

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

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**

Certificate number: DGM – 596  
Certificate type: EC Certificate

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