CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

Digitally signed by Ceaicovschi Tudor
Date: 2025.12.22 14:46:23 EET
Reason: MoldSign Signature
Location: Moldova

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
MOLDOVA EUROPEANA 1998-07-23	2011-10-30	2023-10-24	2026-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

ITALCERT

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.
Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

www.imq.it

CERTIFICATO N.
CERTIFICATE N. **9190.CRC3**

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

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC) Italy

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

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

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

CISQ

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.

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

www.imq.it

ALLEGATO N. **9190.CRC3-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC) Italy

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

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

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

CISQ

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.

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

www.imq.it

ALLEGATO N. **9190.CRC3-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC) Italy

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

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

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

CISQ

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.

IQNET

Building trust together.

Certificate

CISQ/IMQ has issued an IQNET recognized certificate that the organization:

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC) Italy

VIA GRAMADORA 12/14 - 47122 FORLI' (FC) Italy

has implemented and maintains a
Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

which fulfils the requirements of the following standard:
ISO 9001:2015

Issued on: **2023/10/04**
Expires on: **2026/10/07**

Registration Number: **IT – 112265-9190.CRC3**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:
AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic **Cro Cert** Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC** Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifiointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Declaration of Conformity

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

Declaration of Conformity

HL-7- 0512 DC DOI 2013/08 (4)

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

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

Product Code	Description	GMDN Classification Code
5556	Clauss Fibrinogen 50	55997
5556H	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: 05 Aug 2013

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

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

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

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

Facility ID: F001410

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

ISO 13485:2016
EN ISO 13485:2016

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

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

File Number	A12241	Cycle Start Date	May 23, 2023
Certificate Number	1459.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

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

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

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

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

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

Facility ID: F001410

Additional Regulatory Requirements

Brazil:
- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

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

File Number	A12241	Cycle Start Date	May 23, 2023
Certificate Number	1459.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

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

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

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

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

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

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

ISO 13485:2016
EN ISO 13485:2016

The design and manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kits.

UKAS MANAGEMENT SYSTEMS 4426

Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

File Number	A12241	Cycle Start	May 23, 2023
Certificate Number	1458.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 123789 0004 Rev. 00

Manufacturer:

Lorne Laboratories Ltd
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley, Berkshire RG6 4UT
UNITED KINGDOM

SRN Manufacturer - GB-MF-000029354

Authorized Representative:

Advena Ltd.
Tower Business Centre,
2nd Floor, Tower Street,
Swatar, BKR 4013, MALTA

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V13 123789 0004 Rev. 00

Report No.: 75959970_AR
Valid from: 2025-05-07
Valid until: 2030-05-06

Marta Carnielli
Head of Certification IVD

Issue date: 2025-05-07

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 123789 0004 Rev. 00

Classification:	Class D
Device Group:	IVR 0101 - Immunohaematology (Blood grouping): ABO system
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	-

Rev.	Dated	Report	Description
00	2025-05-07	75959970_AR	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

МиниМед®
поставщик лабораторий

ООО "МиниМед", 241520, Российская Федерация, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, 17 А

Тел. (4832) 92-97-97, 92-24-52, -53, -55, -56, -57, -58, -60, -61, -62
Многоканальный номер - 8-800-100-48-32
Факс (4832) 92-24-54, 92-24-59, 92-24-61

ИНН 3234007127 www.minimed.ru e-mail: info@minimed.ru

Регистрационное удостоверение № ФСР 2011/11306 от 07.12.2015 г.

Паспорт

Краситель Азур-эозин по Романовскому (МиниМед-Р) ТУ 9398-003-29508133-2011

Серия	*98*	**Дата изготовления**	*03.2023 г.*	**Использовать до**	*03.2024 г.*

1. Назначение

Предназначен для окрашивания форменных элементов крови.

2. Технические требования

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1. Краситель	Темно-синяя сиропообразная жидкость без нерастворимых примесей	*соответствует*
1.2. Буфер фосфатный	Прозрачная бесцветная жидкость	*соответствует*
2. Плотность раствора красителя при комнатной температуре 20±2°С, г/см^3	1,000 – 1,100	*1,01*
3. Время наступления окраски мазка (при разведении красителя 1:19), мин, не более	50	*30*
4. Окраска форменных элементов крови	эритроциты – розовые с серым оттенком, бежево-коричневые	розовые с серым оттенком
	ядра лейкоцитов – фиолетовые	фиолетовые
	цитоплазма лимфоцитов – голубая, серо-голубая;	голубая
	цитоплазма нейтрофилов – бледно-розовая, серо-розовая;	бледно-розовая
	зернистость нейтрофилов – фиолетовая, красно-фиолетовая;	красно-фиолетовая
	зернистость эозинофилов – желто-оранжевая, розово-фиолетовая;	желто-оранжевая
	зернистость базофилов – фиолетовая;	фиолетовая
	тромбоциты – розово-фиолетовые, розово-сине-фиолетовые	розово-фиолетовые

3. Транспортирование и хранение

Транспортирование красителя-фиксатора должно проводиться всеми видами крытого транспорта при температуре от 0 до 25°С в соответствии с правилами перевозки грузов, действующими на данном виде транспорта. Краситель следует хранить при температуре от +5° до +25°С в темном месте, вдали от кислот и щелочей в течение всего срока годности.

