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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**
Platelet Agitator	PF15-Pro, PF48-Pro, PF96-Pro, PF96i, PF96h

Intended Purpose	**Basic UDI-DI**
Helmer platelet agitators are electromechanical devices that provide a side-to-side motion for the purposes of agitating platelets as part of the overall process of manufacturing platelet concentrate. They are intended to be used by blood supply establishments where regulations require further processing of the platelets prior to infusion. They are non-measuring, non-sterile, and are not intended to be sterilized prior to use..	081639402TFR0076W

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	I	IEC61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use — 3rd ed ISO14971:2012 Application of risk management to medical devices ISO 15223-2:2012 Medical devices — Symbols to be used with medical device labels IEC62366:2015 Medical Devices – Application of Usability Engineering 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.

COMPANY REPRESENTATIVE: Renee Schultz **SIGNATURE:**

TITLE: Director of Regulatory Affairs

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