CryoConcepts
THE CRYO EXPERTS

MANUFACTURER'S DECLARATION OF CONFORMITY

CryoConcepts 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: *205 Webster Street*
Bethlehem, PA 18015
United States of America

Authorized Representative: *EmergoEurope*
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Medical Device:
Products covered by this declaration fall in the product family **Cryosurgical Products** covered by this declaration fall in the product family **Cryosurgical Products** 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
H-105	H-105	5 Application w/ 2 - 2mm Buds and 3 - 5mm Buds – Sample Kit

GMDN Code: 11067 – General Cryosurgical System, Mechanical

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

Conformity Assessment Route: Annex V, Section 3.2

Notified Body:
PreSafe Denmark A/S
Notified Body Number 0543
Tuborg, Parvej 8
2900 Hellerup, Denmark

Certificate(s): DGM - 0931

***Date of CE Marking*:** 04 March 2020

Issued By: PreSafe Denmark A/S

Responsible Person: Gloria Ferko, VP Quality & Regulatory

Gloria M. Ferko 12 March 2020
Gloria Ferko, VP Quality & Regulatory