



# EC CERTIFICATE

## Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,  
Danehill, Lower Earley, Berkshire RG6 4UT, UK

## EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro  
Diagnostic Medical Devices

Scope of Certificate:

**The design and manufacture of in vitro diagnostic reagents for  
identification of blood groups**

Device Classification:

**Annex II, List A and B**

Device Descriptions:

**Please refer to Attachment 1**

Model:

**Please refer to Attachment 1**

|                 |            |                  |             |
|-----------------|------------|------------------|-------------|
| File Number     | A12241     | Cycle Start Date | 23 May 2017 |
| Certificate No. | 354.170425 | Effective Date   | 23 May 2017 |
|                 |            | Expiry Date      | 22 May 2022 |

Authorised by

**B. Rodgers**

**Certification Manager**

For and on Behalf of UL International (UK) Ltd

**We hereby declare that an examination of the full quality assurance system has been carried out per report 11640248, following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing model numbers.**

**Notified Body**

**0843**

UL International (UK) Limited  
Wonersh House, The Guildway, Old Portsmouth Road,  
Guildford, Surrey, GU3 1LR, United Kingdom



# EC CERTIFICATE

## Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,  
Danehill, Lower Earley, Berkshire RG6 4UT, UK

### Attachment 1 of 1

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

| Device Description            | Model                | Classification  |
|-------------------------------|----------------------|-----------------|
| Anti-A Monoclonal             | 600005/600010/600000 | Annex II List A |
| Anti-B Monoclonal             | 610005/610010/610000 | Annex II List A |
| Anti-A,B Monoclonal           | 620005/620010/620000 | Annex II List A |
| Anti-C Monoclonal             | 690005               | Annex II List A |
| Anti-E Monoclonal             | 691005               | Annex II List A |
| Anti-c Monoclonal             | 692005               | Annex II List A |
| Anti-e Monoclonal             | 693005               | Annex II List A |
| Anti-K Monoclonal             | 760005/760010        | Annex II List A |
| Anti-D Clone 2 Monoclonal     | 710010/710000        | Annex II List A |
| Anti-D Clone 1 Monoclonal     | 730010/730000        | Annex II List A |
| Anti-D Duoclone Monoclonal    | 740010/740000        | Annex II List A |
| Anti-Jka Polyclonal           | 323002/323000        | Annex II List B |
| Anti-Jkb Polyclonal           | 324002/324000        | Annex II List B |
| Anti-Fyb Polyclonal           | 317002/317000        | Annex II List B |
| AHG Elite Clear               | 415010/415100/415000 | Annex II List B |
| AHG Elite Green               | 435010/435100/435000 | Annex II List B |
| Anti-Fya Monoclonal           | 774000/774002        | Annex II List B |
| Anti-C+D+E Monoclonal         | 700005/700010/700000 | Annex II List A |
| Anti-Human IgG Clear          | 401010/401000        | Annex II List B |
| Anti-Human IgG Green          | 402010/402000        | Annex II List B |
| Monoclonal Rh Control         | 640010               | Annex II List A |
| Monoclonal D Negative Control | 650010               | Annex II List A |

File Number A12241  
Certificate No. 354.170425

Cycle Start Date 23 May 2017  
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Expiry Date 22 May 2022

Authorised by

**B. Rodgers**  
**Certification Manager**  
For and on Behalf of UL International (UK) Ltd

**Notified Body**

**0843**



# 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 |
|------------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| <b>Safety</b>          | 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                                     |                  |
| <b>EMC</b>             | 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                                                |                  |
| <b>Quality systems</b> | 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.                                                                                                                                    |                  |

**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 28th, 2020 (included)**

**Valable jusqu'au / Expiry date : July 27th, 2023 (included)**

**Etabli le / Issued on : July 17th, 2020**

**cofrac**

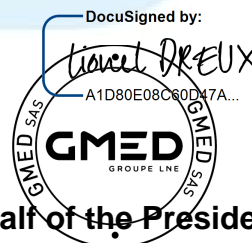


**CERTIFICATION DE SYSTEMES DE MANAGEMENT**  
Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

GMED N° 10462-7

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

Renouvelle le certificat 10462-6



**On behalf of the President**  
**Lionel DREUX**  
**Certification Director**

## 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).

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## 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 27<sup>th</sup>, 2023).*

