



Certificate No. 14713-9-2017

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

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

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.

Robin W. Newman MSN EdD CPNP
Director
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 11, 2017 to September 10, 2019.





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Name of Manufacturer

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

Name of Product(s)

Catalog Number

10360	EasyRA Analyzer - ISE & LIS
10340	EasyRA Analyzer - LIS
10990	EasyRA Start-Up Kit, Chemistry
10991	EasyRA Start-Up Kit, Chemistry & ISE
10997	EasyRA Monitor
10998	EasyRA Touch Screen Monitor
10999	EasyRA CPU
10218-4	Albumin Reagent Kit, ALB
10214-4	Alkaline Phosphatase Reagent Kit, ALP
10205-4	Alanine Aminotransferase Reagent Kit, ALT
10217-4	Amylase Reagent Kit, AMY
10206-4	Aspartate Aminotransferase Reagent Kit, AST
10201-4	Glucose Trinder Reagent Kit, GLU-T
10210-4	Calcium Reagent Kit, CA
10204-4	Cholesterol Reagent Kit, CHOL
10211-4	HDL Cholesterol Reagent Kit, HDL
10219-4	Gamma-Glutamyl Transferase Reagent Kit, GGT
10215-4	Lactate Dehydrogenase Reagent Kit, LDH
10213-4	Total Protein Reagent Kit, TP
10202-4	Blood Urea Nitrogen Reagent Kit, BUN
10222-4	Creatine Kinase Reagent Kit, CK
10209-4	Carbon Dioxide Reagent Kit, CO2
10203-4	Creatinine Reagent Kit, CREA
10260-4	Urine Creatinine Reagent Kit, CREA-U
10212-4	Direct Bilirubin Reagent Kit, DBIL
10223-4	Iron Reagent Kit, FE
10200-4	Glucose Hexokinase Reagent Kit, GLU-H
10220-4	Magnesium Reagent Kit, MG
10225-4	Microalbumin Reagent Kit, uALB
10221-4	Phosphorous (Inorganic) Reagent Kit, PHOS
10207-4	Total Bilirubin Reagent Kit, TBIL
10216-4	Triglycerides Reagent Kit, TRIG
10208-4	Uric Acid Reagent Kit, URIC
10224-4	LDL Cholesterol Reagent Kit, LDL
10230-2	HbA1c Reagent Kit, HbA1c
10226-4	Creatine Kinase - MB Reagent Kit, CKMB
10227-4	Lipase Reagent Kit, LIP
10228-4	C-Reactive Protein Reagent Kit, CRP
10229-4	Total Iron Binding Capacity Reagent Kit, TIBC
10280	HbA1c Hemolyzing Solution
10651	Chemistry Calibrator Kit
10652	Urine Creatinine Calibrator Kit
10653	HDL Calibrator Kit
10654	CO2 Calibrator Kit
10655	LDL Calibrator Kit
10656	uALB Calibrator Kit
10657	Total Iron Binding Capacity Calibrator Kit
10658	HbA1c Calibrator Kit
10659	CRP Calibrator Kit
10793	EasyQC Quality Control Kit - Level A
10794	EasyQC Quality Control Kit - Level B





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10795	HbA1c Quality Control Kit - Level 1
10796	HbA1c Quality Control Kit - Level 2
10797	CRP Quality Control Kit - Level 1
10798	CRP Quality Control Kit - Level 2
10799	CRP Quality Control Kit - Level 3
2815	EasyQC Tri-Level Quality Control Kit
10660	Cleaner Kit - Chemistry and ISE
10661	Cleaner Kit - Chemistry
10670	Surfactant Kit
10764	Precision Test Dye Kit
10680	Wash1 Kit Chemistry
5201	Na+ Electrode, ISE Module
5202	K+ Electrode, ISE Module
5204	Reference Electrode, ISE Module
5205	Li+ Electrode, ISE Module
5206	Spacer Electrode, ISE Module
10523	eCl- Electrode, ISE Module
5423-0041	Reagent Pack, Na+/K+/Cl-/Li+, ISE Module
5622	Troubleshooting Kit, ISE Module
5408	ISE Module Urine Diluent (500mL)
5412	ISE Module Urine Diluent (125mL)
2596	Sample Cups (2mL)
10290	Single Reagent Wedge Kit
10295	Dual Reagent Wedge Kit
10299	Reagent Wedge Caps (50)
10531	Pump Tubing Kit, ISE
10700	Cuvette Segments (50)
10729	Tubing - Diluent Bottle
10731	Waste Pump Tubing Kit - Chemistry
10721	Sample Ring A
10722	Sample Ring B
10735	Probe
10724	Wash Cup
10738	Sample Cups - Small Nesting (1mL), 100
10739	Sample Cups - Large Nesting (2mL), 100
10748	Sample Cups - Small Nesting (1mL), 500
10749	Sample Cups - Large Nesting (2mL), 500
10741	Sample Tube Holders - 16mm x 100
10742	Sample Tube Holders - 13mm x 100
10743	Sample Tube Holders - 13mm x 75
10744	Sample Cup Holders
10745	Anti-Evaporation Caps
10725	Reagent Tray - Vented
10726	Reagent Tray Cover - Open
10727	Reagent Tray Cover - Closed
10730	Air Filter Replacement
10732	Waste Bottle
10733	Diluent Bottle
10734	Diluent/Waste Bottle Rack
10736	Tubing - External Waste Bottle - Chemistry and ISE
10737	Tubing - External Waste Bottle - Chemistry
10820	USB Connection Cable
10821	RS-232 Cable
10822	Fuses

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

