CryoConcepts
THE CRYO EXPERTS

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 can be made available by the authorized representative in Europe.

Manufacturer's Name:	CryoConcepts, LP
Business Address:	1100 Conroy Place Easton, PA 18040 United States of America
Authorized Representative:	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem 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 & Regulatory

Walter H. Peters 24 MAY 2023

Walter Peters, Director of Quality & Regulatory