



EC Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
Blood Bank Refrigerator	iBR105-GX, HBR105-GX, iBR113-GX, HBR113-GX, iBR120-GX, HBR120-GX, iBR125-GX, HBR125-GX, iB225, iBR226-GX, HB225, HBR226-GX, iBR245-GX, iBR256-GX, HBR256-GX, iB456, iBR458-GX, HB456, HBR458-GX, iBX080, iBX020	
Laboratory/Pharmacy Refrigerator	iLR105-GX, iPR105-GX, HLR105-GX, HPR105-GX, iLR113-GX, iPR113-GX, HLR113-GX, HPR113-GX, iLR120-GX, iPR120-GX, HLR120-GX, HPR120-GX, iLR125-GX, iPR125-GX, HLR125-GX, HPR125-GX, iPR225, iPR226-GX, HPR225, HPR226-GX, iLR245-GX, iPR245-GX, HLR245-GX, HPR245-GX, iLR256-GX, iPR256-GX, HLR256-GX, HPR256-GX, iPR456, iPR458-GX, HPR456, HPR458-GX	
Plasma Freezer	iBF105-GX, HBF105-GX, iBF120-GX, HBF120-GX, iBF125-GX, HBF125-GX	
Laboratory Freezer	iLF105-GX, HLF105-GX, iLF120-GX, HLF120-GX, iLF125-GX, HLF125-GX	
MANUFACTURER		
Name of company	Address	
Helmer Inc.	14400 Bergen Boulevard, Noblesville, Indiana 46060 USA	
REGISTRATION INFORMATION		
Notified Body	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: Laura DeVault

TITLE: Regulatory Affairs Specialist

SIGNATURE:

DATE: January 1, 2022

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