

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C543645_NA_DNK

Initial certification date:
18 November 2022

Valid:
01 June 2023 – 30 September 2024

This is to certify that the management system of
Cortex Technology ApS
Niels Jernes Vej 6B, 9220 Aalborg Ø, Denmark

has been found to conform to the Quality Management System standard:
ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

**Design, Production, Inspection, sales, distribution and Servicing of Cryosurgery Devices
for Dermatology**

Place and date:
Høvik, 01 June 2023



For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

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Management Representative



Cortex Technology ApS
Niels Jerners Vej 68
9220 Aalborg Ø

DNV Business Assurance
Presafe Denmark A/S
Tuborg Parkvej 8, 2.
2900 Hellerup
Tel: +45 39454800
VAT no.: DK 34080771

Date:	Our reference:	Your reference:
5 th Nov 2024	Jeremy Harvey	Morten Fjordback

To Whom it may concern

We hereby confirm that the Recertification of ISO 13485 was performed in June 2024 and all findings have been resolved.

The Recertification was done as a combined audit with MDR-Certification (QMS part).

The Certificate no C543645 is currently in technical review together with the MDR audit. The re-issuance of ISO 13485 is merely delayed due to administrative handling from our side.

Sincerely
for Presafe Denmark A/S

Jeremy Harvey
Area Manager Medical Europe

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