



# EC Certificate

Certificate Number:

DGM – 657

This is to certify that the quality system of:

**CIMPAX ApS**  
**Lille Pilevang 4**  
**3550 Slangerup**  
**Denmark**

has been approved in conformity with the requirements of:

## **Annex II, section 3.2 - Full quality assurance system**

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

The certificate covers the following activities:

**Design and manufacture of laparoscopic hand instruments and diathermy pencils in class IIb and insufflation needles, catheters, and accessories for delivery of anaesthetics in class IIa**

The EC 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. This EC certificate is issued pursuant to the Presafe Denmark A/S' terms and conditions for the certification of 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 as per the Directive.

  
Heidi Jørgensen  
Authorized person

For Presafe Denmark A/S

Date of issue: 2013-09-26  
Expires: 2016-12-02  
Initial date of 2008-12-04  
Reference: aur2a1109v51f682



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

**DGM**

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The following products in class IIb are covered by the certificate:

**Laparoscopic hand instruments**

**Diathermy pencils**

The following products in class IIa are covered by the certificate:

**Insufflation needles**

**Catheters**

**Accessories for delivery of anaesthetics**

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