

Certificate of Regulatory Compliance

	<i>On Market*</i>	<i>Discontinued*</i>
Refrigerators		
Undercounter	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
Upright	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
Pass-Thru	iBR226-GX, HBR226-GX, iPR226-GX, HPR226-GX, iBR458-GX, HBR458-GX, iPR458-GX, HPR458-GX	iB225, HB225, iPR225, HPR225, iB456, HB456, iPR456, HPR456
Compartment Access	iBX020-GX, iBX080-GX	iBX020, iBX080
Freezers		
Undercounter (-30°C)	iBF105-GX, HBF105-GX, iLF105-GX, HLF105-GX	iPF105, HPF105, iLF105, HLF105, iPF104-ADA, HPF104-ADA, iLF104-ADA, HLF104-ADA
Upright (-30°C / -35°C)	iBF120-GX, HBF120-GX, iLF120-GX, HLF120-GX iBF125-GX, HBF125-GX, iLF125-GX, HLF125-GX	iPF120, HPF120, iLF120, HLF120, iPF125, HPF125, iLF125, HLF125
ULT (-86°C)	iUF118-GX, iUF126-GX	iUF116, iUF118, iUF124, iUF126

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

January 3, 2024

 Date



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	<i>On Market*</i>	<i>Discontinued*</i>
Platelet Storage Systems		
Platelet Incubators	PC100-Pro, PC900-Pro, PC1200-Pro, PC2200-Pro, PC3200-Pro, PC4200-Pro	PC100i, PC100h, PC900i, PC900h, PC1200i, PC1200h, PC2200i, PC2200h, PC3200i, PC3200h, PC4200i, PC4200h
Platelet Agitators	PF15-Pro, PF48-Pro, PF96-Pro	PF15i, PF15h, PF48i, PF48h, PF96i, PF96h
Plasma Thawing Systems	DH2, DH4, DH8 Plasma Thawers DT1 Digital Thermometer accessory	
Cell Washing Systems	UltraCW II	UltraCW

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