

# Quality System Certificate

Certificate No.:  
**DGM – 930**

Reference:  
**Aur5a2005v90f858**

Date of issue:  
**2020-11-27**

Valid Until:  
**2022-12-12**

Initial date of issue:  
**2019-12-12**

This is to certify that the quality system of:

**CryoConcepts, LP**  
**205 Webster Street**  
**18015 Bethlehem**  
**Pennsylvania**  
**USA**

fulfills the requirements in:

**DS/EN ISO 13485:2016**

The certificate covers the following activities:

**The design, manufacture and distribution of cryosurgical devices intended for the surgical destruction of target tissue by applying cryogenic gases**

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001:2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

**Presafe Denmark A/S**

Notified Body, Identification No. 0543  
Tuborg Parkvej 8, 2900 Hellerup, Denmark



Heidi Jørgensen  
Authorized person

For Presafe Denmark A/S