

MEDICA

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
Tel: +31 70 345 8570
Fax: +31 70 346 7299

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 IVD 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	

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Declaration of Conformity

Product Name:

EasyLyte consumables and accessories per attachment

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
Single Registration Number (SRN): NL-AR-000000116
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the Class A products listed are in conformity with the provisions of Regulation (EU) 2017/746 In Vitro Diagnostic Medical Devices. These products are classified as class A IVDR devices based on Rule 5, ANNEX VIII Regulation (EU) 2017/746. In addition, they are in conformity with the Annex I, "General Safety and Performance Requirements" and provisions of regulation of (EU) 2017/746 for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, REACH (1907/2006EC), 1272/2008/EC CLP and the corresponding national laws of the Member States.

Medica Corporation is solely responsible for the contents of this document.

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

Signature:



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



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List of Consumables and Accessories

Catalog No.	Products	EDMA Code	Intended Use	Basic UDI	Class
2070	EasyLyte Easysampler	21 07 11 02	Used for automated batch sampling of serum, plasma or diluted urine on the analyzer	0379497ELNAKCL26	A
2095	EasyLyte Maintenance Kit	21 07 11 02	Used to perform routine maintenance on the EasyLyte analyzers	0379497ELNAKCLCALIQZ	A
2100	EasyLyte Calcium Tubing Kit	21 07 11 02	Used to move patient sample from the probe to the electrode stack for sample analysis on the analyzer	0379497ELNAKCAPHJM	A
2104	EasyLyte Tubing Kit	21 07 11 02	Used to move patient sample from the probe to the electrode stack for sample analysis on the analyzer	0379497ELNAKCLCALIQZ	A
2105	EasyLyte Quarterly Operating Kit	21 07 11 02	Used to perform quarterly maintenance on the analyzer	0379497ELNAKCLCALIQZ	A
2107	EasyLyte Sample Probe	21 07 11 02	Used to aspirate samples for patient analysis	0379497ELNAKCL26	A
2108	EasyLyte Solutions Valve	21 07 11 02	Used to retrieve solutions from the EasyLyte analyzer solution packs	0379497ELNAKCL26	A
2111	EasyLyte Urine Diluent, 500 mL	11 04 04 90	Used to dilute urine samples in patient analysis	0379497ELNAKCLCALIQZ	A
2118	EasyLyte/EasyStat/EasyBloodGas /EasyElectrolytes Daily Rinse/ Cleaning Solution Kit	11 01 01 27	Used to remove protein deposits that have built up on the electrodes in the flow path	0379497ELNAKCLCALIQZ	A
2257	EasyLyte Sample Detector	21 07 11 02	Used during the analysis of patient samples	0379497ELNAKCL26	A
2258	EasyLyte Membrane Assembly	21 07 11 02	Used during patient sample analysis on the EasyLyte analyzer	0379497ELNAKCL26	A
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02	Used to analyze patient samples in capillary mode on the EasyLyte analyzers	0379497ELNAKCL26	A
2293	EasyLyte Capillary Tubes	21 07 11 02	Used to analyze patient samples in capillary mode	0379497ELNAKCLCALIQZ	A
2309	EasyLyte Wash Solution, 50mL	11 04 04 90	Used to clean the electrode flow path on the analyzer	0379497ELNAKCLCALIQZ	A
2323	EasyLyte Probe Wipers	21 07 11 02	Used to remove excess sample material from the probe	0379497ELNAKCL26	A
2492	EasyLyte Internal Filling Solution	11 04 04 90	Used to fill the electrode housing on the Na/K, Na/K/Cl and Na/K/Li analyzer	0379497ELNAKCL26	A
2541	EasyLyte Printer Paper	21 07 11 02	Used to print sample results performed on the analyzer	0379497ELNAKCLCALIQZ	A
2544	EasyLyte C Series Printer Paper	21 07 11 02	Used to print sample results performed on the analyzer	0379497ELNAKCLCALIQZ	A
2571	EasyLyte Troubleshooting Kit	21 07 11 02	Used to troubleshoot the Na/K/Cl/Ca/pH analyzers	0379497ELNAKCLCALIQZ	A
2572	EasyLyte Troubleshooting Kit	21 07 11 02	Used to troubleshoot the analyzer	0379497ELNAKCLCALIQZ	A
2577	EasyLyte Standard Solution, Urine	11 04 04 90	Used to analyze the performance of the EasyLyte analyzer in urine mode	0379497ELNAKCLCALIQZ	A
2578	EasyLyte Red Dye Test Solution	11 30 01 11	Used to troubleshoot fluid flows issues on the EasyLyte Analyzer	0379497ELNAKCLCALIQZ	A
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02	Used to perform a cleaning cycle in capillary mode	0379497ELNAKCL26	A
2595	EasyLyte EasySampler Sample Cups	21 07 11 02	Used to hold patient samples	0379497ELNAKCL26	A



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Catalog No.	Products	EDMA Code	Intended Use	Basic UDI	Class
2596	EasyLyte Sample Cup	21 07 11 02	Used to hold patient samples	0379497ELNAKCLCALIQZ	A
2598	EasyLyte Daily Cleaner Cup	21 07 11 02	Used to hold daily cleaning solution when using the EasySampler	0379497ELNAKCLCALIQZ	A
2843	EasyLyte QC Sample Cups	21 07 11 02	Used to hold patient samples	0379497ELNAKCLCALIQZ	A
2934	EasyLyte Barcode Reader Kit	21 07 11 02	Used to read the barcodes	0379497ELNAKCLCALIQZ	A
7118	EasyLyte Calcium/EasyLyte Expand Daily Rinse/Cleaning Solution Kit	11 01 01 27	Used to remove protein deposits from the fluid and sensor paths on the Ca/pH analyzer.	0379497ELNAKCLCALIQZ	A

References of common specifications and/or technical standards applied for this declaration of conformity, or parts thereof:

No.	Title
EN ISO 13485:2016 EN ISO 13485:2016+AC2018	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 15223-1:2021	Symbols to be used with medical devices labels
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 14971:2019	Application of risk management to medical devices
EN 23640:2011	Stability testing of in vitro diagnostic reagents
EN ISO EC17050-1: 2004	Conformity assessment. Supplier's declaration of conformity.
EN ISO 18113-2: 2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 2: In vitro diagnostic reagents for professional use.

EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Sorocouci Sergiu
Of Global Biomarketing Group
has completed training for the operation and service of the
EasyLyte, EasyBloodGas, and EasyStat analyzers.

November 25, 2004

Date



MEDICA

Randall Rollins

*Signed: Randall Rollins
Technical Service Manager*