

# Declaration of Conformity

helena  
Biosciences Europe

HL-7-DC-0814 Rev. 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
5560	APTT Si L Minus	55981

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

Full Name: C.J. Sandercock

Title: QA and Regulatory Affairs Officer

Signed:



Date: 24 Nov 2020



Helena Biosciences Europe,  
Gateshead, Tyne and Wear,  
NE11 0SD, United Kingdom  
Tel +44 (0)191 482 8440

[info@helena-biosciences.com](mailto:info@helena-biosciences.com)

[www.helena-biosciences.com](http://www.helena-biosciences.com)

EC REP

Prince Technologies B.V.  
Waanderweg 62,  
7812 HZ Emmen,  
The Netherlands

# 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

Page: 1 of 2



003

...making excellence a habit.™

Certificate No: **MD 69326**

Location

Helena Laboratories (UK) Ltd  
trading as Helena Biosciences Europe  
Sunderland Enterprise Park  
Colima Avenue  
Sunderland  
SR5 3XB  
United Kingdom

Registered Activities

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: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

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](http://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.

# Declaration of Conformity

helena  
Biosciences Europe

HL-7- 0137 DC DOI 2013/10 (6)

## **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.

<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
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: 31<sup>st</sup> October 2013

**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- 0511 DC DOI 2013/08 (3)

## **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.

<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5376	Clauss Fibrinogen 100	55997
5376H	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: 05 Aug 2013

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

# Certificate of Approval

This is to certify that the Management System of:

**ELITechGroup B.V.**

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

**ISO 13485:2016**

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

**The scope of this approval is applicable to:**

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.



**Paul Graaf**

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited



001

# Certificate Schedule

Location	Activities
<p><b>ELITechGroup B.V.</b> Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands</p>	<p><b>ISO 13485:2016</b> Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.</p>
<p><b>ELITechGroup B.V.</b> Kanaaldijk 90, 6956 AX Spankeren, The Netherlands</p>	<p><b>ISO 13485:2016</b> Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.</p>



001

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60150763 0001

**Report No.:** 21234760 013

**Manufacturer:** KABE LABORTECHNIK GmbH  
Jägerhofstr. 17  
51588 Nümbrecht  
Deutschland

**Products:**

- Cannulas for blood collection
- MBU Capillaries

(see attachment for details)

Replaces certificate, Registration No.: HD 60105393 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-10-07

**Date:** 2020-10-07

Notified Body

  
Dr. K. Kluge



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60150763 0001  
**Report No.:** 21234760 013

**Manufacturer:** KABE LABORTECHNIK GmbH  
Jägerhofstr. 17  
51588 Nümbrecht  
Deutschland

Products included:

- Cannulas for blood collection

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- MBU Capillaries

**Date:** 2020-10-07

**Notified Body**

*Dr. K. Kluge*  
**Dr. K. Kluge**



# Zertifikat

**Qualitätsmanagementsystem  
EN ISO 13485:2016**



Registrier-Nr.: SX 1614112-1  
Organisation: KABE-Labortechnik GmbH  
Jägerhofstr. 17  
51588 Nümbrecht  
Deutschland

Geltungsbereich: Entwicklung, Herstellung und Vertrieb von In-vitro-Diagnostik-Produkten und Verbrauchsmaterialien für die Probengewinnung, -vorbereitung und -aufbewahrung sowie von Medizinprodukten zur einmaligen Anwendung

TÜVRheinland

Die Zertifizierungsstelle der TÜV Rheinland LGA Products GmbH bescheinigt, dass die Organisation ein Qualitätsmanagementsystem für Medizinprodukte eingeführt hat und anwendet. Der Nachweis wurde erbracht, dass die Forderungen der oben genannten Norm erfüllt sind. Das Qualitätsmanagementsystem unterliegt einer jährlichen Überwachung.

Bericht Nr.: 1092786-40  
Gültig ab: 25.10.2021  
Gültig bis: 15.10.2024  
Datum: 25.10.2021



A handwritten signature in black ink, appearing to be 'F. Schwingen'.