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## 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   |
|------------------------------------------------------------------------|-----------------------------------------|-------------|
| <b>Metabolites divers / Miscellaneous metabolites</b>                  |                                         |             |
| 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                               |             |
| <b>Enzymes / Enzymes</b>                                               |                                         |             |
| 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                               |             |
| <b>Electrolytes - Oligo-éléments / Electrolytes - Trace-elements</b>   |                                         |             |
| 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                          |             |
| <b>Lipides / Lipids</b>                                                |                                         |             |
| 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                          |             |
| <b>Contrôles-Calibrants-Standards / Controls-Calibrators-Standards</b> |                                         |             |
| 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 |
|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-----------|
| <b>Protéines spécifiques / Specific proteins</b>                                                                                          |                                       |           |
| 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     |
| <b>Vitamines/Vitamins</b>                                                                                                                 |                                       |           |
| VITAMIN D                                                                                                                                 | VITD-0250                             | 54476     |
| VITAMIN D CALIBRATOR SET                                                                                                                  | VITD-0043                             | 54474     |
| VITAMIN D CONTROL SET                                                                                                                     | VITD-0049                             | 54475     |
| <b>ISE Solutions pour électrodes selectives d'ions /<br/>ISE Solutions for ion-selective electrodes</b>                                   |                                       |           |
| 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                             |           |
| <b>Solutions de lavage pour les équipements ELITech Clinical Systems /<br/>Cleaning solutions for ELITech Clinical Systems Equipments</b> |                                       |           |
| 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                             |           |
| <b>Tests d'agglutination / Agglutination tests</b>                                                                                        |                                       |           |
| CRP LATEX                                                                                                                                 | LXCR-0112                             | 53707     |



# 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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14

Expiry Date: 2021-04-13



003

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...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: 2018-11-28

Effective Date: 2018-04-14

Expiry Date: 2021-04-13

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-7-0135DC 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

Tel +44 (0)191 482 8440  
Fax +44 (0)191 482 8442  
info@helena-biosciences.com  
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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-7-0137DC 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-7-0512DC 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

Tel +44 (0)191 482 8440  
Fax +44 (0)191 482 8442  
[info@helena-biosciences.com](mailto:info@helena-biosciences.com)  
[www.helena-biosciences.com](http://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-7-0664DC 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

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



*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. \_\_\_\_\_

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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.

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Current issue  
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Data di scadenza  
Expiring date  
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ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)  
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SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
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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.*

## **EC DECLARATION OF CONFORMITY**

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

| <b>Product Name</b> | <b>Catalogue Number</b> |
|---------------------|-------------------------|
| 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, Wonerish 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:

| <b>Product Name</b> | <b>Catalogue Number</b> |
|---------------------|-------------------------|
| 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:

| <b>Product Name</b>        | <b>Catalogue Number</b> |
|----------------------------|-------------------------|
| 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
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- BS EN ISO 18113-2:2011
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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

# MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:  
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:  
20 декабря 2000

Действителен:  
21 июня 2018 - 31 августа 2021

Настоящим удостоверяется, что система менеджмента организации:

## АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация,  
196240

была признана соответствующей стандарту:

**ISO 9001:2015**

Настоящий сертификат действителен для следующей области:

**ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО  
ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.**

Место и дата:  
Москва, 21 июня 2018



**FINAS**  
Finnish Accreditation Service  
S001 (EN ISO/IEC 17021)

От выпускающего офиса:  
**DNV GL – Business Assurance**  
Трехпрудный переулок 9, стр. 2, Москва,  
Российская Федерация



