

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number:

MD 69326

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



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

Products For Health Care

Declaration of Conformity

Product Name:

EasyLyte and accessories per attachment

EasyElectrolyte and accessories per attachment

EasyStat and accessories per attachment

EasyBloodGas and accessories per attachment

Model/Type:

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

EasyElectrolyte Na/K/Cl, Na/K/Li

pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct

pH/pCO2/pO2

Manufacturer

 Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

 Emergo Europe, Molenstraat 15
NL-2513 BH 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 in conformity with the Annex III, essential requirements and provisions of council Directive: 98/79/EC

Place and Date: Bedford, Massachusetts, USA, March 1, 2012

Signature:



Name: Photios Makris

Title: Director of Regulatory Affairs

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO ₂ Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO ₂ Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 10
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution Kit	11 01 01 27
6402	Red Test Dye Solution	11 70 31 90
6503	EasyBloodGas Capillary Tube Kit	21 04 10 01
6603	EasyBloodGas Demonstration Kit	21 04 10 01
6306	EasyBloodGas Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
6506	EasyBloodGas Sensor Module	21 04 10 01
6507	EasyStat/EasyBloodGas Valve Module	21 04 10 01
6508	Compression Plate	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 04 10 01
7309	Bi-Level Hematocrit Quality Control	13 01 70 03
7603	EasyStat Demonstration Kit	21 04 10 01
7303	EasyStat/EasyBloodGas Capillary Tube Kit	21 04 10 01
7306	EasyStat Sampler	21 04 10 01
7304	EasyStat Pump Tube	21 04 10 01
7506	EasyStat Sensor Module	21 04 10 01
7302	Probe Wipers	21 04 10 01

EasyElectrolyte Accessories

Catalog No.	Accessory	EDMA Code
4102	EasyElectrolyte Reagent Module Na/K/Cl	11 03 01
4103	EasyElectrolyte Reagent Module Na/K/Li	11 03 01
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
4203	EasyElectrolyte Cl Electrode	11 04 01 03
4204	EasyElectrolyte Li Electrode	11 04 01 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	Red Test Dye Solution	11 70 31 90
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Demonstration Kit, Na/K/Cl	21 04 10 01
4406	EasyElectrolyte Demonstration Kit, Na/K/Li	21 04 10 01
4404	EasyElectrolyte Capillary Tube Kit	21 04 10 01
4306	EasyElectrolyte Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
4506	EasyElectrolyte Sensor Module	21 04 10 01
4507	EasyElectrolyte Valve Module	21 04 10 01
4508	Compression Plate	21 04 10 01
7302	Probe Wipers	21 04 10 01
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 04 10 01
4539	EasyElectrolyte Sensor Module, Li	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2070	EasyLyte EasySampler	21 04 10 01
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ 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
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 04 10 01
2120	EasyLyte Na/K 800mL Solutions Pack	11 03 01
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 03 01
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 03 01
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 03 01
2028	EasyLyte Na/K/Cl/Li 800mL Solutions Pack	11 03 01
2109	EasyLyte Na/K 400mL Solutions Pack	11 03 01
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 03 01
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 03 01
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 03 01
2026	EasyLyte Na/K/Cl/Li 400mL Solutions Pack	11 03 01
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 04 10 01
2108	EasyLyte Solutions Valve	21 04 10 01
2107	EasyLyte Sample Probe	21 04 10 01
2257	EasyLyte Sample Detector	21 04 10 01
2104	EasyLyte Tubing Kit	21 04 10 01
2100	EasyLyte Calcium Tubing Kit	21 04 10 01
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 04 10 01
2541	EasyLyte Printer Paper (3 rolls)	21 04 10 01