Dipl.-Ing. F. Schwingen

TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Deutschland



# Zertifikat



**Qualitätsmanagementsystem  
EN ISO 13485:2016**

Registrier-Nr.: SX 1614112-1  
Organisation: KABE-Labortechnik GmbH  
Jägerhofstr. 17  
51588 Nümbrecht  
Deutschland

Der Geltungsbereich beinhaltet folgende zusätzlichen Standorte:

Nr.	Standorte	Geltungsbereich
/01	c/o KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Deutschland	Entwicklung, Herstellung und Vertrieb von In-vitro-Diagnostik-Produkten und Verbrauchsmaterialien für die Probengewinnung, -vorbereitung und -aufbewahrung sowie von Medizinprodukten zur einmaligen Anwendung
/02	c/o KABE-Labortechnik GmbH Werner-von-Siemens-Str. 1 51674 Wiehl Deutschland	Lager

Bericht Nr.: 1092786-40  
Gültig ab: 25.10.2021  
Gültig bis: 15.10.2024  
Datum: 25.10.2021



Dipl.-Ing. F. Schwingen  
TÜVRheinland LGA Products GmbH  
Tillystraße 2 | 90431 Nürnberg · Deutschland



*IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.  
IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.*

CERTIFICATO n. 4265/4/C  
CERTIFICATE No. \_\_\_\_\_

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI  
*WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY*

**KIMA S.R.L.**

UNITÀ OPERATIVE / OPERATIVE UNITS

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)  
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

**UNI CEI EN ISO 13485:2016**

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

**EA: 29**

Commercializzazione di prodotti del Gruppo: kit diagnostici,  
terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi,  
provette con vuoto predeterminato e aghi sterili.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology,  
plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.  
*Refer to the documentation of the Quality Management System for details of application to reference standard requirements.*

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,  
si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

*For timely and updated information about any changes in the certification status referred to in this certificate,  
please contact the number +39 02 725341 or email address info@icim.it.*

Data emissione  
*First issue*  
18/01/2007

Emissione corrente  
*Current issue*  
18/01/2019

Data di scadenza  
*Expiring date*  
17/01/2022

**ICIM S.p.A.**

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)  
www.icim.it



SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



www.cisq.com

CISQ è la Federazione Italiana di Organismi di  
Certificazione dei sistemi di gestione aziendale.  
*CISQ is the Italian Federation of management  
system Certification Bodies.*

**DICHIARAZIONE DI CONFORMITÀ CE**  
**EC DECLARATION OF CONFORMITY**

conforme all'Allegato III della Direttiva 98/79/CE "Dispositivi Medico-Diagnostici In Vitro" e s.m.i.  
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante **VACUTEST KIMA S.r.l. - articoli per laboratori analisi**  
manufacturer **disposable labware**

indirizzo **Via dell'Industria, 12**  
address **35020 Arzergrande (PD) - Italia**

telefono **+39-049-9720624**  
phone

fax **+39-049-9720182**  
fax

posta elettronica **info@vacutestkima.it**  
e-mail

identificazione dei prodotti  
product identification

**Sistema di prelievo di sangue e altri liquidi biologici  
mediante provette con vuoto predeterminato in plastica  
"VACUTEST KIMA".**

**"VACUTEST KIMA" vacuum blood and biological liquids  
collection tubes in plastic.**

nome commerciale  
brand name

**"VACUTEST KIMA"**

classificazione dei prodotti  
product classification

**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.  
devices other than those mentioned in Annex II of the Directive 98/79/EC as amended**

**Si dichiara**

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. "Dispositivi Medico-Diagnostici In Vitro".

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

**Hereby we declare**

*under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".*

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data  
place and date

**Arzergrande, 01/01/2015**

firma  
signature

**Assicuratore Qualità / Quality Manager  
Giovanni Chiarin**





*IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.*

CERTIFICATO n. 4264/4/C  
CERTIFICATE No. \_\_\_\_\_

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI  
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

**KIMA S.R.L.**

UNITÀ OPERATIVE / OPERATIVE UNITS

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)  
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

**UNI EN ISO 9001:2015**

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

**EA: 29**

Commercializzazione di prodotti del Gruppo: kit diagnostici,  
terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi,  
provette con vuoto predeterminato e aghi sterili.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology,  
plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.  
*Refer to the documentation of the Quality Management System for details of application to reference standard requirements.*

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.  
*The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.*

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,  
si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

*For timely and updated information about any changes in the certification status referred to in this certificate,  
please contact the number +39 02 725341 or email address info@icim.it.*

Data emissione  
First issue  
18/01/2007

Emissione corrente  
Current issue  
18/01/2019

Data di scadenza  
Expiring date  
17/01/2022

  
ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)  
www.icim.it



SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



www.cisq.com

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Certificazione dei sistemi di gestione aziendale.  
*CISQ is the Italian Federation of management  
system Certification Bodies.*



# CERTIFICATE

**EC No 1434-IVDD-134/2019**  
**Full Quality Assurance System**

**Directive 98/79/EC on in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**Lorne Laboratories Ltd**

**Unit 1 Cutbush Park Industrial Estate, Danehill,  
Lower Earley, Berkshire RG6 4UT, United Kingdom**

for the design, manufacture and final inspection of in vitro diagnostic medical devices  
List A