*S. Groobine*

**Сергей Грубин**  
Представитель руководства

# Certificate

mdc medical device certification GmbH  
certifies that

**NOVATEC**   
IMMUNDIAGNOSTICA GMBH  
NovaTec Immundiagnostica GmbH  
Waldstraße 23 A6  
63128 Dietzenbach  
Germany

for the scope

development, manufacturing and distribution of  
in-vitro diagnostics (ELISA, Immunoblot, PCR)

has introduced and applies a

## Quality Management System

The mdc audit has proven that this quality management system  
meets all requirements of the following standard

**EN ISO 13485**

Medical devices – Quality management systems –  
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

|                  |                  |
|------------------|------------------|
| Valid from       | 2018-12-04       |
| Valid until      | 2021-12-03       |
| Registration no. | D1055500014      |
| Report no.       | P18-00810-122884 |
| Stuttgart        | 2018-10-09       |



Head of Certification Body



mdc medical device certification GmbH  
Kriegerstraße 6  
D-70191 Stuttgart, Germany  
Phone: +49-(0)711-253597-0  
Fax: +49-(0)711-253597-10  
Internet: <http://www.mdc-ce.de>

For electronic publication only

# Product List – CE Marked

Certified by

ISO 13485:2016

EC – Directive 98 / 79 EC  
For In-Vitro-Diagnostics

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2020-02-1

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**NovaLisa®**

**Virology**

**Prod. No.**

**Name**

|           |                                      |
|-----------|--------------------------------------|
| ADVA0010  | Adenovirus IgA                       |
| ADVG0010  | Adenovirus IgG                       |
| ADVM0010  | Adenovirus IgM                       |
| CHIG0590  | Chikungunya Virus IgG capture        |
| CHIM0590  | Chikungunya Virus IgM $\mu$ -capture |
| CMVG0110  | Cytomegalovirus (CMV) IgG            |
| ACMV7110  | Avidity Cytomegalovirus (CMV) IgG    |
| CMVM0110  | Cytomegalovirus (CMV) IgM            |
| DENG0120  | Dengue Virus IgG                     |
| DENM0120  | Dengue Virus IgM                     |
| DVM0640   | Dengue Virus IgM $\mu$ -capture      |
| NS1D4020  | Dengue Virus NS1 Antigen             |
| EBVA0150  | Epstein-Barr Virus (VCA) IgA         |
| EBVG0150  | Epstein-Barr Virus (VCA) IgG         |
| AEBV7150  | Avidity Epstein-Barr Virus (VCA) IgG |
| EBVM0150  | Epstein-Barr Virus (VCA) IgM         |
| EBVG0580  | Epstein-Barr Virus (EBNA) IgG        |
| HANG0670  | Hantavirus IgG                       |
| HANM0670  | Hantavirus IgM                       |
| HEVG0780  | Hepatitis E Virus (HEV) IgG          |
| HEVM0780  | Hepatitis E Virus (HEV) IgM          |
| HSVG0250  | Herpes simplex Virus 1+2 (HSV) IgG   |
| HSVM0250  | Herpes simplex Virus 1+2 (HSV) IgM   |
| HSV1G0500 | Herpes simplex Virus 1 (HSV 1) IgG   |
| HSV1M0500 | Herpes simplex Virus 1 (HSV 1) IgM   |
| HSV2G0540 | Herpes simplex Virus 2 (HSV 2) IgG   |
| HSV2M0540 | Herpes simplex Virus 2 (HSV 2) IgM   |
| INFA0290  | Influenza Virus A IgA                |
| INFG0290  | Influenza Virus A IgG                |
| INFM0290  | Influenza Virus A IgM                |
| INFA0300  | Influenza Virus B IgA                |
| INFG0300  | Influenza Virus B IgG                |
| INFM0300  | Influenza Virus B IgM                |
| MEAG0330  | Measles Virus IgG                    |
| AMEA7330  | Avidity Measles Virus IgG            |
| MEAM0330  | Measles Virus IgM                    |
| MUMG0340  | Mumps Virus IgG                      |
| MUMM0340  | Mumps Virus IgM                      |
| PAIA0360  | Parainfluenza Virus 1,2,3 IgA        |
| PAIG0360  | Parainfluenza Virus 1,2,3 IgG        |
| PARG0370  | Parvovirus B 19 IgG                  |
| PARM0370  | Parvovirus B 19 IgM                  |
| RSVA0380  | Respiratory syncytial Virus IgA      |
| RSVG0380  | Respiratory syncytial Virus IgG      |
| RSVM0380  | Respiratory syncytial Virus IgM      |
| RUBG0400  | Rubella Virus IgG                    |