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 04 10 01
2596	EasyLyte Sample Cups 2.0mL (500)	21 04 10 01
10745	Anti-Evaporation Caps (500)	21 04 10 01
2293	EasyLyte Capillary Tubes	21 04 10 01
2590	EasyLyte Capillary Adaptor Kit	21 04 10 01
2292	EasyLyte Capillary Adaptor Cleaning Kit	11 04 04 90
2578	EasyLyte Red Dye Test Solution (50mL)	11 04 04 90
2572	EasyLyte Troubleshooting Kit	21 04 10 01
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 04 10 01
2105	EasyLyte Quarterly Operating Kit	21 04 10 01
2095	EasyLyte Maintenance Kit	21 04 10 01
2076	EasyLyte Sample Tray	21 04 10 01
2074	EasyLyte Sample Cup Retainer Ring	21 04 10 01
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 04 10 01



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



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

Catalog No.	EasyLyte Analyzer and Accessories	EDMA Code	Class
2004	EasyLyte Analyzer, Na/K	21 07 11 02	General IVD device, not listed in IVD 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	



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

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	



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 consumables and accessories per attachment

Manufacturer

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

Representative

 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



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

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



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

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.

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
TPHA Microtitre plate kit	043100A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.



Eddy Velthuis
Technical Director

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number:

MD 69326

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Declaration of Conformity

helena
Biosciences Europe

HL-7-0135DC DOI 2015/07 (7)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 28 Jul 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

helena
Biosciences Europe

HL-7-0137DC DOI 2015/07 (7)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

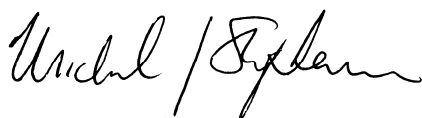
Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 28 Jul 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

helena
Biosciences Europe

HL-7-0138DC DOI 2015/07 (7)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

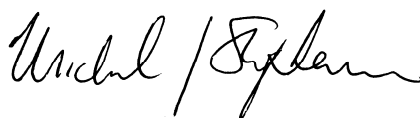
Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 28 Jul 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

helena
Biosciences Europe

HL-7-0511DC DOI 2015/08 (4)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

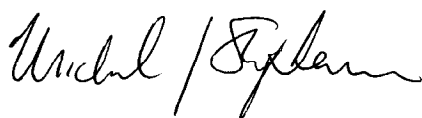
Product Code	Description	GMDN Classification Code
5376	Clauss Fibrinogen 100	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 12 Aug 2015

Tel +44 (0)191 482 8440

Fax +44 (0)191 482 8442

info@helena-biosciences.com

www.helena-biosciences.com

Helena Biosciences Europe

Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,

United Kingdom

Declaration of Conformity

helena
Biosciences Europe

HL-7-0660DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

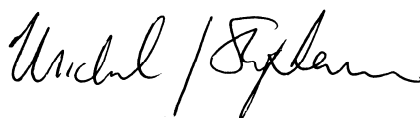
Product Code	Description	GMDN Classification Code
5267	Thromboplastin LI	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

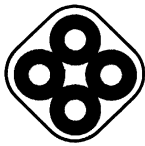
Signed:



Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom



LORNE LABORATORIES LTD. MAREA BRITANIE



KIT DE HEMAGLUTINARE PE PLACĂ DE MICROTITRU INSTRUCȚIUNI DE UTILIZARE

Kit placă de microtitru TPHA: Pentru determinarea calitativă a *Treponema pallidum*.

REZUMAT

Sifilisul este o boală venerică provocată de microorganismul spirochetă *Treponema pallidum*. Întrucât acest organism nu poate fi cultivat în mediul artificial, diagnosticarea sifilisului depinde de corelarea datelor clinice cu anticorpii specifici demonstrați prin teste serologice. Există două tehnici diferite de detectare a sifilisului. Testele TPHA pentru detectarea anticorpilor la *Treponema pallidum* și testele serologice non-treponemice, pentru detectarea unei substanțe asemănătoare anticorpului la persoanele infectate numită reagină.

SCOPUL PROPUȘ

Acesta este un reactiv de test latex pentru determinarea calitativă și semicantitativă a prezenței sau absenței anticorpilor T. pallidum în serul sau plasma pacienților în cazul testării conform tehnicilor recomandate și prezentate în aceste instrucțiuni de utilizare.

