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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	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**		
Platelet Agitator	PF15-Pro, PF48-Pro, PF96-Pro		
Intended Purpose		**Basic UDI-DI**	
Helmer Platelet Agitators are intended to provide the continuous gentle agitation conditions required for the storage of platelet products.		081639402TFR0076W	
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