



A DNV & NEMKO
COMPANY

EC Certificate

Certificate Number: DGM – 605

This is to certify that the quality system of:

OraSure Technologies, Inc.

220 East First Street
Bethlehem, PA 18015-1360
USA

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 amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

Design, development, manufacture and final inspection of Cryosurgical devices in class 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: 2014-12-05
Expires: 2019-12-05
Initial date of issue: 2007-07-05
Reference: Aur2a1410v240f646



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

DGM

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

HISTOFREEZER®

Freeze 'n Clear Skin Clinic™ Advanced Wart and Verruca Remover

Freeze 'n Clear Skin Clinic™ Advanced skin tag remover

The authorized EC representative:

Qarad bvba

Cipalstraat 3
B-2440 GEEL
Belgium

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