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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	Westervoortedijk 60, 6827 AT, Arnhem, 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**
Electro-mechanical water bath that provides a faster method of thawing plasma than a sink filled with warm water. It is NOT INTENDED to warm the plasma prior to infusion. They are intended to be used by blood supply establishments where regulations require further processing of the plasma prior to infusion. They are non-measuring, non-sterile, and are not intended to be sterilized prior to use.	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:	13	

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.
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COMPANY REPRESENTATIVE: Renee Schultz **SIGNATURE:** 

TITLE: Director of Regulatory Affairs

PLACE: 14400 Bergen Blvd, Noblesville In 46606 USA **DATE:** September 29, 2023