



U.S. FOOD & DRUG

ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 1855-11-2020

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Three Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

HELMER SCIENTIFIC

14400 Bergen Blvd

NOBLESVILLE, IN USA 46060

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from November 12, 2020 to November 11, 2022.





Certificate No. 1855-11-2020

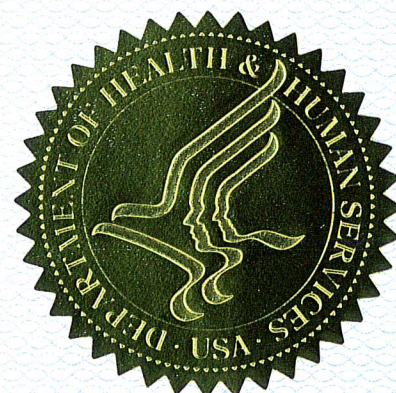
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Name of Manufacturer

HELMER SCIENTIFIC
14400 Bergen Blvd
NOBLESVILLE, IN USA 46060

Name of Product(s)

PF15i Platelet Agitator
PF15h Platelet Agitator
PF15-PRO Platelet Agitator
PF48i Platelet Agitator
PF48h Platelet Agitator
PF48-PRO Platelet Agitator
PF96i Platelet Agitator
PF96h Platelet Agitator
PF96-PRO Platelet Agitator
PC100i Platelet Incubator
PC100h Platelet Incubator
PC100-PRO Platelet Incubator
PC900i Platelet Incubator
PC900h Platelet Incubator
PC900-PRO Platelet Incubator
PC1200i Platelet Incubator
PC1200h Platelet Incubator
PC1200-PRO Platelet Incubator
PC2200i Platelet Incubator
PC2200h Platelet Incubator
PC3200i Platelet Incubator
PC3200h Platelet Incubator
PC4200i Platelet Incubator
PC4200h Platelet Incubator
DH2 Plasma Thawing System
DH4 Plasma Thawing System
DH8 Plasma Thawing System
iLF105 Laboratory Freezer
iLF105-GX Laboratory Freezer
iLF120 Laboratory Freezer
iLF120-GX Laboratory Freezer
iLF125 Laboratory Freezer
iLF125-GX Laboratory Freezer
HLF105 Laboratory Freezer
HLF105-GX Laboratory Freezer
HLF120 Laboratory Freezer
HLF120-GX Laboratory Freezer
HLF125 Laboratory Freezer
HLF125-GX Laboratory Freezer
HLF104-ADA Laboratory Freezer
iLF104-ADA Laboratory Freezer
iPF105 Plasma Freezer
iBF105-GX Plasma Freezer
iPF120 Plasma Freezer
iBF120-GX Plasma Freezer
iPF125 Plasma Freezer
iBF125-GX Plasma Freezer
HPF105 Plasma Freezer
HBF105-GX Plasma Freezer
HPF120 Plasma Freezer
HBF120-GX Plasma Freezer
HPF125 Plasma Freezer

