

MANUFACTURER'S DECLARATION OF CONFORMITY

CryoConcepts, LP declares that the Class IIa medical device, CryOmega II, meets the provision of the Council Directive 93/42/EEC for Medical Devices as transposed in the national laws of the Member States. All supporting documentation is retained under the premises of the manufacturer and can be made available by the authorized representative in Europe.

Manufacturer's Name: CryoConcepts, LP
Business Address: 205 Webster Street
Bethlehem, PA 18015
United States of America

Authorized Representative: Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Medical Device: CryOmega II

GMDN Code: 44724 – Cryogenic Spray, Cutaneous

Classification: Class IIa Medical Device, Article 9 & Rule 9 in accordance with Annex IX of the MDD 93/42/EEC

Conformity Assessment Route: Annex V, Section 3.2

Notified Body:

DNV Product Assurance AS
Veritasveien 3
1363 Hovik
Norway

Certificate(s): 10000463860-PA-NoMA-DNK – Rev 0.0

Date of CE Marking: 04 March 2020

Issued By: DNV Product Assurance AS

Responsible Person: Walter Peters, Director of Quality and Regulatory

 13 Dec 2021

Walter Peters, Director of Quality and Regulatory