



Declaration of Conformity



We: ELITechGroup B.V.
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

Declare under sole responsibility that the product indicated below (including all spares and accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE marking.

Product : **Clinical chemistry analyzer**
Product No. : **6003-400**
Model : **Selectra ProM**
GMDN code : **56678**

Product classification

As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure

In accordance with Annex III of the IVDD

The product (including all spares and accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL)
- All other member states of the European Union (EU)
- All other states that are part of the European Economic Area (EEA), including Switzerland

Spankeren, March 2015

A. Altink
Managing Director



Declaration of Conformity



List of applied (harmonized) standards

	Standard version	Description	Certification by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
	IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	DEKRA
	IEC 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.	DEKRA
	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages), conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th, 2023).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 29 juillet 2020

Valérie LAMBERT,

Responsable des Affaires Réglementaires

Regulatory Affairs Manager

Responsable de los Asuntos Reglamentarios

Cécile GOUBAULT,

Directeur Général Délégué

Managing Director

Directora General

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250	53597
ALBUMIN ENVOY	ALBU-0850	
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP SL	CRSL-0630/0250	53250
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPST-0850	
GLUCOSE HK SL	GHSL-0600/0250	53301
GLUCOSE PAP SL	GPST-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230	59123
PHOSPHORUS ENVOY	PHOS-0850	
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN ENVOY	PROB-0850	53985
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA ENVOY	URSL-0850	53587
UREA UV SL	URSL-0407/0427/0420/0500/0507/0250/0455	
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	53583
URIC ACID SL	AUSL-0250	
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	
ALP ENVOY	PIVD-0850	52928
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	52923
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	
AMYLASE ENVOY	AMSL-0850	52940
AMYLASE SL	AMSL-0390/0400/0230	
AST ENVOY	ASVD-0850	52954
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL	CMSL-0410/0430/0230	
CK NAC SL	CKSL-0410/0430/0230	53003
GAMMA-GT PLUS SL	GISL-0400/0420/0250	53027
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	53072
LDH-L SL	LLSL-0400/0420/0230	
LIPASE ENVOY	LPSL-0850	53108
LIPASE SL	LPSL-0230	
Electrolytes - Oligo-éléments / Electrolytes - Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250	45789
CALCIUM ENVOY	CALA-0850	
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL ENVOY	CHSL-0850	53359
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
HDL CHOLESTEROL	CHDL-0250/0600	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	
LDL CHOLESTEROL	CLDL-0250	53395
LDL CHOLESTEROL ENVOY	LDLL-0850	
TRIGLYCERIDES ENVOY	TGML-0850	53460
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
μALBUMIN IP	IMAL-0400	53475
μALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
μALBUMIN IP CONTROL I	IMAL-0046	53478
μALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IIPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS
Zone Industrielle
61500 SEES FRANCE

pour les activités
for the activities

Conception, production, contrôle et commercialisation de produits de chimie cliniques pour le diagnostic in vitro. Validation de la combinaison réactifs et automates. Distribution d'automates et de produits de chimie cliniques pour le diagnostic in vitro.

Design, production, control and sales of clinical chemistry products intended to be used for in vitro diagnostics. Validation of the combination reagents and analyzers. Distribution of clinical chemistry analyzers and products for in vitro diagnostics.

réalisées sur le(s) site(s) de
performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité / Effective date : July 25th, 2023 (included)

Valable jusqu'au / Expiry date : July 27th, 2026 (included)

Etabli le / Issued on : July 25th, 2023

cofrac

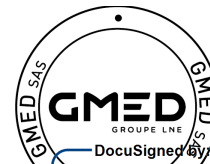


CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 10462-8

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 10462-7



On behalf of the President
Marjorie PERRIMON
Certification Director

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-7-0136DC DOI 2015/07 (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.

Product Code	Description	GMDN Classification Code
5185	Calibration Plasma	55995

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

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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

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United Kingdom

Declaration of Conformity

helena
Biosciences Europe

HL-7-0512DC DOI 2015/08 (5)

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
5556	Clauss Fibrinogen 50	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

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Helena Biosciences Europe

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

United Kingdom

Declaration of Conformity

helena
Biosciences Europe

HL-7-0664DC 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
5267L	Thromboplastin L	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

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

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
Anti-A Monoclonal	600010

has been classified as List A (Directive 98/79/EC, Annex II) and complies 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) and the Commission Decision on Common Technical Specifications 2009/108/EC.

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex IV of Directive 98/79/EC and was carried out by UL International (UK) Ltd, Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey GU3 1LR, United Kingdom, Notified Body Number 0843.

The certificates issued by UL-UK Ltd to show compliance are numbers 354.170425 and 355.130523.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 23 May 2017.



Eddy Velthuis
Technical Director

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
Anti-B Monoclonal	610010

has been classified as List A (Directive 98/79/EC, Annex II) and complies 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) and the Commission Decision on Common Technical Specifications 2009/108/EC.

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex IV of Directive 98/79/EC and was carried out by UL International (UK) Ltd, Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey GU3 1LR, United Kingdom, Notified Body Number 0843.

The certificates issued by UL-UK Ltd to show compliance are numbers 354.170425 and 355.130523.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 23 May 2017.



Eddy Velthuis
Technical Director

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
Anti-D Duoclone Monoclonal	740010

has been classified as List A (Directive 98/79/EC, Annex II) and complies 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) and the Commission Decision on Common Technical Specifications 2009/108/EC.

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
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The certificates issued by UL-UK Ltd to show compliance are numbers 354.170425 and 355.130523.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 23 May 2017.



Eddy Velthuis
Technical Director



CERTIFICATE

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:

Name:	GMDN code:
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

**СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»**

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



ИСО 13485

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС33.17919

Срок действия с 21.03.2022 по 20.03.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС33

ООО «Научно-исследовательский институт проектирования и измерений»
141730, Московская область, город Лобня, улица Борисова, дом 14, корпус 2, помещение 006, офис 1

ВЫДАН

Общество с ограниченной ответственностью «МИНИМЕД»

ИНН: 3234007127 ОГРН: 1023202138332

Адрес: 241520, Брянская обл. Брянский р-н, село Супонево, ул Шоссейная, зд 17А

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

применительно к видам работ согласно приложению №1 к настоящему
сертификату

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

Выдан на основании решения экспертной комиссии,
протокол РОСС RU.32001.04ИБФ1.ОС33.17919П от 21.03.2022



Проверка
подлинности
сертификата
соответствия



Руководитель органа

подпись

К.Р. Василенко

инициалы, фамилия

Эксперт

подпись

М.Т. Антипин

инициалы, фамилия

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



ПРИЛОЖЕНИЕ № 1

К сертификату соответствия № РОСС RU.32001.04ИБФ1.ОС33.17919
(является неотъемлемой частью сертификата соответствия)

ИСО 13485

Срок действия с 21.03.2022 по 20.03.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС33

ООО «Научно-исследовательский институт проектирования и измерений»
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Применительно к видам работ: Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики.



Руководитель органа

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