PRINCIPIUL

TPHA (Testul de hemaglutinare a Treponemei Pallidum) este un test de hemaglutinare indirect pentru detectarea calitativă și semicantitativă a anticorpilor T. Pallidum specifici în serul uman. Eritrocitele aviare stabilizate, sensibilizate cu o soluție T. Pallidum antigenică, aglutinează în prezența anticorpilor T. Pallidum pentru a conferi un model caracteristic. Neaglutinarea indică, în general, absența anticorpilor (consultați **Limitări**).

DESCRIEREA KITULUI

Kitul TPHA Lorne detectează anticorpii la T. pallidum. Celulele de testare sunt eritrocite aviare conservate acoperite cu componente antigenice ale T. pallidum patogen (tulpina Nichols). Orice reacții nespecifice sunt detectate cu ajutorul celulelor martor; eritrocite aviare neacoperite cu antigene T. pallidum. Reacțiile nespecifice pot fi, de asemenea, eliminate prin absorbție cu ajutorul celulelor martor. Anticorpii la treponemele nepatogenice sunt absorbiți de un extract din treponemele Reiter în suspensia de celule. Reactivul nu conține sau nu sunt compuse din substanțe CMR, substanțe perturbatoare pentru sistemul endocrin sau care ar putea provoca sensibilizare sau o reacție alergică în cazul utilizatorului. Reactivii sunt furnizați la diluarea optimă pentru utilizare cu toate tehnicile recomandate fără să fie necesară diluarea sau adăugarea suplimentară. Pentru numărul de referință al lotului și data de expirare, consultați **Eticheta flaconului**.

DEPOZITARE

Toate componentele kitului vor rămâne stabile până la data de expirare imprimată pe etichetă, când sunt depozitate bine închise la 2-8 °C și este prevenită contaminarea în timpul utilizării. A nu se congela: reactivii congelați ar putea modifica funcționalitatea testului. Depozitați flacoanele în poziție verticală. Depozitarea în poziție orizontală poate provoca aglomerări de celule. În cazul modificării poziției, amestecați ușor pentru a dizolva eventualele agregate prezente.

Deteriorarea reactivilor: Prezența aglomerărilor, particulelor și turbidității.

SPECIMENE

Ser sau plasmă proaspătă. Stabile 8 zile la 2-8 °C sau 3 luni la -20 °C.

Probleme care prezintă fibrină trebuie centrifugate înainte de testare. Nu utilizați probe intens hemolizate sau lipemice.

PRECAUȚII

1. Kitul este destinat exclusiv pentru diagnosticare *in-vitro*.
2. Nu utilizați kitul după data de expirare (consultați **Eticheta de pe flacon și de pe cutie**).
3. Purați echipament de protecție când manipulați reactivii, cum ar fi mănuși de unică folosință și un halat de laborator.
4. Reactivii din acest kit au fost procesați pentru a reduce încărcătura biologică, dar nu sunt livrați sterili. După

deschiderea flaconului, conținutul ar trebui să rămână viabil până la data de expirare.

5. Nu se cunosc teste care să garanteze faptul că produsele derivate din surse umane sau animale nu prezintă agenți infecțioși. Fiți atenți când utilizați și când eliminați un flacon și conținutul acestuia.

ELIMINAREA REACTIVULUI DIN KIT ȘI CUM SE ACȚIONEAZĂ ÎN CAZ DE STROPIRE

Pentru informații privind eliminarea reactivului din kit și metodele de decontaminare a unui loc în caz de stropire, consultați **Fișele cu date de securitate ale materialului**, disponibile la cerere.

