



Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity


Product Name:

EasyLyte Analyzer and accessories per attachment

Model/Type:

Na/K, Na/K/Cl, Na/K/Li,
Na/K/Cl/Li, Na/K/Ca/pH,
Na/K/Cl/Ca/Li

Manufacturer

 Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA
Single Registration Number (SRN): US-MF-000037250

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
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Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and their corresponding amendments.

Place and Date: Bedford, Massachusetts, USA, 26 May 2022

Signature:



Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs



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Catalog No.	EasyLyte Analyzer and Accessories	EDMA Code	Class
2004	EasyLyte Analyzer, Na/K	21 07 11 02	General IVD device, not listed in IVDD Annex II and not intended for self-testing
2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
2021	EasyLyte Analyzer, Na/K/Cl/Li	21 07 11 02	
2030	EasyLyte Analyzer, Na/K/Cl/Ca/Li	21 07 11 02	
C2004	EasyLyte Analyzer, Na/K	21 07 11 02	
C2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
C2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
C2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
C2030	EasyLyte Analyzer, Na/K/Cl/Ca/Li	21 07 11 02	
L2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
L2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
L2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
L2021	EasyLyte Analyzer, Na/K/Cl/Li	21 07 11 02	
2101	EasyLyte K+ Electrode	11 04 01 06	
2102	EasyLyte Na+ Electrode	11 04 01 07	
2103	EasyLyte Reference Electrode	11 04 04 01	
2113	EasyLyte Cl- Electrode	11 04 01 03	
2106	EasyLyte Lithium Electrode	11 04 01 04	
2150	EasyLyte Ca++ Electrode	11 04 01 02	
2151	EasyLyte pH Electrode	11 70 31 02	
2152	EasyLyte Disposable Reference Electrode	11 04 04 01	
2109	EasyLyte Solutions Pack, 400mL	11 04 04 02	
2120	EasyLyte Solutions Pack, 800mL	11 04 04 02	
2112	EasyLyte Plus Solutions Pack, 400mL	11 04 04 02	
2121	EasyLyte Plus Solutions Pack, 800mL	11 04 04 02	
2115	EasyLyte Lithium Solutions Pack, 400mL	11 04 04 02	
2122	EasyLyte Lithium Solutions Pack, 800mL	11 04 04 02	
2114	EasyLyte Calcium Solutions Pack, 400mL	11 04 04 02	
2123	EasyLyte Calcium Solutions Pack, 800mL	11 04 04 02	
2026	EasyLyte Na/K/Cl/Li Solutions Pack, 800mL	11 04 04 02	
2028	EasyLyte Na/K/Cl/Li Solutions Pack, 400mL	11 04 04 02	
2124	EasyLyte Na/K/Cl/Ca/Li Solutions Pack, 800mL	11 04 04 02	



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Catalog No.	EasyLyte Analyzer and Accessories	EDMA Code	Class
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04	General IVD device, other than listed in IVDD Annex II and other than intended for self-testing
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04	
L2026	EasyLyte Solutions Pack, Na/K/Cl/Li, 800mL	11 04 04 02	
L2112	EasyLyte Solutions Pack, Na/K/Cl, 400mL	11 04 04 02	
L2121	EasyLyte Solutions Pack, Na/K/Cl, 800mL	11 04 04 02	
L2122	EasyLyte Solutions, Na/K/Li Pack, 800mL	11 04 04 02	
L2123	EasyLyte Solutions Pack, Na/K/Ca/pH, 800mL	11 04 04 02	