

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 be 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