



Cortex Technology ApS
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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

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Area Manager Medical Europe

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