EC Declaration of Conformity

PRODUCT IDENTIFICATION	Platelet Storage Products
Product name	**Model/number**
Platelet Incubator	PC100i, PC100h, PC900i, PC900h, PC1200i, PC1200h, PC2200i, PC2200h, PC3200i, PC3200h, PC4200i, PC4200h, PC100-Pro, PC900-Pro, PC1200-Pro, PC2200-Pro, PC3200-Pro, PC4200-Pro

MANUFACTURER		
Name of company	**Address**	**Representative**
Helmer Inc.	14400 Bergen Boulevard Noblesville, Indiana 46060 USA	Renee Schultz

REGISTRATION INFORMATION	
Notified Body ID#	**Certificate Number**
BSI 2797	CE 544457

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Westervoortedijk 60 6827 AT, Arnhem The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT	
Device classification	**Route to compliance**
Class IIa Rule 2	Annex V of MDD 93/42/EEC Council Directive as amended by 2007/47/EEC

Helmer Inc. declares that the above-mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices as amended by 2007/47/EEC and Directive 93/42/EEC, RoHS Recast Directive 2011/65/EU including the amendment to Annex II described in Commission Delegated Directive (EU) 2015/863.

COMPANY REPRESENTATIVE: Renee Schultz

TITLE: Director of Regulatory Affairs **SIGNATURE:** 

DATE: September 29, 2023