



## EC Declaration of Conformity

PRODUCT IDENTIFICATION	Platelet Storage Products
<b>Product name</b>	<b>Model/number</b>
Plasma Thawing System	DH2, DH4, DH8

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

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT	
Device classification	Route to compliance
Class I Rule 12	Annex VII 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, and RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in medical devices as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Renee Schultz

**TITLE:** Quality and Regulatory Manager

**SIGNATURE:**

**DATE:** 1 January 2021

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