MARTORI ȘI RECOMANDĂRI

1. Se recomandă testarea în paralel a martorilor pozitivi și negativi TPHA cu fiecare lot de teste. Testele trebuie considerate nevalide dacă probele martor nu prezintă rezultatele prevăzute.
2. Înainte de utilizare, trebuie să așteptați ca reactivii să ajungă la 18-25 °C.
3. Evitați contaminarea reactivilor sau serului cu salivă, deoarece aceasta va determina rezultate fals pozitive la specimene.
4. Nu schimbați între ele componentele de la diferite kituri.
5. Utilizarea kitului și interpretarea rezultatelor trebuie efectuate de personal calificat și instruit în mod corespunzător în conformitate cu cerințele țării în care se utilizează kitul, iar utilizatorul trebuie să stabilească în ce măsură se poate utiliza kitul în alte tehnici.

COMPONENTELE KITULUI FURNIZATE

- 1) R1: Celule de testare (Capac galben, 1x7,5 ml): Eritrocite aviare stabilizate, sensibilizate cu antigene T. Pallidum (Nichols), conservant, pH 7,2.
- 2) R2: Celule martor (Capac verde, 1x7,5 ml): Suspensie stabilizată de eritrocite aviare, conservant, pH, 7,2.
- 3) R3: Diluant TPHA (Capac alb, 2x10 ml): Soluție salină tampon fosfat, pH 7,2, extract T. pallidum (Reiter), conservant.
- 4) Martor + (Capac roșu, 1x1 ml): Ser uman imun prediluat 1:20, conservant.
- 5) Martor - (Capac albastru, 1x1 ml): Ser animal, conservant.

MATERIALE ȘI ECHIPAMENTE CARE SUNT NECESARE, DAR NU SUNT FURNIZATE

- a) Pipete de precizie.
- b) Plăci de microtitru cu godeuri în formă de U.

TEHNICA DE EVALUARE CALITATIVĂ

1. Așteptați ca reactivii și proba să ajungă la temperatura camerei.
2. Agitați ușor, însă temeinic, flacoanele cu celulele de testare și martor chiar înainte de utilizare.
3. Diluați proba 1:20 cu diluant (10 µl ser + 190 µl diluant (R3)).
4. Pipetați în godeurile alăturate ale plăcii de microtitru:

	Godeu de testare	Godeu martor
Probă 1:20 sau martor*	25 µl	25 µl
Celule martor	--	75 µl
Celule de testare	75 µl	--

*Pentru fiecare martor pozitiv sau martor negativ ori probă de la pacient testată, este necesar câte 1 godeu de testare și 1 godeu martor.

5. Amestecați bine placa de microtitru până când obțineți o probă/celule omogenă(e).
6. Acoperiți placa de microtitru și incubați la temperatura camerei timp de 45-60 min. Țineți placa departe de microtitru de vibrații, căldură și lumina directă a soarelui.
7. Examinați macroscopic modelele de aglutinare a celulelor.

TEHNICA DE EVALUARE SEMICANTITATIVĂ

1. Fiecare specimen necesită 8 godeuri ale unei plăci de microtitru, etichetate de la A la H.
2. Puneți 25 µl de diluant în godeurile B până la H inclusiv.
3. Transferați 25 µl din proba diluată 1:20, în cadrul **Tehnicii de evaluare calitativă** de mai sus, în godeurile A și B.
4. Luați 25 µl de probă diluată din godeul B și dublați diluțiile probei din godeurile B până la H inclusiv, eliminând 25 µl de probă diluată din godeul H.
5. Adăugați 75 µl de celule de testare în godeurile A până la H inclusiv.
6. Agitați ușor placa de microtitru pentru a amesteca bine conținutul.
7. Acoperiți placa de microtitru și incubați la temperatura camerei timp de 45-60 min. Țineți placa de microtitru departe de vibrații, căldură și lumina directă a soarelui.
8. Examinați macroscopic modelele de aglutinare a celulelor.

