



## EC Declaration of Conformity

PRODUCT IDENTIFICATION		Platelet Storage Products
Product name	Model/number	
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:**

A handwritten signature in blue ink, appearing to read 'Renee Schultz', written over a light blue horizontal line.

**DATE:** 1 January 2021

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