CryoConcepts
THE CRYO EXPERTS

MANUFACTURER'S DECLARATION OF CONFORMITY

CryoConcepts, LP declares that the Class IIa medical device, Histofreezer® Portable Cryosurgical Wart Treatment System, 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:
EmergoEurope
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Medical Device:
Products covered by this declaration fall in the product family **Cryosurgical Products** covered by this declaration and include the following variants of the Histofreezer® Portable Cryosurgical System:

Variants:

1001-0411 1001-0408	H-602	60 Application Kit w/ 60 - 2mm Buds
1001-0410 1001-0409	H-505	50 Application Kit w/ 52 - 5mm Buds
1001-0413 1001-0412	H60	60 Application Kit w/ 24 - 2mm Buds and 36 - 5mm Buds
1001-0341	H30M	30 Application Kit w/ 15 - 2mm Buds and 15 - 5mm Buds Sample Kit

GMDN Code: 11067 – General Cryosurgical System, Mechanical

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 and Regulatory