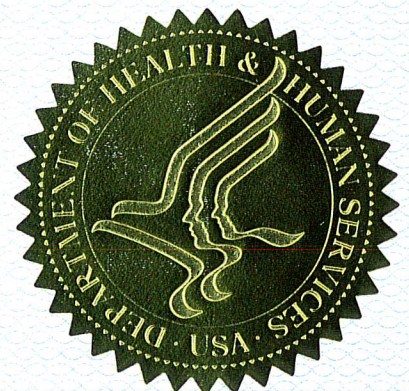




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HBFI25-GX Plasma Freezer
HPFI04-ADA Plasma Freezer
iPF104-ADA Plasma Freezer
iUF116 Ultra-Low Freezer
iUF118 Ultra-Low Freezer
iUF124 Ultra-Low Freezer
iUF126 Ultra-Low Freezer
iLR105 Lab/Pharmacy Refrigerator
iLR105-GX Laboratory Refrigerator
iLR111 Laboratory Refrigerator
iLR113-GX Laboratory Refrigerator
iLR120 Laboratory Refrigerator
iLR120-GX Laboratory Refrigerator
iLR125 Laboratory Refrigerator
iLR125-GX Laboratory Refrigerator
iLR245 Laboratory Refrigerator
iLR245-GX Laboratory Refrigerator
iLR256 Laboratory Refrigerator
iLR256-GX Laboratory Refrigerator
HLR105 Lab/Pharmacy Refrigerator
HLR105-GX Laboratory Refrigerator
HLR111 Laboratory Refrigerator
HLR113-GX Laboratory Refrigerator
HLR120 Laboratory Refrigerator
HLR120-GX Laboratory Refrigerator
HLR125 Laboratory Refrigerator
HLR125-GX Laboratory Refrigerator
HLR245 Laboratory Refrigerator
HLR245-GX Laboratory Refrigerator
HLR256 Laboratory Refrigerator
HLR256-GX Laboratory Refrigerator
SLR105 Lab/Pharmacy Refrigerator
SRL104-ADA Lab/Pharmacy Refrigerator
HLR104-ADA Lab/Pharmacy Refrigerator
iLR104-ADA Lab/Pharmacy Refrigerator
iB105 Blood Bank Refrigerator
iBR105-GX Blood Bank Refrigerator
iB111 Blood Bank Refrigerator
iBR113-GX Blood Bank Refrigerator
iB120 Blood Bank Refrigerator
iBR120-GX Blood Bank Refrigerator
iB125 Blood Bank Refrigerator
iBR125-GX Blood Bank Refrigerator
iB225 Blood Bank Pass-Thru Refrigerator
iBR226-GX Blood Bank Pass-Thru Refrigerator
iB245 Blood Bank Refrigerator
iBR245-GX Blood Bank Refrigerator
iB256 Blood Bank Refrigerator
iBR256-GX Blood Bank Refrigerator
iB456 Blood Bank Pass-Thru Refrigerator
iBR458-GX Blood Bank Pass-Thru Refrigerator
HB105 Blood Bank Refrigerator
HBR105-GX Blood Bank Refrigerator
HB111 Blood Bank Refrigerator
HBR113-GX Blood Bank Refrigerator
HB120 Blood Bank Refrigerator
HBR120-GX Blood Bank Refrigerator
HB125 Blood Bank Refrigerator





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HBR125-GX Blood Bank Refrigerator
HB225 Blood Bank Pass-Thru Refrigerator
HBR226-GX Blood Bank Pass-Thru Refrigerator
HB245 Blood Bank Refrigerator
HBR245-GX Blood Bank Refrigerator
HB256 Blood Bank Refrigerator
HBR256-GX Blood Bank Refrigerator
HB456 Blood Bank Pass-Thru Refrigerator
HBR458-GX Blood Bank Pass-Thru Refrigerator
HB104-ADA Blood Bank Refrigerator
iB104-ADA Blood Bank Refrigerator
iPR105-GX Pharmacy Refrigerator
iPR111 Pharmacy Refrigerator
iPR113-GX Pharmacy Refrigerator
iPR120 Pharmacy Refrigerator
iPR120-GX Pharmacy Refrigerator
iPR125 Pharmacy Refrigerator
iPR125-GX Pharmacy Refrigerator
iPR225 Pharmacy Pass-Thru Refrigerator
iPR226-GX Pharmacy Pass-Thru Refrigerator
iPR245 Pharmacy Refrigerator
iPR245-GX Pharmacy Refrigerator
iPR256 Pharmacy Refrigerator
iPR256-GX Pharmacy Refrigerator
iPR456 Pharmacy Pass-Thru Refrigerator
iPR458-GX Pharmacy Pass-Thru Refrigerator
HPR105-GX Pharmacy Refrigerator
HPR111 Pharmacy Refrigerator
HPR113-GX Pharmacy Refrigerator
HPR120 Pharmacy Refrigerator
HPR120-GX Pharmacy Refrigerator
HPR125 Pharmacy Refrigerator
HPR125-GX Pharmacy Refrigerator
HPR225 Pharmacy Pass-Thru Refrigerator
HPR226-GX Pharmacy Pass-Thru Refrigerator
HPR245 Pharmacy Refrigerator
HPR245-GX Pharmacy Refrigerator
HPR256 Pharmacy Refrigerator
HPR256-GX Pharmacy Refrigerator
HPR456 Pharmacy Pass-Thru Refrigerator
HPR458-GX Pharmacy Pass-Thru Refrigerator

-----END OF PRODUCT LIST-----

