EU DECLARATION OF CONFORMITY

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

Device identification:

CryoPro® Mini, CryalJet Mini, Basic UDI-DI: 5710188020028G

CryoPro® Maxi, CryalJet Maxi, Basic UDI-DI: 5710188020018E

The following is an integrated part of the CE marking of the CryoPro/CryalJet devices:

Accessory	**Ref.**	**UDI-DI**
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
Bent Spray extension, 0.55 mm	OS BS	5710188020312
Straight Spray extension, 0.55 mm	OS SS	5710188020275
Acne Soft Spray Tip	OS SOFT	5710188020725
Luer Lock adapter	OS LL	5710188020732
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

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

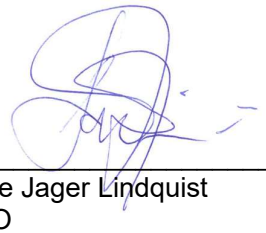
Intended purpose: The CryoPro® is a handheld device for cutaneous cryosurgery that uses localized application of liquid nitrogen to treat skin lesions by tissue freezing. Treatment can be performed using open spray or contact probe techniques by healthcare professionals such as dermatologists, family 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.

Our 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

2025-01-24
Date