4. Гарантии изготовителя

Изготовитель гарантирует соответствие красителя Азур-эозина по Романовскому (МиниМед-Р) требованиям ТУ 9398-003-29508133-2011 при соблюдении потребителем условий транспортирования, хранения и применения в течение всего срока годности.

Начальник ПТО **Бабич В.А.**

Общество с ограниченной ответственностью НАЧАЛЬНИК ПТО г. БРЯНСК БАБИЧ ВА МИНИМЕД

nova biomedical

Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC In Vitro Diagnostic Medical Device Directive (IVDD)

Product name:	Nova Stat Profile Prime Plus Analyzer System including Reagents, Calibrators and Controls
Catalog Numbers:	List Attached (Two Pages)
Classification:	Other/General
Manufacturer:	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454 USA
Representative:	William Jacques, Director of Regulatory and Quality
Authorized Representative:	Nova Biomedical GmbH Hessenring 13 A, Geb. G 64546 Mörfelden-Walldorf Germany Tel: +49 6105 4505-0
Conformity Assessment Route:	Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 50581:2012	Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2:101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Signature: _____

William Jacques, Director of Regulatory and Quality

CE

Date: Jul/24/2020

List of Catalog Items Covered:

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
57400	Stat Profile Prime Plus® Analyzer	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
59508	Stat Profile Prime Plus® Analyzer (Remanufactured)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57820	Stat Profile Prime Plus MicroSensor Card™ with COOX	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57821	Stat Profile Prime Plus MicroSensor Card™ BUN, Creatinine	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57822	Stat Profile Prime Plus MicroSensor Card™ with COOX (High Volume)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57823	Stat Profile Prime Plus Reference Cartridge	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57825	Stat Profile Prime Plus Calibrator Cartridge 100 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57826	Stat Profile Prime Plus Calibrator Cartridge 200 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57827	Stat Profile Prime Plus Calibrator Cartridge 300 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57828	Stat Profile Prime Plus Calibrator Cartridge 400 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57829	Stat Profile Prime Plus Calibrator Cartridge 500 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57831	Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57832	Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57833	Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57834	Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57835	Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57838	Stat Profile Prime Plus Auto QC Cartridge 160 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57839	Stat Profile Prime Plus Auto QC Cartridge 320 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57840	Stat Profile Prime Plus Auto QC Cartridge 480 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57841	Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57842	Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57843	Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57844	Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1, 2, 3	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57845	Stat Profile Prime Plus Ampuled Controls Chemistry Levels 4,5	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
58379	Stat Profile Prime Plus BUN, Creatinine - Blank Sensor Card	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58642	Stat Profile Prime Plus MicroSensor Card™	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58643	Stat Profile Prime Plus MicroSensor Card™ (High Volume)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
55229	Nova Linearity Level 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
56198	Linearity Standard Set G Multipack	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00
61656	Nova Linearity Creatinine/BUN/Hct Levels 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Holder of Certificate: **Nova Biomedical Corporation**
200 Prospect Street
Waltham MA 02454
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; The provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology, In-Vitro Diagnostic General Use Consumables; and Distribution of Lancets.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 02

Report No.: 72198686

Valid from: 2024-10-25
Valid until: 2027-10-24

Date, 2024-10-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Nova Biomedical Corporation
200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; the provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology and In-Vitro Diagnostic General Use Consumables.

Nova Biomedical Corporation
39 Manning Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care test strips.

Nova Biomedical Corporation
165 Lexington Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care Instruments
.

