



**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. 8914-4-2018**

**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/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 April 06, 2018 to April 05, 2020.**







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**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2**

**Name of Manufacturer/Distributor**

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

**Name of Product(s)**

**Catalog #**

2004	EasyLyte Na/K Analyzer
2014	EasyLyte Plus Na/K/Cl Analyzer
2015	EasyLyte Lithium Na/K/Li Analyzer
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer
2021	EasyLyte Na/K/Cl/Li Analyzer
2070	EasyLyte EasySampler
2030	EasyLyte EXPAND Na/K/Cl/Ca/Li Analyzer
C2004	EasyLyte Na/K Analyzer
C2014	EasyLyte Plus Na/K/Cl Analyzer
C2015	EasyLyte Lithium Na/K/Li Analyzer
C2016	EasyLyte Calcium Na/K/Ca/pH Analyzer
L2014	EasyLyte Plus Na/K/Cl Analyzer
L2015	EasyLyte Lithium Na/K/Li Analyzer
L2016	EasyLyte Calcium Na/K/Ca/pH Analyzer
L2021	EasyLyte Na/K/Cl/Li Analyzer
2028	EasyLyte Na/K/Cl/Li Solutions Pack, 400mL
2026	EasyLyte Na/K/Cl/Li Solutions Pack, 800mL
2109	EasyLyte Na/K Solutions Pack, 400mL
2120	EasyLyte Na/K Solutions Pack, 800mL
2112	EasyLyte Na/K/Cl Solutions Pack, 400mL
2121	EasyLyte Na/K/Cl Solutions Pack, 800mL
2115	EasyLyte Na/K/Li Solutions Pack, 400mL
2122	EasyLyte Na/K/Li Solutions Pack, 800mL
2114	EasyLyte Na/K/Ca/pH Solutions Pack, 400mL
2123	EasyLyte Na/K/Ca/pH Solutions Pack, 800mL
2124	EasyLyte Na/K/Cl/Ca/Li Solutions Pack, 800mL
L2028	EasyLyte Na/K/Cl/Li Solutions Pack, 400mL
L2026	EasyLyte Na/K/Cl/Li Solutions Pack, 800mL
L2112	EasyLyte Na/K/Cl Solutions Pack, 400mL
L2121	EasyLyte Na/K/Cl Solutions Pack, 800mL
L2115	EasyLyte Na/K/Li Solutions Pack, 400mL
L2122	EasyLyte Na/K/Li Solutions Pack, 800mL
L2114	EasyLyte Na/K/Ca/pH Solutions Pack, 400mL
L2123	EasyLyte Na/K/Ca/pH Solutions Pack, 800mL
2074	Sample Cup Retainer Ring
2076	Sample Tray
2095	EasyLyte Maintenance Kit
2100	EasyLyte Calcium Tubing Kit
2101	EasyLyte K+ Electrode
2102	EasyLyte Na+ Electrode
2103	EasyLyte Reference Electrode
2104	EasyLyte Tubing Kit
2105	EasyLyte Quarterly Operating Kit
2106	EasyLyte Li+ Electrode
2107	EasyLyte Sample Probe
2108	EasyLyte Solutions Valve
2111	Urine Diluent (500mL)
2113	EasyLyte Cl- Electrode
2118	Daily Cleaning Solution Kit
2150	EasyLyte Ca++ Electrode
2151	EasyLyte pH Electrode





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**Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2**

2152	EasyLyte Disposable Reference Electrode
2257	EasyLyte Sample Detector
2258	EasyLyte Membrane Assembly
2292	EasyLyte Capillary Adapter Cleaning Kit
2293	Capillary Tubes
2309	Wash Solution (50mL)
2323	EasyLyte Probe Wipers (6 ct.)
2492	EasyLyte Internal Filling Solution (125mL)
2541	EasyLyte Printer Paper (3 rolls)
2544	EasyLyte C Series Printer Paper (5 rolls)
2571	Calcium Troubleshooting Kit
2572	Troubleshooting Kit
2577	Standard Urine Solution (50mL)
2578	Red Test Dye Solution (50mL)
2590	EasyLyte Capillary Adapter Kit
2595	500µL Sample Cups (500 ct.)
2596	2mL Sample Cups (500 ct.)
10745	Anti-Evaporation Caps (500 ct.)
2598	EasyLyte Daily Cleaner Cup
2814	Bi-Level Quality Control Kit
2815	Tri-Level Quality Control Kit
2843	Quality Control Sample Cups (60 ct.)
7118	Daily Rinse/Cleaning Solution Kit

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

