EC CERTIFICATE

Production Quality Assurance

Certificate No.:	Project No.:	Valid Until
10000463860-PA-NoMA-DNK – Rev 0.0	PRJN-252967-2021-PA-DNK	26 May 2024

This is to certify that the quality system of:

CryoConcepts, LP

205 Webster Street, 18015 Bethlehem, Pennsylvania, USA

For production and final product inspection/testing of:

Disposable cryosurgical devices

Has been assessed with respect to:

The conformity assessment procedure described in Annex V of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 20 May 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Check Validity

Eugenie Winger Husebye
Technical Reviewer

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM-931 to DNV Product Assurance AS (NB 2460)	20 May 2024

Products covered by this Certificate:

Product Description	Product Name	Class
CryoClear	CryoClear	IIa
CryOmega II	CryOmega II	IIa
CryoTag Skin Tag Remover	CryoTag Skin Tag Remover	IIa
Freeze ’n Clear Skin Clinic™, Advanced Wart & Verruca Remover	Freeze ’n Clear Skin Clinic™, Advanced Wart & Verruca Remover	IIa
Freeze ’n Clear Skin Clinic™, Advanced Skin Tag Remover	Freeze ’n Clear Skin Clinic™, Advanced Skin Tag Remover	IIa
Histofreezer® Portable Cryosurgical System	Histofreezer® Portable Cryosurgical System	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
CryoConcepts, LP	205 Webster Street, 18015 Bethlehem, Pennsylvania,USA

EU Representative

Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10000463860-PA-NoMA-DNK Rev.0.0

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
CryoConcepts, LP

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A site has been relocated.

Sites covered by certificate (replaces information on certificate)	
Site Name	**Site Address**
CryoConcepts, LP	1100 Conroy Place, Easton, PA 18040, USA

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Correction of issue date from “20 May 2024” to “20 May 2021”	28 October 2021
1.0	HQ has been relocated and moved from 205 Webster Street, 18015 Bethlehem, Pennsylvania, USA to 1100 Conroy Place, Easton, PA 18040, USA	08 June 2023

Place and date:
Høvik, 08 June 2023

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer