



EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding section 4

Certificate No.:
DGM – 605

Reference:
Aur2a1908v440f646

Date of issue:
2019-12-03

Valid Until:
2024-05-26

Initial date of issue:
2007-07-05

This is to certify that the quality system of:

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015-1360
USA

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 quality system meets the requirements of the MDD, Annex II. For the placing on the market of class III products covered by this certificate an Annex II section 4 certificate is required.

The certificate covers the following devices:

Design, development, manufacture and final inspection of Cryosurgical devices 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 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



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

Product family

HISTOFREEZER®

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

Freeze 'n Clear Skin Clinic™ Advanced skin tag remover

Additional site(s) covered by the certificate:

OraSure Technologies, Inc.
1745 Eaton Avenue Bethlehem
Pennsylvania 18018
USA

OraSure Technologies, Inc.
150 Webster Street Bethlehem
Pennsylvania 18015
USA

OraSure Technologies, Inc.
2500 Emrick Boulevard Suite 100 Bethlehem
Pennsylvania 18020
USA

The authorized EC representative:

Qarad bvba
Cipalstraat 3
B-2440 GEEL
Belgium