



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. 2039-11-2017

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

Name of Manufacturer/Distributor

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Name of Product(s)

Catalog #

6001	EasyBloodGas Analyzer
6002	EasyBloodGas Analyzer
6003	EasyBloodGas Analyzer
6011	EasyBloodGas Analyzer
6030	EasyBloodGas Analyzer
6050	EasyBloodGas Analyzer
6040	EasyBloodGas Analyzer
6060	EasyBloodGas Analyzer
6061	EasyBloodGas Analyzer
6201	EasyStat/EasyBloodGas pH Electrode
6202	EasyStat/EasyBloodGas pCO ₂ Electrode
6203	EasyStat/EasyBloodGas pO ₂ Electrode
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode
6101	EasyBloodGas Reagent Module
6301	EasyBloodGas Troubleshooting 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
2118	Daily Cleaning Solution
6402	Red Test Dye Solution
6503	EasyBloodGas Capillary Tube Kit
6603	EasyBloodGas Demonstration Kit
6306	EasyBloodGas Sampler
6504	EasyBloodGas/EasyElectrolyte Pump Tube
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper
6506	EasyBloodGas Sensor Module
6507	EasyBloodGas Valve Module
6508	Compression Plate
6518	Serial Cable, 25-pin
6537	Serial Cable, 9-pin
6520	Barcode Reader Kit
7302	Probe Wipers

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