**Products list in attachments: 1**

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended)  
implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 23.05.2023

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019



Application No: 649/2019  
Module: H7

  
mgr Anna Wyroba  
Vice-President



Certificate No **1434-IVDD-134/2019**  
Issued under the Contract No **MD-59/2019**  
Bears the PCBC hologram.  
Warsaw, 10.04.2019



**ANNEX 1 TO CERTIFICATE**  
**VALID ONLY WITH CERTIFICATE**  
**No 1434-IVDD-134/2019**

The products detailed below are covered under the scope of this certificate:

<b>Name:</b>	<b>GMDN code:</b>
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593



  
mgr Anna Wyroba  
Vice-President



Annex 1 to certificate No. **1434-IVDD-134/2019**  
Issued under the Contract No. **MD-59/2019**  
Bears the PCBC hologram.  
Warsaw, 10.04.2019



# CERTIFICATE OF REGISTRATION

## Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate  
Danehill  
Lower Earley  
Berkshire RG6 4UT UNITED KINGDOM

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

**ISO 13485:2016**

**EN ISO 13485:2016**

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

Authorized by



**Michael J. Windler, P.E.**

**Manager of Global Regulatory Service**  
Distinguished Member of the Technical Staff  
Life and Health Sciences, UL LLC



Check Certificate  
Status: [here](#)

File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.



UL LLC  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA



# CERTIFICATE OF REGISTRATION

## Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate  
Danehill  
Lower Earley  
Berkshire RG6 4UT UNITED KINGDOM

REPs Facility ID: F001410

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

### ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design and manufacture of in vitro diagnostic reagents for the detection of the blood groups.



Authorized by



Check Certificate  
Status: [here](#)

**Michael J. Windler, P.E.**  
Manager of Global Regulatory Service  
Distinguished Member of the Technical Staff  
UL Life and Health Sciences  
UL LLC

File Number	A12241	Cycle Start Date	May 23, 2020
Certificate Number	1459.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory  
Services UL, LLC is an MDSAP  
Recognized Auditing  
Organization**

UL LLC  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA



## Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate  
Danehill  
Lower Earley  
Berkshire RG6 4UT UNITED KINGDOM

REPs Facility ID: **F001410**

### Additional Regulatory Requirements

#### Brazil:

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

#### Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

File Number	A12241	Cycle Start Date	May 23, 2020
Certificate Number	1459.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory  
Services UL, LLC is an MDSAP  
Recognized Auditing  
Organization**

UL LLC  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA



# CERTIFICATE

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**EC No 1434-IVDD-135/2019**  
**EC Design-Examination**

**Directive 98/79/EC on in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Lorne Laboratories Ltd**

**Unit 1 Cutbush Park Industrial Estate, Danehill, Lower  
Earley, Berkshire RG6 4UT, United Kingdom**

in vitro diagnostic medical devices  
List A

**Products list in attachments: 1**

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 07.03.2022

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019



Application No: 650/2019  
Module: H6

  
mgr Anna Wyroba  
Vice-President



Certificate No **1434-IVDD-135/2019**  
Issued under the Contract No **MD-59/2019**  
Bears the PCBC hologram.  
Warsaw, 10.04.2019



**ANNEX 1 TO CERTIFICATE**  
**VALID ONLY WITH CERTIFICATE**  
**No 1434-IVDD-135/2019**

The products detailed below are covered under the scope of this certificate:

**Name:**

**GMDN code:**

**Monoclonal Rh Control - 640010**

**52705**

**Monoclonal D Negative Control - 650010**

**52705**



  
**mgr Anna Wyroba**  
**Vice-President**



Annex 1 to certificate No. **1434-IVDD-135/2019**  
Issued under the Contract No. **MD-59/2019**  
Bears the PCBC hologram.  
Warsaw, 10.04.2019



# CERTIFICATE

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**EC No 1434-IVDD-133/2019**  
**EC Design-Examination**

**Directive 98/79/EC on in vitro diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Lorne Laboratories Ltd**

**Unit 1 Cutbush Park Industrial Estate, Danehill, Lower  
Earley, Berkshire RG6 4UT, United Kingdom**

in vitro diagnostic medical devices  
List A

**Products list in attachments: 1**

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 23.05.2023

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019



Application No: 649/2019  
Module: H6

  
mgr Anna Wyroba  
Vice-President



Certificate No **1434-IVDD-133/2019**  
Issued under the Contract No **MD-59/2019**  
Bears the PCBC hologram.  
Warsaw, 10.04.2019



