EC Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Blood Bank Refrigerator	iB105, iBR105-GX, HB105, HBR105-GX, iB111, iBR113-GX, HB111, HBR113-GX, iB120, iBR120-GX, HB120, HBR120-GX, iB125, iBR125-GX, HB125, HBR125-GX, iB225, iBR226-GX, HB225, HBR226-GX, iB245, iBR245-GX, HB245, iB256, iBR256-GX, HB256, HBR256-GX, iB456, iBR458-GX, HB456, HBR458-GX, iBX080, iBX020
Laboratory/Pharmacy Refrigerator	iLR105, iLR105-GX, iPR105, iPR105-GX, HLR105, HLR105-GX, HPR105, HPR105-GX, SLR105, iLR111, iLR113-GX, iPR111, iPR113-GX, HLR111, HLR113-GX, HPR111, HPR113-GX, iLR120, iLR120-GX, iPR120, iPR120-GX, HLR120, HLR120-GX, HPR120, HPR120-GX, iLR125, iLR125-GX, iPR125, iPR125-GX, HLR125, HLR125-GX, HPR125, HPR125-GX, iPR225, iPR226-GX, HPR225, HPR226-GX, iLR245, iLR245-GX, iPR245, iPR245-GX, HLR245, HLR245-GX, HPR245, HPR245-GX, iLR256, iLR256-GX, iPR256, iPR256-GX, HLR256, HLR256-GX, HPR256, HPR256-GX, iPR456, iPR458-GX, HPR456, HPR458-GX
Plasma Freezer	iPF105, iPF120, iPF125, HPF105, HPF120, HPF125, iBF105-GX, HBF105-GX
Laboratory Freezer	iLF105, iLF120, iLF125, HLF105, HLF120, HLF125, ILF105-GX, HLF105-GX

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	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 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:

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

DATE: 1 January 2021