INTERPRETAREA REZULTATELOR

Citiți rezultatele comparând modelele de aglutinare a celulelor de testare cu cele ale celulelor martor. Valorile sunt evaluate și raportate după următoarele criterii:

Grad de hemaglutinare	Valoare	Rezultat
Strat fin de celule care acoperă complet fundul godeului, uneori cu margini plate	4+	Reactiv
Strat fin de celule care acoperă parțial fundul godeului	3+	Reactiv
Strat fin de celule înconjurat de un cerc roșu	2+	Reactiv
Strat fin de celule care acoperă o suprafață mai mică și este înconjurat de un cerc roșu mai mic	1+	Reactiv
Buton de celule cu o gaură mică în mijloc	±	Borderline
Un buton definit și compact de celule, uneori cu o gaură foarte mică în mijloc.	-	Negativ

INTERPRETAREA REZULTATELOR

1. Martorul negativ nu trebuie să prezinte niciun semn de aglutinare, nici la celulele de testare, nici la cele martor.
2. Martorul pozitiv trebuie să prezinte modele de aglutinare numai la celulele de testare.
3. Orice model de aglutinare afișat de celulele martor indică prezența unor anticorpi nespecfici și nu poate fi interpretat.
4. Probele cu un model borderline (de graniță) trebuie retestate și raportate ca negative dacă este reprodus același model.
5. Probele reactive trebuie eliminate la titrare după cum se arată la tehnica de evaluare semicantitativă de mai sus. Titru serului este definit drept cel mai înalt grad de diluare care prezintă un rezultat reactiv.
6. Diagnosticul clinic nu trebuie efectuat pe baza rezultatului unui singur test, ci trebuie să integreze atât date clinice, cât și de laborator.

LIMITĂRI

1. Întrucât acest kit nu poate face distincție între sifilis și alte infecții treponemale patogene, de ex. Yaws, trebuie analizate întotdeauna dovezile clinice. Se recomandă ca toate rezultatele pozitive să fie confirmate printr-o metodă alternativă, cum ar fi FTA-ABS.
2. Kitul TPHA Syphilis Lorne are un înalt grad de specificitate, dar au fost semnalate rezultate fals pozitive la probe de la pacienți cu mononucleoză, lepră, borelioză, boli autoimune și toxicomanie.
3. Testul TPHA nu este util în stabilirea eficienței terapiei, deoarece nivelul de anticorpi se păstrează (ceea ce ar indica un rezultat pozitiv la test) un anumit timp după ce bolnavul este declarat vindecat din punct de vedere clinic.
4. Rezultatele fals pozitive sau fals negative pot fi provocate și de:
 - Contaminarea materialelor folosite în testare
 - Depozitarea necorespunzătoare a materialelor de testare sau omiterea reactivului
 - Abaterea de la tehnicile recomandate

CARACTERISTICI DE PERFORMANȚĂ SPECIFICE

1. Kitul a fost caracterizat prin procedurile menționate în **Tehnici recomandate**.

2. Înainte de a fi pus pe piață, fiecare lot de TPHA Syphilis Kit Lorne este testat conform **Tehnicilor recomandate** pentru a se asigura reactivitatea adecvată.
3. Bilirubina (≤ 20 mg/dl), hemoglobina (≤ 10 g/l), lipidele (≤ 10 g/l) și factorii reumatoizi (≤ 300 IU/ml) nu afectează rezultatele. Alte substanțe pot influența rezultatele¹.
4. **Sensibilitate analitică:** 0,1 IU/ml, testat conform Primului standard internațional pentru plasma sifilizată umană IgG și IgM, codul NIBSC 05/132.
5. **Efect de prozonă:** Nu a fost detectat niciun efect de prozonă la titre $\geq 1/163840$.
6. **Sensibilitate diagnostic:** 100%
7. **Specificitate diagnostic:** 100%.

DECLINAREA RESPONSABILITĂȚII

1. Utilizatorul este singurul responsabil pentru performanța reactivilor în cazul utilizării altor metode decât cele menționate în **Tehnici recomandate**.
2. Orice abatere trebuie validată înainte de utilizare cu ajutorul procedurilor de laborator stabilite.

