

# Certificate of Regulatory Compliance

## On Market\*

## Discontinued\*

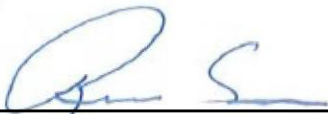
### Refrigerators

<b>Undercounter</b>	iBR105-GX, HBR105-GX, iLR105-GX, HLR105-GX, iPR105-GX, HPR105-GX	iB105, HB105, iLR105, HLR105, SLR105, iB104-ADA, HB104-ADA, iLR104-ADA, HLR104-ADA, SLR104-ADA
<b>Upright</b>	iBR113-GX, HBR113-GX, iLR113-GX, HLR113-GX, iPR113-GX, HPR113-GX, iBR120-GX, HBR120-GX, iLR120-GX, HLR120-GX, iPR120-GX, HPR120-GX, iBR125-GX, HBR125-GX, iLR125-GX, HLR125-GX, iPR125-GX, HPR125-GX, iBR245-GX, HBR245-GX, iLR245-GX, HLR245-GX, iPR245-GX, HPR245-GX, iBR256-GX, HBR256-GX, iLR256-GX, HLR256-GX, iPR256-GX, HPR256-GX,	iB111, HB111, iLR111, HLR111, iPR111, HPR111, iB120, HB120, iLR120, HLR120, iPR120, HPR120, iB125, HB125, iLR125, HLR125, iPR125, HPR125, iB245, HB245, iLR245, HLR245, iPR245, HPR245, iB256, HB256, iLR256, HLR256, iPR256, HPR256
<b>Pass-Thru</b>	iBR226-GX, HBR226-GX, iPR226-GX, HPR226-GX, iBR458-GX, HBR458-GX, iPR458-GX, HPR458-GX	iB225, HB225, iPR225, HPR225, iB456, HB456, iPR456, HPR456
<b>Compartment Access</b>	iBX020, iBX080	

### Freezers

<b>Undercounter (-30°C)</b>	iBF105-GX, HBF105-GX, iLF105-GX, HLF105-GX	iPF105, HPF105, iLF105, HLF105, iPF104-ADA, HPF104-ADA, iLF104-ADA, HLF104-ADA
<b>Upright (-30°C / -35°C)</b>	iBF120-GX, HBF120-GX, iLF120-GX, HLF120-GX, iBF125-GX, HBF125-GX, iLF125-GX, HLF125-GX	iPF120, HPF120, iLF120, HLF120, iPF125, HPF125, iLF125, HLF125
<b>ULT (-86°C)</b>	iUF118, iUF126	iUF116, iUF124

Helmer Inc. hereby certifies that the above-mentioned products are manufactured and or procured under a quality system that is compliant with FDA 21CFR Part 820 (GMP), certified to ISO13485:2016 and 93/42/EEC. Our FDA establishment registration number is 2182537. All devices are listed with the FDA and unless exempted, have been cleared for market through the 510k notification process. FDA and AABB requirements for performance are used as design criteria for applicable devices. Our products are certified to applicable safety standards by a Nationally Recognized Testing Laboratory. Each device is labeled with a unique control number. Calibrated instrumentation traceable to NIST standards and ISO17025 is utilized in the design, manufacturing, and inspection processes. Product design, manufacturing, and test records are maintained in accordance with the certified quality management system requirements. *\*Market status may vary by country*



Director of Regulatory Affairs

September 6, 2022

Date



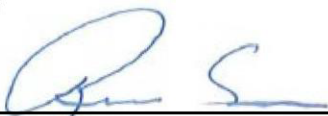
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QSR009/Q

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	<i>On Market*</i>	<i>Discontinued*</i>
<b>Platelet Storage Systems</b>		
<b>Platelet Incubators</b>	PC100-Pro, PC900-Pro, PC1200-Pro PC2200i, PC2200h, PC3200i, PC3200h, PC4200i, PC4200h	PC100i, PC100h, PC900i, PC900h, PC1200i, PC1200h
<b>Platelet Agitators</b>	PF15-Pro, PF48-Pro, PF96-Pro, PF96i, PF96h	PF15i, PF15h, PF48i, PF48h
<b>Plasma Thawing Systems</b>	DH2, DH4, DH8 Plasma Thawers DT1 Digital Thermometer accessory	
<b>Cell Washing Systems</b>	UltraCW II	UltraCW

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