

CORTEX TECHNOLOGY

DoC-12522 EU Declaration of Conformity CryoPro v3 [Effective]

Document no.: 12522	Effective Date: 2026-03-25	Version: 3
Author: Freya Neumann; Peter Tonsberg Løkke	Approver: Freya Neumann	Reviewer: Peter Tonsberg Løkke

EU DECLARATION OF CONFORMITY

Manufacturer: Cortex Technology Aps.
Niels Jernes vej 6B
9220 Aalborg Øst
Denmark
SRN: DK-MF-000002984

Device identification:		<u>Basic UDI-DI</u>	<u>Serial number</u>
	CryoPro® Mini	5710188020028G	SN-MINI S2621121 and later
	CryoPro® Maxi	5710188020018E	SN-MAXI L2622473 and later
	CryalJet Mini	5710188020028G	SN-MINI S2621121 and later
	CryalJet Maxi	5710188020018E	SN-MAXI L2622473 and later

Accessories/components that are an integrated part of the CE marking of the CryoPro®/CryalJet devices are listed in the accessory overview on page 2.

CryoPro® is a class IIa medical device according to MDR Annex VIII.

Intended purpose: The CryoPro® is a handheld device for cutaneous cryosurgery that uses localized application of liquid nitrogen to treat skin lesions by tissue freezing. Treatment can be performed using open spray or contact probe techniques by healthcare professionals such as dermatologists, family physicians, and nurses trained in cryosurgery in a normal well-lit and ventilated clinical setting.

The devices mentioned are in conformity with the requirements of EU Medical Device Regulations 2017/745. The procedure for conformity is in accordance with Annex IX of the Regulations.

The Notified Body is DNV Product Assurance AS with notified body number 2460. Our EU Quality Management System Certificate number is C543644-Rev 1.

This declaration is issued under the sole responsibility of the Manufacturer.

Signature on behalf of Cortex Technology Aps.



Lone Jager Lindquist
CEO
Cortex Technology ApS

2026-03-25

Date

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List of accessories/components included in CE marking

Accessory	Basic UDI-DI	Ref.	UDI-DI
Spray tip	5710188SPRAY3M		
Spray Tip "A", 1 mm		OS A	5710188020329
Spray Tip "B", 0.75 mm		OS B	5710188020336
Spray Tip "C", 0.55 mm		OS C	5710188020343
Spray Tip "D", 0.45 mm		OS D	5710188020350
Conical Spray Tip "A"		COS A	5710188020367
Conical Spray Tip "B"		COS B	5710188020374
Conical Spray Tip "C"		COS C	5710188020381
Conical Spray Tip "D"		COS D	5710188020398
Bent Spray extension "C", 0.55 mm, 75 mm long		OS BS CL	5710188020312
Straight Spray extension "C", 0.55 mm 75 mm long		OS SS CL	5710188020275
Straight Spray extension "B", 0.75 mm, 25 mm short		OS SS BS	5710188020190
Bent Spray extension "B", 0.75 mm, 75 mm long		OS BS BL	5710188020206
Straight Spray extension "A", 1.00 mm, 25 mm short		OS SS AS	5710188020213
Straight Spray extension "C", 0.55 mm, 25 mm short		OS SS CS	5710188020220
Acne Soft Spray Tip		OS SOFT	5710188020725
Contact Probe	5710188CONTACTWN		
1 mm Contact probe		CP 1 mm	5710188020619
2 mm Contact probe		CP 2 mm	5710188020626
3 mm Contact probe		CP 3 mm	5710188020619
4 mm Contact probe		CP 4 mm	5710188020640
5 mm Contact probe		CP 5 mm	5710188020657
6 mm Contact probe		CP 6 mm	5710188020664
8 mm Contact probe		CP 8 mm	5710188020671
10 mm Contact probe		CP 10 mm	5710188020688
15 mm Contact probe		CP 15 mm	5710188020695
20 mm Contact probe		CP 20 mm	5710188020701
30 mm Contact probe		CP 30 mm	5710188020718
Sharp Pointed Contact probe		CP SP	5710188020602
Luer Lock adapter	5710188LUER58	OS LL	5710188020732
Liquid Nitrogen Filter	5710188FILTERUD	LNF	5710188020770

Changes Made to the document:

Complete change history: Ver. 2 | Effective Date 2026-02-02: Change:
added Basis-UDI-DI for CryalJet, new Conical
Spray Tip, Straight Spray, Bent Spray, Liquid
Nitrogen Filter

- Ver. 3 | Effective Date 2026-03-25: Change:
BasicUDI-DI added for all accessories;
layout/formatting changed for better overview,
including moving accessory table to separate
page

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Signatures:

**Controlled
Document
Approved:**

I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.

Name:

Freya Neumann
cortex.dk\frn

2026-03-25 12:54:08 (UTC+00:00)

Electronically Signed in **SimplerOMS**

Timestamp

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