|          |                                  |
|----------|----------------------------------|
| ARUB7400 | Avidity Rubella Virus IgG        |
| RUBM0400 | Rubella Virus IgM $\mu$ -capture |
| TICG0440 | TBE / FSME IgG                   |
| TICM0440 | TBE / FSME IgM                   |
| PTICG044 | TBE / FSME IgG plus              |
| VZVA0490 | Varicella-Zoster Virus (VZV) IgA |
| VZVG0490 | Varicella-Zoster Virus (VZV) IgG |
| VZVM0490 | Varicella-Zoster Virus (VZV) IgM |
| ZVG0790  | Zika Virus IgG capture           |
| ZVM0790  | Zika Virus IgM $\mu$ -capture    |

## **NovaLisa<sup>®</sup>**      **Bacteriology**

| <b>Prod. No.</b> | <b>Name</b>                                   |
|------------------|-----------------------------------------------|
| BAR0900          | Bartonella                                    |
| BOPA0030         | Bordetella pertussis IgA                      |
| BOPG0030         | Bordetella pertussis IgG                      |
| BOPM0030         | Bordetella pertussis IgM                      |
| BPTA0610         | Bordetella pertussis toxin (PT) IgA           |
| BPTG0610         | Bordetella pertussis toxin (PT) IgG           |
| BORG0040         | Borrelia burgdorferi IgG                      |
| BORM0040         | Borrelia burgdorferi IgM                      |
| BRUG0050         | Brucella IgG                                  |
| BRUM0050         | Brucella IgM                                  |
| CHLA0070         | Chlamydia trachomatis IgA                     |
| CHLG0070         | Chlamydia trachomatis IgG                     |
| CHLM0070         | Chlamydia trachomatis IgM                     |
| CHLA0510         | Chlamydia pneumoniae IgA                      |
| CHLG0510         | Chlamydia pneumoniae IgG                      |
| CHLM0510         | Chlamydia pneumoniae IgM                      |
| CORG0090         | Corynebacterium diphtheriae toxin IgG         |
| CORG5009         | Corynebacterium diphtheriae toxin 5S IgG      |
| PCORG009         | Corynebacterium diphtheriae toxin 5S IgG plus |
| COX1G0600        | Coxiella burnetii (Q-Fever) Phase 1 IgG       |
| COX2G0600        | Coxiella burnetii (Q-Fever) Phase 2 IgG       |
| COX2M0600        | Coxiella burnetii (Q-Fever) Phase 2 IgM       |
| HELA0220         | Helicobacter pylori IgA                       |
| HELG0220         | Helicobacter pylori IgG                       |
| PHELA022         | Helicobacter pylori IgA plus                  |
| PELG022          | Helicobacter pylori IgG plus                  |
| LEGG0650         | Legionella Pneumophila IgG                    |
| LEGM0650         | Legionella Pneumophila IgM                    |
| LEPG0660         | Leptospira IgG                                |
| LEPM0660         | Leptospira IgM                                |

|          |                                      |
|----------|--------------------------------------|
| MYCA0350 | Mycoplasma pneumoniae IgA            |
| MYCG0350 | Mycoplasma pneumoniae IgG            |
| MYCM0350 | Mycoplasma pneumoniae IgM            |
| TETG0430 | Clostridium tetani toxin IgG         |
| TETG5043 | Clostridium tetani toxin 5S IgG      |
| PTETG043 | Clostridium tetani toxin 5S IgG plus |

