

Quality System Certificate

Certificate No.:
DGM – 610

Reference:
aur5a2108v310f176

Date of issue:
2021-09-30

Valid Until:
2024-09-30

Initial date of issue:
2007-05-25

This is to certify that the quality system of:

Cortex Technology ApS
Plastvænget 9
9560 Hadsund
Denmark

fulfills the requirements in:

DS/EN ISO 13485:2016

The certificate covers the following activities:

Manufacture, testing and service of cryosurgical units and cryosurgical accessories

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