EC Certificate

Certificate Number: DGM – 596

This is to certify that the quality system of:

Trudell Medical International
725 Third St., London
Ontario, N5V 5G4
Canada

has been approved in conformity with the requirements of:

Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as ammended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

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

This EC certificate is issued in accordance with Presafe Denmark A/S' 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 Directive.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue:	2017-06-19
Expires:	2022-06-19
Initial date of issue:	2007-02-15
Reference:	aur2a1706v250f502

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

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

Nebulizers
Nebulizer compressor

The following product family in class Im is covered by the certificate:

Respiratory Devices

The authorized EC representative:

Trudell Medical International Europe Limited
Biocity Nottingham
Pennyfoot St.
Nottingham NG1 1GF
United Kingdom

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