**NovaLisa® Parasites**

| <b>Prod. No.</b> | <b>Name</b>                          |
|------------------|--------------------------------------|
| CHAG0560         | Chagas (Trypanosoma cruzi) IgG       |
| TRYP0570         | Chagas                               |
| ENTG0140         | Entamoeba histolytica IgG            |
| LEIG0310         | Leishmania infantum IgG              |
| MAL0620          | Malaria                              |
| TOXA0460         | Toxoplasma gondii IgA                |
| TOXG0460         | Toxoplasma gondii IgG                |
| ATOX7460         | Avidity Toxoplasma gondii IgG        |
| TOXM0460         | Toxoplasma gondii IgM $\mu$ -capture |

**NovaLisa® Worms**

| <b>Prod. No.</b> | <b>Name</b>              |
|------------------|--------------------------|
| ASCG0020         | Ascaris lumbricoides IgG |
| ECHG0130         | Echinococcus IgG         |
| FIL0760          | Filariasis               |
| SCHG0410         | Schistosoma mansoni IgG  |
| SCHM0410         | Schistosoma mansoni IgM  |
| STRO0690         | Strongyloides            |
| TAEG0420         | Taenia solium IgG        |
| TOCG0450         | Toxocara canis IgG       |
| TRIG0480         | Trichinella spiralis IgG |

**NovaLisa® Fungi**

| <b>Prod. No.</b> | <b>Name</b>               |
|------------------|---------------------------|
| ASPG0680         | Aspergillus fumigatus IgG |
| ASPM0680         | Aspergillus fumigatus IgM |
| CANA0060         | Candida albicans IgA      |
| CANG0060         | Candida albicans IgG      |
| CANM0060         | Candida albicans IgM      |

## **NovaLisa<sup>®</sup> Hormones**

### **THYROID HORMONES**

**(ELISAs for the determination of thyroid hormones and antibodies)**

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
| ATG1010          | Anti-TG     |
| ATPO1020         | Anti-TPO    |
| FT41050          | Free T4     |
| TSH1030          | TSH         |

## **Hormones**

### **STEROID HORMONES**

**(ELISAs for the determination of steroid hormones in plasma and serum)**

| <b>Prod. No.</b> | <b>Name</b>        |
|------------------|--------------------|
| DNOV001          | Cortisol           |
| DNOV002          | Testosterone       |
| DNOV003          | 17 beta-Estradiol  |
| DNOV004          | 17-OH Progesterone |
| DNOV005          | DHEA-S             |
| DNOV006          | Progesterone       |
| DNOV008          | Androstenedione    |
| DNOV009          | Free Testosterone  |
| DNOV011          | Total Estriol      |
| DNOV012          | Aldosterone        |

### **STEROID HORMONES IN URINE**

**(ELISAs for the determination of steroid hormones in urine)**

| <b>Prod. No.</b> | <b>Name</b>      |
|------------------|------------------|
| DNOV010          | Urinary Cortisol |

### **STEROID HORMONES IN SALIVA**

**(ELISAs for the determination of steroid hormones in saliva)**

| <b>Prod. No.</b> | <b>Name</b>            |
|------------------|------------------------|
| DSNOV20          | Cortisol Saliva        |
| DSNOV21          | Testosterone Saliva    |
| DSNOV24          | DHEA-S Saliva          |
| DSNOV27          | Androstenedione Saliva |

## PROTEIN HORMONES

(ELISAs for the determination of proteins in plasma and serum)

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
| DNOV030          | LH          |
| DNOV031          | FSH         |
| DNOV032          | Prolactin   |
| DNOV033          | AFP         |
| DNOV034          | beta HCG    |

## THYROID HORMONES

(ELISAs for the determination of thyroid hormones and antibodies)

| <b>Prod. No.</b> | <b>Name</b>   |
|------------------|---------------|
| DNOV051          | Free T3       |
| DNOV053          | Total T3      |
| DNOV054          | Total T4      |
| DNOV057          | Thyroglobulin |

