

Quality System Certificate

Certificate No.:
DGM – 930

Reference:
Aur5a2208v130f858

Date of issue:
2022-12-12

Valid Until:
2025-12-12

Initial date of issue:
2019-12-12

This is to certify that the quality system of:

CryoConcepts, LP
1100 Conroy Place
Easton
PA 18040
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

Zeshaan Sayd
Authorized person

For Presafe Denmark A/S