EC Certificate
Production Quality Assurance
Directive 93/42/EEC on Medical devices, Annex V

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 931	Aur5a2005v80f858	2020-06-17	2024-05-26	2019-12-12

This is to certify that the quality system of:

CryoConcepts, LP
205 Webster Street
18015 Bethlehem
Pennsylvania
USA

has been audited under the requirements of:

Annex V, section 3.2 - Production Quality Assurance, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex V.

The scope of the certification is:

The manufacture of disposable cryosurgical devices

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 pursuant to the 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 V, section 4.

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:

CryOmega

CryoClear

Histofreezer

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

Freeze 'n Clear Skin Clinic™ Advanced Skin Tag Remover and the Cryotag Skin Tag Remover

The authorized EC representative:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands