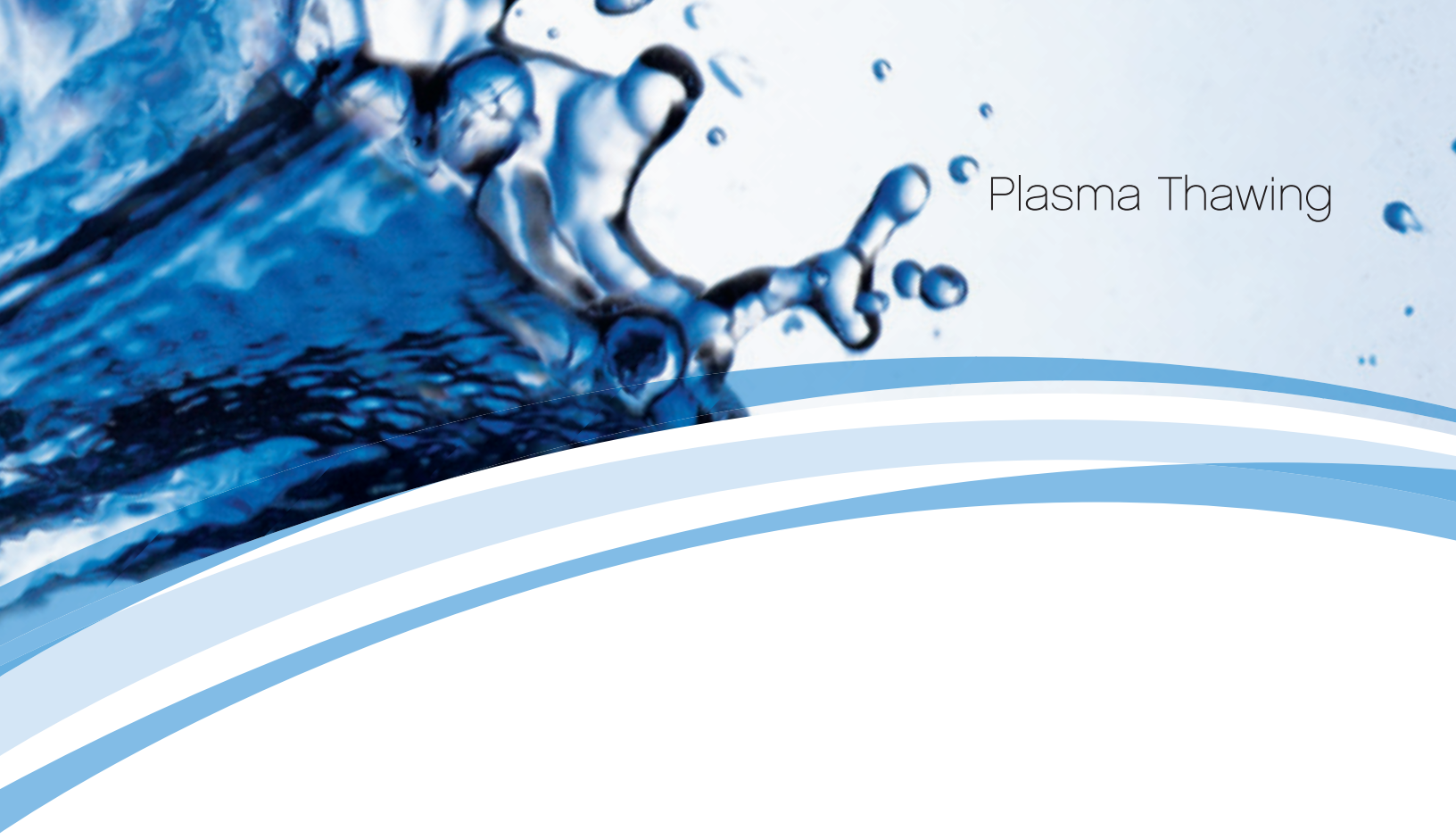


Plasma Thawing

QuickThaw®

DH2 · DH4 · DH8

Distinctly HELMER

Model DH8

Model DH4

Model DH2

QuickThaw®

QuickThaw® Plasma Thawing Systems from Helmer use both controlled temperature and agitation to substantially reduce thaw times while ensuring the safety of your plasma or cryoprecipitate. A range of sizes is available to meet your needs, including 2 bag, 4 bag, and 8 bag capacities. The DH4 and DH8 models have dual baskets with independent controls that accommodate a variety of bag configurations. The DH2 features a single basket and very compact footprint.

The QuickThaw is also convenient to operate, allowing you to load, program, and walk away. The QuickThaw does the rest.

Advantages Over Other Plasma Thawing Systems

Reduce Unused Plasma

Rapid thawing with the QuickThaw reduces the amount of plasma that must be thawed in advance. The baskets agitate the units in 36.5ºC water for optimal heat transfer and the most rapid, yet safe, thawing. Reducing unused thawed plasma results in cost savings for you.

Flexible, Convenient, and Safe

Each QuickThaw basket in the DH4 and DH8 operates independently, giving you the flexibility of starting batches of plasma at different times. In addition, the baskets automatically lift plasma bags out of the water when a cycle is complete, offering the convenience of walk-away time savings. For added safety, the baskets also lift out upon high alarm activation.

Maximum Versatility

Both random and apheresis plasma bags may be thawed in any unit (whether flat or folded). With the use of the removable dividers in the DH8 model, oversized units (wider than 6 in / 153 mm) may be thawed. The QuickThaw is suitable for thawing cryoprecipitate and red blood cells as well as warming saline.

Space Saving

The compact size of QuickThaw Plasma Thawing Systems conserves space on your benchtop. The small footprint of the DH2 makes it an ideal back-up unit.

Overwrap Protection

The QuickThaw uses Helmer overwrap bags, the most convenient method to protect plasma during thawing. Overwraps eliminate the need for snap-seal pockets to separate the plasma from an internal water supply. Pockets crack over time, causing the need for replacement and the possibility of internal system contamination. Helmer disposable overwraps provide long term security and the QuickThaw's open tank design allows for easy cleaning, with no hidden areas.

Thawing Capabilities

Plasma can be loaded and unloaded into the QuickThaw without waiting for the water to be added and drained. Competitive snap-seal pocket systems need pumps to move water from a holding reservoir into the thawing chamber before and after each cycle, increasing thaw times and decreasing throughput.

Durable, Dependable Design

Microprocessor Temperature Controller

- LED digital temperature display.
- Chamber temperature is programmable in 0.1ºC increments.
- Visual heater status indicator.
- Audible and visual high temperature alarm.

Agitation Controls

- Independent controls and LED display for each basket.
- Set time or remaining cycle time is displayed in minutes.
- 14 time selections are available for programming cycle length.
- Cycles can be interrupted to check units or add more plasma.

Construction

- Polished stainless steel tank and baskets.
- Bacteria-resistant powder coated exterior.
- Chamber volume and high capacity heater enhance heat transfer efficiencies for faster thawing.
- Quick connect drain system efficiently empties the chamber for easy cleanup.
- Large opening for easy cleaning.

Stainless Steel Chamber

DH8 Basket With Frozen Plasma

QuickThaw Control Panel for DH2

QuickThaw Control Panel for DH4 and DH8

Accessories

DT1 Digital Thermometer (Part No. 500606-1)

Solar-powered thermometer with LCD read-out displays the chamber temperature to a tenth of a degree. The stainless steel probe inserts into the water chamber. The QuickThaw is equipped with a built-in thermometer holder.

Plasma Overwraps

Disposable Helmer Plasma Overwraps protect frozen random and apheresis plasma against contaminants and isolate a broken bag.

Standard Overwraps
(Part No. 400273-1)

Carton of 1000 overwrap bags. Four dispenser boxes of 250 bags each.

Large Overwraps (Part No. 400303-1)

Carton of 250 overwrap bags. For use with DH8 only.

Chamber Cover

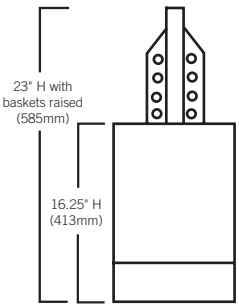
CT2 (Part No. 400769-1)
Cover for use with DH2
CT4 (Part No. 400275-1)
Cover for use with DH4.
CT8 (Part No. 400276-1)
Cover for use with DH8.

CleanBath (Part No. 400348-1)

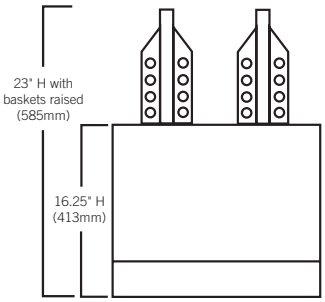
Additive used to inhibit bacterial growth. Each 8 oz. bottle of CleanBath treats approximately 300 gallons of water. Sample bottle (1/2 ounce) is included with each QuickThaw unit.