**ANNEX 1 TO CERTIFICATE**  
**VALID ONLY WITH CERTIFICATE**  
**No 1434-IVDD-133/2019**

The products detailed below are covered under the scope of this certificate:

<b>Name:</b>	<b>GMDN code:</b>
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593



  
mgr Anna Wyroba  
Vice-President



Annex 1 to certificate No. **1434-IVDD-133/2019**  
Issued under the Contract No. **MD-59/2019**  
Bears the PCBC hologram.  
Warsaw, 10.04.2019

## EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6  
Full Quality Assurance System  
In Vitro Diagnostic Medical Devices

Registration No.: HL 60119814 0001

Report No.: 21265422 001

**Manufacturer:** Macherey-Nagel GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Deutschland

**Products:** Products for self-testing  
(see attachment for products and sites included)  
Replaces Certificate, Registration No.: HL 60076687 0001

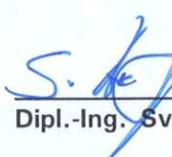
**Expiry Date:** 2022-05-28

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2017-05-29

**Date:** 2017-05-29

Notified Body

  
Dipl.-Ing. Sven Hoffmann



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HL 60119814 0001  
**Report No.:** 21265422 001

**Manufacturer:** Macheray-Nagel GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Deutschland

**Products for self-testing:**

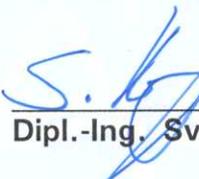
- Single and multi-parameter disposable test strips for urine analysis
- indicator test strips and papers for measurement of pH in urine

**Additional site for warehousing and logistics:**

Bahnstr. 120  
52355 Düren, Germany

**Date:** 2017-05-29

**Notified Body**

  
**Dipl.-Ing. Sven Hoffmann**



# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28



Dipl.-Ing. S. Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

# Certificate

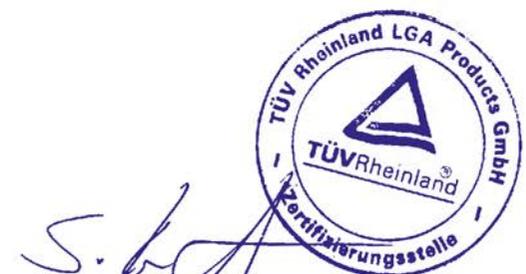
Quality Management System  
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

No.	Facility	Scope
/02	MACHEREY-NAGEL GmbH & Co. KG Valenciener Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90  
Effective date: 2020-05-29  
Expiry date: 2023-05-28  
Issue date: 2020-05-28



Dipl.-Ing. S. Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

including the locations according to annex

Scope: Design and development, production and distribution  
of products for filtration, rapid tests, water analysis,  
chromatography and bioanalysis

Proof has been furnished by means of an audit that the  
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-05-29 until 2023-05-28.

2020-05-25



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Annex to certificate

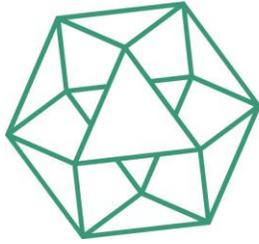
Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

No.	Location	Scope
/01	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for chromatography and bioanalysis
/02	MACHEREY-NAGEL GmbH & Co. KG Valenciennener Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, water analysis. Service and administration
/03	MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2020-05-25

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**Monobind Inc.**  
**100 North Pointe Drive**  
**Lake Forest, CA 92630**  
**USA**

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

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**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)**

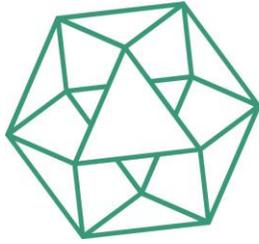
Approved by:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Caroline Dore Geraghty  
Director of Medical Devices /  
Head of Notified Body

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Registration Number: MD19.4585  
Certification Granted: May 18, 2010  
Effective Date: September 25, 2019  
Expiry Date: September 24, 2022





# NSAI

## **Annex to Certificate Number: MD19.4585**

### **Scope of Registration:**

**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

#### **Activity**

#### **Location**

Headquarters, Administration,  
Design, Manufacturing,  
Distribution

Monobind Inc.  
100 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585

Manufacturing, Distribution

Monobind Inc.  
103 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585/A

**Verified by:  
Operations Manager**

EasyLyte EasyBloodGas EasyStat  
*Training Certificate*

*This is to certify that*

*Sorocovici 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*

# 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 and accessories per attachment

EasyElectrolytes and accessories per attachment

### Model/Type:

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

EasyElectrolytes Na/K/Cl, Na/K/Li

### Manufacturer

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

### Representative

 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 the corresponding national laws of the Member States.

