

EC Certificate

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, section 3.2 - Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law.

The scope of the certification is:

**Design, development and manufacture and final inspection of
Cryosurgical devices in class IIa and Oral specimen collection
kits in class III**

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 DS Certificering A/S. This EC certificate is issued pursuant to the DS Certificering A/S rules for the certification of medical devices and entitles the certificate holder to affix the CE mark.



Benedikte Blom
Authorized person

Valid from:	2012-06-04
Valid until:	2017-06-03
Initial date of issue:	2007-07-05
Reference:	aur2a1111v194f646

DS Certificering A/S

Notified Body, Identification No. 0543
Kollegievej 6, DK-2920 Charlottenlund, Denmark

The following product families in class III are covered by the certificate
and by the EC Design Examination Certificate DGM-622:

ORASURE® oral specimen collection kits
INTERCEPT® oral specimen collection kits

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 b.v.b.a
Volmolenheide 13
2400 Mol
Belgium

Certificate number: DGM – 605
Certificate type: EC Certificate

Valid from: 2012-06-04
Valid until: 2017-06-03
Initial date of issue: 2007-07-05
Reference: aur2a1111v194f646