## DIABETES MONITORING

(ELISAs for the determination of specific analytes in plasma and serum)

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
| DNOV111          | Insulin     |
| DNOV112          | C-Peptide   |

## CIRCULATING IMMUNO COMPLEXES

(ELISAs for the determination of specific analytes in plasma and serum)

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
| DNOV093          | CIC-C1q     |
| DNOV094          | CIC-C3d     |
| DNOV096          | CH-50       |

## TUMOR MARKERS

(ELISAs for the determination of specific analytes in plasma and serum)

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
| DNOV 060         | CEA         |
| DNOV061          | CA 125      |
| DNOV062          | CA 15-3     |
| DNOV063          | CA 19-9     |

## MISCELLANEOUS

(ELISAs for the determination of specific analytes in plasma and serum)

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
|------------------|-------------|

|         |          |
|---------|----------|
| DNOV100 | Ferritin |
| DNOV101 | HGH      |
| DNOV102 | IgE      |

## **NovoLisa<sup>®</sup> Autoimmune**

### Autoimmune

(ELISAs for the determination of specific autoimmune antibodies)

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
|------------------|-------------|

|          |          |
|----------|----------|
| ATG1010  | Anti-TG  |
| ATPO1020 | Anti-TPO |

### Rheumatology

(ELISAs for the determination of specific analytes in plasma and serum)

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
|------------------|-------------|

|         |                       |
|---------|-----------------------|
| RFM3010 | Rheumatoid Factor IgM |
|---------|-----------------------|

## **NovoLisa<sup>®</sup> Recombinant Antigens**

| <b>Prod. No.</b> | <b>Name</b> |
|------------------|-------------|
|------------------|-------------|

|           |                                    |
|-----------|------------------------------------|
| BORG0040  | Borrelia burgdorferi IgG           |
| BORM0040  | Borrelia burgdorferi IgM           |
| CHAG0560  | Chagas (Trypanosoma cruzi) IgG     |
| TRYP0570  | Chagas                             |
| HANG0670  | Hantavirus IgG                     |
| HANM0670  | Hantavirus IgM                     |
| HELA0220  | Helicobacter pylori IgA            |
| PHELA022  | Helicobacter pylori IgA plus       |
| HEVG0780  | Hepatitis E Virus (HEV) IgG        |
| HEVM0780  | Hepatitis E Virus (HEV) IgM        |
| HSV1G0500 | Herpes simplex Virus 1 (HSV 1) IgG |
| HSV1M0500 | Herpes simplex Virus 1 (HSV 1) IgM |
| HSV2G0540 | Herpes simplex Virus 2 (HSV 2) IgG |
| HSV2M0540 | Herpes simplex Virus 2 (HSV 2) IgM |
| MAL0620   | Malaria                            |
| STRO0690  | Strongyloides                      |
| ZVG0790   | Zika Virus IgG capture             |
| ZVM0790   | Zika Virus IgM $\mu$ -capture      |

## **NovaLisa<sup>®</sup> Quantitative Assays (WHO standardized)**

| <b>Prod. No.</b> | <b>Name</b>                                   |
|------------------|-----------------------------------------------|
| BPTA0610         | Bordetella pertussis toxin (PT) IgA           |
| BPTG0610         | Bordetella pertussis toxin (PT) IgG           |
| CORG0090         | Corynebacterium diphtheriae toxin IgG         |
| CORG5009         | Corynebacterium diphtheriae toxin 5S IgG      |
| PCORG009         | Corynebacterium diphtheriae toxin 5S IgG plus |
| RFM3010          | Rheumatoid Factor IgM                         |
| RUBG0400         | Rubella Virus IgG                             |
| TETG0430         | Clostridium tetani toxin IgG                  |
| TETG5043         | Clostridium tetani toxin 5S IgG               |
| PTETG043         | Clostridium tetani toxin 5S IgG plus          |
| TOXG0460         | Toxoplasma gondii IgG                         |
| ATOX7460         | Avidity Toxoplasma gondii IgG                 |
| TSH1030          | TSH                                           |

