EC Certificate
Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding section 4

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 596	aur2a1907v290f502	2019-08-22	2022-06-19	2007-02-15

This is to certify that the quality system of:

Trudell Medical International
725 Baransway Drive,
London ON,
N5V 5G4,
Canada

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 certificate covers the following devices:

Design, manufacture and final test of respiratory devices, nebulizer compressors and Aerobika* Oscillating Positive Expiratory Pressure Manometer in class Im and IIa.

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

Heidi Jørgensen
Authorized person
For Presafe Denmark A/S

EC Certificate
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The following product(s)/product families in class IIa are covered by the certificate:

Product family:

Nebulizers

Nebulizer compressor

The following product(s)/product families in class Im are covered by the certificate:

Product family:

Respiratory Devices

The authorized EC representative:

Emergo Europe,
Prinsessegracht 20,
2514 AP The Hague,
The Netherlands