

Certificate of Regulatory Compliance

Plasma Thawers	DH2, DH4, DH8
Digital Thermometer	DT1
Platelet Rotators	PAS20, PAS40
Platelet Incubators	PC100i/h, PC900 i/h, PC1200 i/h, PC2200 i/h PC3200 i/h, PC4200 i/h, PC100-Pro, PC900-Pro, PC1200-Pro PFS396, PF396i
Platelet Agitators	PF/S15, PF15/i/h, PF/S42, PF/S84, PF48i/h, PF96i/h, PF15-Pro, PF48-Pro, PF96-Pro
Refrigerators	Model: iB, HB, iLR, HLR, iPR, HPR, SLR, iBX, iBR, HBR Size: 104, 105, 111, 113, 120, 125, 225, 245, 256, 456, 080, 020, 105-GX, 113-GX
Freezers	Model: iPF, HPF, iLF, HLF, iUF, HBF Size: 104, 105, 120, 125, 116, 118, 124, 126, 105-GX, 113-GX
Cell Washer	UltraCW, UltraCWII

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.

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 is utilized in the design, manufacturing, and inspection processes. Product design, manufacturing, and test records are maintained.



Quality and Regulatory Approval

January 1, 2021

Date