Thawing Process

Load	Insert plasma into Helmer overwrap bag and load in basket.
Program	Set length of thawing cycle and press the cycle start button.
Agitation	The basket lowers into the water chamber and the agitation cycle begins.
Lift-Out	Upon completion of the programmed cycle, the basket automatically lifts out of the water chamber for easy access.



DH2
Front View



DH4 and DH8
Front View

Median Thaw Times

For plasma stored at -30°C

BAG CONFIGURATION	TIME
250ml flat	10 minutes
300ml flat	14 minutes
250ml flat, thick plastic	16 minutes
250ml folded	17 minutes
500ml flat apheresis	18 minutes

Specifications

Model	Thawing Capacity*	Chamber Volume (gal / liter)	Chamber Material	Baskets	Chamber Drain Time (minutes)	Exterior Dimensions (W x H x D) (in/mm)	Chamber Dimensions (W x H x D) (in/mm)	Electrical	Net Weight
DH2	2 bags	2.2 / 8.5	Stainless Steel	Stainless Steel	1.5	11.25 x 16.25 x 14.75 286 x 413 x 375	8 x 11 x 7.5 204 x 280 x 191	100V / 50Hz / 3A 115V / 50/60Hz / 2.5A 230V / 50/60Hz / 1.25A	38 lb / 18 kg
DH4	4 bags	4.75 / 18	Stainless Steel	Stainless Steel	3	18.5 x 16.25 x 14.75 470 x 413 x 375	15.5 x 11 x 7.5 394 x 280 x 191	100V / 50Hz / 8A 115V / 50/60Hz / 6A 230V / 50/60Hz / 3A	58 lb / 26 kg
DH8	8 bags	8.5 / 32	Stainless Steel	Stainless Steel	5.5	18.5 x 16.25 x 22 470 x 413 x 559	15.5 x 11 x 15 394 x 280 x 381	100V / 50Hz / 11.5A 115V / 50/60Hz / 10A 230V / 50/60Hz / 5A	74 lb / 34 kg

Certified to applicable UL and CSA standards by a NRTL

*Carefully determine usage needs to insure that the appropriate sized unit is purchased.

ISO 13485:2003
FM 536286

Distinctly HELMER

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FAX: +1.317.773.9082 • www.helmerinc.com

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER			
Name of Company		**Address**	**SRN**
Helmer Scientific DBA Helmer Inc.		14400 Bergen Blvd Noblesville IN USA	US-MF-000003326
AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com
PRODUCT IDENTIFICATION			
Product Name	**Code / Catalog Number**		
Plasma Thawer	DH2, DH4, DH8		
Intended Purpose		**Basic UDI-DI**	
Intended to by used by blood banks, hospitals and clinics to decrease the thaw time for fresh frozen plasma. It is NOT INTENDED to warm the plasma prior to infusion.		081639402TFR0036N	
RISK CLASS FOR DEVICES			
Device Classification		**Common Specifications / Standards**	
Class:	I	EN61010-1 2010 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use EN ISO14971:2012 Application of risk management to medical devices EN ISO 15223-2:2012 Medical devices — Symbols to be used with medical device labels EN 62366:2012 Medical Devices – Application of Usability Engineering EN ISO 13485:2016 Medical devices — Quality management systems EN60601-1 Medical electrical equipment – Part 1-2: – Collateral Standard: Electromagnetic disturbances EN1041 Information to be supplied by the manufacturer with medical device	
Rule:	1		

Helmer Scientific declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- RoHS Recast Directive 2011/65/EU including the amendment to Annex II described in Commission Delegated Directive (EU) 2015/863.

COMPANY REPRESENTATIVE: Renee Schultz **SIGNATURE:** 

TITLE: Director of Regulatory Affairs

PLACE: 14400 Bergen Blvd, Noblesville In USA **DATE:** 01 May 2021

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14140-9-2022

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

Name of Manufacturer
HELMER Inc.
14400 Bergen Blvd
NOBLESVILLE, IN USA 46060

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 30, 2022 to September 29, 2024.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14140-9-2022

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

HELMER Inc.
14400 Bergen Blvd
NOBLESVILLE, IN
USA 46060

Name of Product(s)

DH2 Plasma Thawing System
DH4 Plasma Thawing System
DH8 Plasma Thawing System
----------END OF PRODUCT LIST----------

Certificate US22/819944906

The management system of:

Helmer Inc.