## **NovaLisa<sup>®</sup> Quantitative Assays**

| <b>Prod. No.</b> | <b>Name</b>                                   |
|------------------|-----------------------------------------------|
| ATG1010          | Anti-TG                                       |
| ATPO1020         | Anti-TPO                                      |
| BPTA0610         | Bordetella pertussis toxin (PT) IgA           |
| BPTG0610         | Bordetella pertussis toxin (PT) IgG           |
| CORG0090         | Corynebacterium diphtheriae toxin IgG         |
| CORG5009         | Corynebacterium diphtheriae toxin 5S IgG      |
| PCORG009         | Corynebacterium diphtheriae toxin 5S IgG plus |
| FT41050          | Free T4                                       |
| HELA0220         | Helicobacter pylori IgA                       |
| HELG0220         | Helicobacter pylori IgG                       |
| PHELA022         | Helicobacter pylori IgA plus                  |
| PHELG022         | Helicobacter pylori IgG plus                  |
| RFM3010          | Rheumatoid Factor IgM                         |
| RUBG0400         | Rubella Virus IgG                             |
| ARUB7400         | Avidity Rubella Virus IgG                     |
| TETG0430         | Clostridium tetani toxin IgG                  |
| TETG5043         | Clostridium tetani 5S toxin IgG               |
| PTETG043         | Clostridium tetani toxin 5S IgG plus          |
| TICG0440         | TBE / FSME IgG                                |
| PTICG044         | TBE / FSME IgG plus                           |
| TOXG0460         | Toxoplasma gondii IgG                         |
| ATOX7460         | Avidity Toxoplasma gondii IgG                 |
| TSH1030          | TSH                                           |

## Antigen Assays

| Prod. No. | Name                     |
|-----------|--------------------------|
| NS1D4020  | Dengue Virus NS1 Antigen |

## NovaLisa<sup>®</sup> IgM $\mu$ -capture Assays

| Prod. No. | Name                                 |
|-----------|--------------------------------------|
| CHIM0590  | Chikungunya Virus IgM $\mu$ -capture |
| DVM0640   | Dengue Virus IgM $\mu$ -capture      |
| RUBM0400  | Rubella Virus IgM $\mu$ -capture     |
| TOXM0460  | Toxoplasma gondii IgM $\mu$ -capture |
| ZVM0790   | Zika Virus IgM $\mu$ -capture        |

## NovaLisa<sup>®</sup> Antibody Assays

| Prod. No. | Name                           |
|-----------|--------------------------------|
| ASCG0020  | Ascaris lumbricoides IgG       |
| CHAG0560  | Chagas (Trypanosoma cruzi) IgG |
| TRYP0570  | Chagas                         |
| ENTG0140  | Entamoeba histolytica IgG      |
| LEIG0310  | Leishmania infantum IgG        |
| MAL0620   | Malaria                        |
| STRO0690  | Strongyloides                  |
| TAEG0420  | Taenia solium IgG              |
| TOCG0450  | Toxocara canis IgG             |
| TRIG0480  | Trichinella spiralis IgG       |

## NovaLisa<sup>®</sup> Avidity Assays

| Prod. No. | Name                                 |
|-----------|--------------------------------------|
| ACMV7110  | Avidity Cytomegalovirus (CMV) IgG    |
| AEBV7150  | Avidity Epstein-Barr Virus (VCA) IgG |
| AMEA7330  | Avidity Measles Virus IgG            |
| ARUB7400  | Avidity Rubella Virus IgG            |
| ATOX7460  | Avidity Toxoplasma gondii IgG        |



**NovaLisa<sup>®</sup>      Liquor Diagnostic**

| <b>Prod. No.</b> | <b>Name</b>              |
|------------------|--------------------------|
| BORG0040         | Borrelia burgdorferi IgG |
| BORM0040         | Borrelia burgdorferi IgM |