BIBLIOGRAFIE

1. David S.Jacobs et al. Laboratory Test Handbook, 3rd edition, Lexi-Comp Inc, 1994.

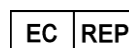
DIMENSIUNI DE KIT DISPONIBILE

Dimensiune kit	Număr de catalog
100 teste per kit	043100A



Lorne Laboratories Limited

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire, RG6 4UT
Regatul Unit
Tel.: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com



Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013, Malta

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ИСО

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.60057

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС40

Общество с ограниченной ответственностью "Прогресс"

Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,
ИНН: 7733398635, ОГРН: 1227700834613, email: progress.reestr@yandex.ru

ВЫДАН

Общество с ограниченной ответственностью «Агат-Мед»

ИНН: 7719187311 ОГРН: 1037739078970

Адрес: Россия, 105173, г. Москва, ул. Главная, д. 6, кв. 12.

Фактический адрес: 143906, Московская область, г. Балашиха, квартал Щитниково, д. 88А

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО
СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВАПрименительно к разработке, производству и продаже медицинских изделий
для in vitro диагностики: реагентов и наборов реагентов для клинической
биохимии, а также калибраторов и контрольных материалов

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ СТАНДАРТА

ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол РОСС RU.32001.04ИБФ1.ОС40.60057П от 03.09.2024Проверка
подлинности
сертификата
соответствия

Руководитель органа

Эксперт

подпись

подпись

Е.К. Яшин

инициалы, фамилия

П.К. Чеснокова

инициалы, фамилия

Сертификат не применяется при обязательной сертификации

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ИСО

РАЗРЕШЕНИЕ

НА ПРИМЕНЕНИЕ ЗНАКА СООТВЕТСТВИЯ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.60057Р

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС40

Общество с ограниченной ответственностью "Прогресс"

Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,
ИНН: 7733398635, ОГРН: 1227700834613, email: progress.reestr@yandex.ru

ВЫДАНО

Общество с ограниченной ответственностью «Агат-Мед»

ИНН: 7719187311 ОГРН: 1037739078970

Адрес: Россия, 105173, г. Москва, ул. Главная, д. 6, кв. 12.

Фактический адрес: 143906, Московская область, г. Балашиха, квартал Щитниково, д. 88А

на основании сертификата соответствия № РОСС RU.32001.04ИБФ1.ОС40.60057

**Настоящее разрешение предоставляет право применения
знака соответствия системы добровольной сертификации
«ПРОМТЕХСТАНДАРТ»:****при маркировке продукции, при оказании работ (услуг), на бланках организации,
в рекламно-информационных материалах, печатных изданиях, вывесках,
выставочных стендах и т.д., на сайтах организации в сети Интернет,
в соответствии с правилами применения знака соответствия
системы добровольной сертификации "ПромТехСтандарт"**

Руководитель органа

Эксперт


подпись

Е.К. Яшин

инициалы, фамилия

П.К. Чеснокова

инициалы, фамилия

Сертификат не применяется при обязательной сертификации

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ИСО

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.13294Э

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС40

Общество с ограниченной ответственностью "Прогресс"

Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,
ИНН: 7733398635, ОГРН: 1227700834613, email: progress.reestr@yandex.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям,

предъявляемым системой добровольной сертификации "ПромТехСтандарт"

к экспертам-аудиторам внутренних проверок системы менеджмента качества на соответствие
требованиям стандарта:**ГОСТ ISO 13485-2017 (ISO 13485:2016)**

Выдан на основании решения экспертной комиссии,

протокол № РОСС RU.32001.04ИБФ1.ОС40.13294ПЭ от 03.09.2024

и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт"



Руководитель органа

Эксперт

подпись

Е.К. Яшин

инициалы, фамилия

подпись

П.К. Чеснокова

инициалы, фамилия

Сертификат не применяется при обязательной сертификации

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ИСО

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.13295Э

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС40

Общество с ограниченной ответственностью "Прогресс"

Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,
ИНН: 7733398635, ОГРН: 1227700834613, email: progress.reestr@yandex.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям,

предъявляемым системой добровольной сертификации "ПромТехСтандарт"

