda 74
040 01 Košice
Slovakia

KEN HYGIENE SYSTEMS A/S, Sverige Filial
Göteborgsvägen 74
433 63 Sävedalen
Sweden