**Place and Date:** Bedford, Massachusetts, USA, September 27, 2018

### Signature:



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

## EasyLyte Accessories

<b>Catalog No.</b>	<b>Accessory</b>	<b>EDMA Code</b>
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
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 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
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 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

**EasyLyte Accessories, continued**

<b>Catalog No.</b>	<b>Accessory</b>	<b>EDMA Code</b>
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
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 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenance Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

## EasyElectrolytes Accessories

<b>Catalog No.</b>	<b>Accessory</b>	<b>EDMA Code</b>
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02



**МЕДИКЛОН**

127276 Москва, Ботаническая ул, 35 , т\ф (495) 231-2272, (499) 502-12-14  
e-mail : [Mediclone@mediclone.ru](mailto:Mediclone@mediclone.ru)

# ООО "Медиклон"

ИНН 7719191607 Р/с **40702810038040106975** в ПАО Сбербанк г.Москва, К/С  
30101810400000000225 КПП 771501001 БИК 044525225 ОКПО 51203590 ОГРН  
1027700153766

Исх 76-21  
01.01.2021

## СВИДЕТЕЛЬСТВО НА ЭКСКЛЮЗИВНОЕ ПРАВО ПРОДАЖИ

Общество с ограниченной ответственностью «МЕДИКЛОН» 127276 Россия Москва ул.Ботаническая, 35, ОГРН 1027700153766 - производитель реагентов для трансфузиологии (Цоликлонов) в лице генерального директора Викторова Н.А. официально удостоверяет, что фирма IM «GBG-MLD» SRL , расположенная по адресу : MD-2001 г Кишинёв, ул.Тигина , 65 , оф. 607 , Республика Молдова , является официальным дистрибьютором (авторизованным дилером) всей продукции производства ООО «МЕДИКЛОН» на всей территории Республики Молдова.

IM «GBG-MLD» SRL имеет право на распространение (реализацию), продвижение (рекламу) а также поддержку продукции, выпускаемой фирмой ООО «МЕДИКЛОН» в Республике Молдова.

IM «GBG-MLD» SRL имеет право участвовать от имени фирмы ООО «Медиклон» в частных и Государственных тендерах и тем самым действовать как официальный представитель фирмы ООО «Медиклон» на всей территории Республики Молдова

ООО «Медиклон» распространяет свои полные гарантии на продукцию, проданную фирмой IM «GBG-MLD» SRL .

Генеральный  
директор ООО «Медиклон»



Н.А.Викторов



**МЕДИКЛОН**

127276 Москва, Ботаническая ул, 35 , т\ф (495) 231-2272, (499) 502-12-14  
e-mail : [Mediclone@mediclone.ru](mailto:Mediclone@mediclone.ru)

# ООО "Медиклон"

ИНН 7719191607 Р/с **40702810038040106975** в ПАО Сбербанк г.Москва, К/С  
30101810400000000225 КПП 771501001 БИК 044525225 ОКПО 51203590 ОГРН  
1027700153766

Исх 76-21  
01.01.2021

## СВИДЕТЕЛЬСТВО НА ЭКСКЛЮЗИВНОЕ ПРАВО ПРОДАЖИ

Общество с ограниченной ответственностью «МЕДИКЛОН» 127276 Россия Москва ул.Ботаническая, 35, ОГРН 1027700153766 - производитель реагентов для трансфузиологии (Цоликлонов) в лице генерального директора Викторова Н.А. официально удостоверяет, что фирма IM «GBG-MLD» SRL , расположенная по адресу : MD-2001 г Кишинёв, ул.Тигина , 65 , оф. 607 , Республика Молдова , является официальным дистрибьютором (авторизованным дилером) всей продукции производства ООО «МЕДИКЛОН» на всей территории Республики Молдова.

IM «GBG-MLD» SRL имеет право на распространение (реализацию), продвижение (рекламу) а также поддержку продукции, выпускаемой фирмой ООО «МЕДИКЛОН» в Республике Молдова.

IM «GBG-MLD» SRL имеет право участвовать от имени фирмы ООО «Медиклон» в частных и Государственных тендерах и тем самым действовать как официальный представитель фирмы ООО «Медиклон» на всей территории Республики Молдова

ООО «Медиклон» распространяет свои полные гарантии на продукцию, проданную фирмой IM «GBG-MLD» SRL .

Генеральный  
директор ООО «Медиклон»



Н.А.Викторов