

## CERTIFICATE OF CONFORMANCE

This certifies that the product conforms to CryoConcepts Specifications for final product release testing.

<b>Product Name and Description:</b>	Kit, Histofreezer H-602 (GER), dual 80mL-Essity
<b>CryoConcepts Item Number:</b>	1001-0408
<b>CryoConcepts Batch/Lot Number:</b>	3307-2389
<b>Expiry Date (YYYY-MM-DD):</b>	2026-11-30
<b>Total Quantity of Kits:</b>	1692

TEST	RELEASE SPECIFICATION	DISPOSITION (circle one)	Reference (Method Used)
Functional Testing	≤ -50°C (core temp.) within 50 seconds	Pass / Fail	200WI
Physical Attribute Testing	Meets Acceptance Criteria	Pass / Fail	200WI

### Statement

The batch complies with Packaging configuration, QC Test Specifications, and Finished Product Test Specifications.

  
 \_\_\_\_\_  
 Quality Assurance

\_\_\_\_\_  
 29 APR 2024  
 Date

  
 \_\_\_\_\_  
 Reviewed By

\_\_\_\_\_  
 29 APR 2024  
 Date



**Notified Body Confirmation Letter Reference: C616307**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

**CryoConcepts, LP**  
1100 Conroy Place  
Easton, PA 18040  
USA

SRN Number: US-MF-000009822

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

Place and date:  
Høvik, 2024/05/23

For the issuing office:  
DNV Product Assurance AS – Notified Body 2460  
Veritasveien 1, 1363 Høvik, Norway



**Rajesh Kumar Chellappan**  
Management Representative

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

<b>Device name and Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD device</b>	<b>MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
CryoClear Basic UDI-ID: 0850077006CryoClear6Q	Class IIa	NA	10000463860-PA-NoMA-DNK – Rev 0.0  Appendix rev 1.0 & rev 2.0 to 10000463860-PA-NoMA-DNK – Rev 0.0  NB no.: DNV 2460
CryoOmega II Basic UDI-ID: 0850077006CryoOmega5R	Class IIa	NA	10000463860-PA-NoMA-DNK – Rev 0.0  Appendix rev 1.0 & rev 2.0 to 10000463860-PA-NoMA-DNK – Rev 0.0  NB no.: DNV 2460
CryoTag Skin Tag Remover Basic UDI-ID: 0850077006HistofreezerKN	Class IIa	NA	10000463860-PA-NoMA-DNK – Rev 0.0  Appendix rev 1.0 & rev 2.0 to 10000463860-PA-NoMA-DNK – Rev 0.0  NB no.: DNV 2460
Freeze’n Clear Skin Clinic Advanced Skin Tag Remover Basic UDI-ID: 0850077006HistofreezerKN	Class IIa	NA	10000463860-PA-NoMA-DNK – Rev 0.0  Appendix rev 1.0 & rev 2.0 to 10000463860-PA-NoMA-DNK – Rev 0.0  NB no.: DNV 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Freeze'n Clear Skin Clinic Advanced Wart & Verruca Remover Basic UDI-ID: 0850077006HistoWartET	Class IIa	NA	10000463860-PA-NoMA-DNK – Rev 0.0  Appendix rev 1.0 & rev 2.0 to 10000463860-PA-NoMA-DNK – Rev 0.0  NB no.: DNV 2460
Histofreezer Portable Cryosurgical System Basic UDI-ID: 0850077006HistoProfES	Class IIa	NA	10000463860-PA-NoMA-DNK – Rev 0.0  Appendix rev 1.0 & rev 2.0 to 10000463860-PA-NoMA-DNK – Rev 0.0  NB no.: DNV 2460

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

**Confirmation Letter Revision History**

Date	NB internal reference traceable to each version of the letter	Action
2024/05/23	C616307	Initial issue

**Lack of fulfilment of conditions**

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.

## Manufacturer's Self-Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*<sup>1</sup>
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	CryoConcepts, LP
Manufacturer address and contact details	1100 Conroy Place Easton, PA 18040 U.S.A  Contact: Walter Peters Title: Director of Quality and Regulatory Email: walt.peters@cryoconcepts.com
Single Registration Number (SRN) (if available)	US-MF-000009822
Authorised Representative name (if applicable)	Emergo Europe BV
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT, Arnhem The Netherlands
Single Registration Number (SRN) (if available)	NL-AR-000000116
Notified body name (if applicable)	DNV
Notified body number (if applicable)	2460
Directive Certificate number(s) to which this confirmation is made (if applicable)	10000463860-PA-NoMK-DNK – Rev. 0.0
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024
End date of extended validity/transition period	31 Dec 2028

We, as the manufacturer declare under our sole responsibility:

<sup>1</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*<sup>2</sup>
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*
  - Expired *before* 20 March 2023:
    - Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device
    - A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)
    - A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)
  - Expired/expires *after* 20 March 2023:
    - A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
    - We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

**Up-classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

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<sup>2</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

- Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

CryoConcepts, LP  
1100 Conroy Place  
Easton, PA 18040  
U.S.A.

Date: 03 MAY 2024

Signature: 

Name: WALTER PETERS

Title: DIRECTOR OF QUALITY AND REGULATORY



### Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device Device name / Basic UDI-DI (under MDR application)	MDR Device classification	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	End date of extended validity/transition period
CryoClear / 0850077006CryoClear6Q	Class IIa	Not applicable	10000463860-PA-NoMK-DNK – Rev. 0.0	26 May 2024	31 Dec 2028
CryoOmega II / 0850077006CryoOmega5R	Class IIa	Not applicable	10000463860-PA-NoMK-DNK – Rev. 0.0	26 May 2024	31 Dec 2028
CryoTag Skin Tag Remover / 0850077006HistoFreezerKN	Class IIa	Not applicable	10000463860-PA-NoMK-DNK – Rev. 0.0	26 May 2024	31 Dec 2028
Freeze 'n Clear Skin Clinic Advanced Skin Tag Remover / 0850077006HistoFreezerKN	Class IIa	Not applicable	10000463860-PA-NoMK-DNK – Rev. 0.0	26 May 2024	31 Dec 2028
Freeze 'n Clear Skin Clinic Advanced Wart & Verruca Remover / 0850077006HistoWartET	Class IIa	Not applicable	10000463860-PA-NoMK-DNK – Rev. 0.0	26 May 2024	31 Dec 2028
HistoFreezer Portable Cryosurgical System / 0850077006HistoProfES	Class IIa	Not applicable	10000463860-PA-NoMK-DNK – Rev. 0.0	26 May 2024	31 Dec 2028