к экспертам-аудиторам внутренних проверок системы менеджмента качества на соответствие
требованиям стандарта:**ГОСТ ISO 13485-2017 (ISO 13485:2016)**

Выдан на основании решения экспертной комиссии,

протокол № РОСС RU.32001.04ИБФ1.ОС40.13295ПЭ от 03.09.2024

и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт"



Руководитель органа

Эксперт

подпись

Е.К. Яшин

инициалы, фамилия

подпись

П.К. Чеснокова

инициалы, фамилия

Сертификат не применяется при обязательной сертификации

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2011/09957

от 30 октября 2012 года

Настоящее регистрационное удостоверение выдано
Закрытое акционерное общество "ЭКОлаб", (ЗАО "ЭКОлаб"),
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1
и подтверждает, что медицинское изделие

Набор реагентов "Антиген кардиолипидный для реакции
микропреципитации "Сифилис-АгКЛ-РМП"
по ТУ 9398-016-70423725-2010 в следующей комплектации
производства

Закрытое акционерное общество "ЭКОлаб", (ЗАО "ЭКОлаб"),
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1
место производства:

Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1

класс потенциального риска 26

ОКП 93 9817

вид медицинского изделия —

соответствующее регистрационному досье № 33508 от 26.09.2012

В соответствии с приказом Росздравнадзора от 30 октября 2012 года № 2280-Пр/12
и приказом от 23 июля 2013 года № 3428-Пр/13 о замене
допущено к обращению на территории Российской Федерации.

Приложение: на 1 листе

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения



М.А. Мурашко
0001831

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ
№ ФСР 2011/09957

Лист 1

Комплект № 1 включает в составе:

- антиген кардиолипиновый (АгКЛ);
- раствор холин-хлорида в 0,9 % растворе натрия хлорида.

Комплект № 2 в составе:

- взвесь АгКЛ.

2

Приказом от 23 июля 2013 года № 3428-Пр/13 о замене допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения

30 октября 2012 года



М.А. Мурашко

0001854

**СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»**

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ



ИСО

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС40.60057

Срок действия с 03.09.2024 по 02.09.2027

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС40.

Общество с ограниченной ответственностью "Прогресс"

Россия, 115191, г. Москва, вн.тер.г. муниципальный округ Донской, переулок Духовской, д. 17, стр. 15, пом. 11н/2,
ИНН: 7733398635, ОГРН: 1227700834613, email: progress.reestr@yandex.ru

ВЫДАН

Общество с ограниченной ответственностью «Агат-Мед»

ИНН: 7719187311 ОГРН: 1037739078970

Адрес: Россия, 105173, г. Москва, ул. Главная, д. 6, кв. 12.

Фактический адрес: 143906, Московская область, г. Балашиха, квартал Щитниково, д. 88А

**НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО
СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА**

Применительно к разработке, производству и продаже медицинских изделий
для in vitro диагностики: реагентов и наборов реагентов для клинической
биохимии, а также калибраторов и контрольных материалов

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ СТАНДАРТА**ГОСТ ISO 13485-2017 (ISO 13485:2016)**

Выдан на основании решения экспертной комиссии,
протокол РОСС RU.32001.04ИБФ1.ОС40.60057П от 03.09.2024



Проверка
подлинности
сертификата
соответствия



Руководитель органа

Эксперт

Е.К. Яшин

инициалы, фамилия

П.К. Чеснокова

инициалы, фамилия

Сертификат не применяется при обязательной сертификации

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

Российская Федерация

Город Балашиха Московской области

Одиннадцатого сентября две тысячи двадцать четвёртого года

Я, Суворова Елена Николаевна, временно исполняющий обязанности нотариуса Балашихинского нотариального округа Московской области Паршуковской Марины Анатольевны, свидетельствую верность копии с представленного мне документа.

Зарегистрировано в реестре: № 50/230-н/50-2024-8-1035.

Уплачено за совершение нотариального действия: 100 руб. 00 коп.



Е.Н.Суворова