14400 Bergen Blvd
Noblesville, IN 46060, United States

has been assessed and certified as meeting the requirements of:

ISO 13485:2016
EN ISO 13485:2016

For the following activities:

Design, development, manufacture, sales and service of biological material storage and processing equipment.

This certificate is valid from 11 February 2022 until 13 April 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 1. Certified since 11 February 2022.
Certified since 4 April 2009 by former Certifying Body.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421

0005

Certificate of Regulatory Compliance

	*On Market**	*Discontinued**
Refrigerators		
Undercounter	iBR105-GX, HBR105-GX, iLR105-GX, HLR105-GX, iPR105-GX, HPR105-GX	iB105, HB105, iLR105, HLR105, SLR105, iB104-ADA, HB104-ADA, iLR104-ADA, HLR104-ADA, SLR104-ADA
Upright	iBR113-GX, HBR113-GX, iLR113-GX, HLR113-GX, iPR113-GX, HPR113-GX, iBR120-GX, HBR120-GX, iLR120-GX, HLR120-GX, iPR120-GX, HPR120-GX, iBR125-GX, HBR125-GX, iLR125-GX, HLR125-GX, iPR125-GX, HPR125-GX, iBR245-GX, HBR245-GX, iLR245-GX, HLR245-GX, iPR245-GX, HPR245-GX, iBR256-GX, HBR256-GX, iLR256-GX, HLR256-GX, iPR256-GX, HPR256-GX,	iB111, HB111, iLR111, HLR111, iPR111, HPR111, iB120, HB120, iLR120, HLR120, iPR120, HPR120, iB125, HB125, iLR125, HLR125, iPR125, HPR125, iB245, HB245, iLR245, HLR245, iPR245, HPR245, iB256, HB256, iLR256, HLR256, iPR256, HPR256
Pass-Thru	iBR226-GX, HBR226-GX, iPR226-GX, HPR226-GX, iBR458-GX, HBR458-GX, iPR458-GX, HPR458-GX	iB225, HB225, iPR225, HPR225, iB456, HB456, iPR456, HPR456
Compartment Access	iBX020, iBX080	
Freezers		
Undercounter (-30°C)	iBF105-GX, HBF105-GX, iLF105-GX, HLF105-GX	iPF105, HPF105, iLF105, HLF105, iPF104-ADA, HPF104-ADA, iLF104-ADA, HLF104-ADA
Upright (-30°C / -35°C)	iBF120-GX, HBF120-GX, iLF120-GX, HLF120-GX iBF125-GX, HBF125-GX, iLF125-GX, HLF125-GX	iPF120, HPF120, iLF120, HLF120, iPF125, HPF125, iLF125, HLF125
ULT (-86°C)	iUF118, iUF126	iUF116, iUF124

Helmer Inc. hereby certifies that the above-mentioned products are manufactured and or procured under a quality system that is compliant with FDA 21CFR Part 820 (GMP), certified to ISO13485:2016 and 93/42/EEC. Our FDA establishment registration number is 2182537. All devices are listed with the FDA and unless exempted, have been cleared for market through the 510k notification process. FDA and AABB requirements for performance are used as design criteria for applicable devices. Our products are certified to applicable safety standards by a Nationally Recognized Testing Laboratory. Each device is labeled with a unique control number. Calibrated instrumentation traceable to NIST standards and ISO17025 is utilized in the design, manufacturing, and inspection processes. Product design, manufacturing, and test records are maintained in accordance with the certified quality management system requirements. **Market status may vary by country*

Director of Regulatory Affairs

September 6, 2022
Date

Certificate of Regulatory Compliance

	*On Market**	*Discontinued**
Platelet Storage Systems		
Platelet Incubators	PC100-Pro, PC900-Pro, PC1200-Pro PC2200i, PC2200h, PC3200i, PC3200h, PC4200i, PC4200h	PC100i, PC100h, PC900i, PC900h, PC1200i, PC1200h
Platelet Agitators	PF15-Pro, PF48-Pro, PF96-Pro, PF96i, PF96h	PF15i, PF15h, PF48i, PF48h
Plasma Thawing Systems	DH2, DH4, DH8 Plasma Thawers DT1 Digital Thermometer accessory	
Cell Washing Systems	UltraCW II	UltraCW

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Director of Regulatory Affairs

September 6, 2022

Date

Helmer 14400 Bergen Boulevard • Noblesville, IN 46060 USA • www.helmerinc.com