



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. 2043-11-2017

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

(One Page)

Name of Manufacturer/Distributor, Address

Name of Manufacturer/Distributor

MEDICA CORP.
5 OAK PARK DRIVE
BEDFORD, MA USA 01730

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.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from November 13, 2017 to November 12, 2019.





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SAFER, FASTER, HEALTHIER, AND MORE EFFECTIVE HEALTH CARE

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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer/Distributor

MEDICA CORP.
5 OAK PARK DRIVE
BEDFORD, MA USA 01730

Name of Product(s)

Catalog #

7001	EasyStat Analyzer
7002	EasyStat Analyzer
7003	EasyStat Analyzer
7004	EasyStat Analyzer
7005	EasyStat Analyzer
7006	EasyStat Analyzer
7007	EasyStat Analyzer
7008	EasyStat Analyzer
7009	EasyStat Analyzer
7012	EasyStat Analyzer
7013	EasyStat Analyzer
7016	EasyStat Analyzer
7017	EasyStat Analyzer
7015	EasyStat Analyzer
7018	EasyStat Analyzer
7101	EasyStat Reagent Module
6201	EasyStat/EasyBloodGas pH Electrode
6202	EasyStat/EasyBloodGas pCO2 Electrode
6203	EasyStat/EasyBloodGas pO2 Electrode
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode
7205	EasyElectrolyte/EasyStat Na Electrode
7206	EasyElectrolyte/EasyStat K Electrode
7207	EasyStat Ca Electrode
7208	EasyStat Cl Electrode
7301	EasyStat Troubleshooting Kit
6402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution
2118	Daily Cleaning Solution Kit
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control
7309	Bi-Level Hematocrit Quality Control
7603	EasyStat Demonstration Kit
7303	EasyBloodGas/EasyStat Capillary Tube Kit
7306	EasyStat Sampler
7304	EasyStat Pump Tube
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper
7506	EasyStat Sensor Module
6507	EasyStat/EasyBloodGas Valve Module
6508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate
7302	Probe Wipers
6518	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 25-pin
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit

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