Nova Biomedical Corporation
4 Enterprise Road, Billerica MA 01821, USA

Production of In-Vitro Diagnostic Instruments including Near Patient / Point of Care; Distribution of Finished Goods; Distribution of Lancets.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

nova® biomedical

CERTIFICATE OF COMPLETION

This is to certify that

Sergiu Sorocovici

has successfully completed ***Stat Profile Prime Plus*** *Service and Application Training.*

April 10-11, 2023

Date of Training

Chișinău / Moldova

Location of Training

Huseyin Dibekkaya

Support Training Program Facilitator
International Regional Support Manager

PRIME PLUS / VET SHELF-LIFE & WARRANTY INFORMATION

REV: 07/2021

Stat Profile® Prime Plus and Stat Profile Prime Plus VET

	DESCRIPTION	WARRANTY	SHELF LIFE
Sensors Cards			
57820	Prime-Plus Sensor Card: w/ COOx (Standard)	14 Days/200 Samples*	12 Mos
57822	Prime-Plus Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58642	Prime-Plus Sensor Card: NO COOx (Standard)	14 Days/200 Samples*	12 Mos
58643	Prime-Plus Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
57821	Prime-Plus: Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58577	Prime-Plus VET- Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58578	Prime-Plus VET- Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
58581	Prime-Plus VET- Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58379	Prime-Plus Sensor Card- BLANK RENAL Sensor Card: (Clinical & VET)	Free of Defects	n/a
57823	Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (CLINICAL)	Free of Defects	18 Mos
59345	Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (VET)	Free of Defects	18 Mos
Calibrators			
57825	Stat Profile Prime Plus® Calibrator Cartridge 100 Sample	100 Samples or 35 Days	18 Mos
57826	Stat Profile Prime Plus® Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
57827	Stat Profile Prime Plus® Calibrator Cartridge 300 Sample	300 Samples or 35 Days	18 Mos
57828	Stat Profile Prime Plus® Calibrator Cartridge 400 Sample	400 Samples or 35 Days	18 Mos
57829	Stat Profile Prime Plus® Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
57831	Stat Profile Prime Plus® Calibrator Cartridge 100 Sample with Creat / BUN	100 Samples or 21 Days	18 Mos
57832	Stat Profile Prime Plus® Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
57833	Stat Profile Prime Plus® Calibrator Cartridge 300 Sample with Creat / BUN	300 Samples or 21 Days	18 Mos
57834	Stat Profile Prime Plus® Calibrator Cartridge 400 Sample with Creat / BUN	400 Samples or 21 Days	18 Mos
57835	Stat Profile Prime Plus® Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
58395	Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
58396	Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
58405	Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
58404	Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
AQC Packs			
57838	Stat Profile Prime Plus® Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
57839	Stat Profile Prime Plus® Auto QC Cartridge 320 Sample	320 Samples or 32 Days	18 Mos
57840	Stat Profile Prime Plus® Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
57841	Stat Profile Prime Plus® Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
57842	Stat Profile Prime Plus® Auto QC Cartridge 210 Sample with Creat / BUN	210 Samples or 21 Days	18 Mos
57843	Stat Profile Prime Plus® Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
58406	Stat Profile Prime Plus® VET Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
58407	Stat Profile Prime Plus® VET Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
58408	Stat Profile Prime Plus® VET Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
58409	Stat Profile Prime Plus® VET Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
57844	Stat Profile Prime Plus® Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57845	Stat Profile Prime Plus® Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

57812	Stat Profile Prime Plus® VET Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57813	Stat Profile Prime Plus® VET Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

Miscellaneous:			
52669	Luer Station Safety Port (5/pack) (Prime/Prime-Pllus)	Free of Defects	
52582	Probe/S-Line Assy : Prime/Prime-Plus	Free of Defects	
49200	Printer Paper (rolls: 5/pkg) (small-style)	Free of Defects	

Electro-Mechanical Components & Assemblies

***Whichever comes first.**

NOTE: THE WARRANTED USE EXPRESSED ABOVE IS ONLY VALID IF IT OCCURS

PRIOR TO THE "USE BEFORE DATE" LISTED ON THE PACKAGE LABEL.

VitalScientific
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00
www.vitalscientific.com

VitalScientific
Diagnostics for Life

DECLARATION DE CONFORMITE CE

Nous, VitalScientific, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (1 page), 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 2026).

DECLARATION OF EC CONFORMITY

We, VitalScientific, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (1 page), 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 , 2026).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, VitalScientific, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (1 página), 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 2026).

Sées, le 24 avril 2025

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

VitalScientific
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00
SIRET 318 365 228 00036

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

Annex

REF	PRODUCT NAME	GMDN Code
ASLO-0250	ANTI-STREPTOLYSIN O	59055
ASLO-5025	ANTI-STREPTOLYSIN O	59055
ASLO-6006	ANTI-STREPTOLYSIN O	59055
ASLO-4001	ANTI-STREPTOLYSIN O	51744
HDLL-0011	CHOLESTEROL HDL 2G CALIBRATOR	44696
HDLL-0041	CHOLESTEROL HDL 2G CALIBRATOR	44696
HDLL-0230	CHOLESTEROL HDL SL 2G	53391
HDLL-0380	CHOLESTEROL HDL SL 2G	53391
HDLL-0390	CHOLESTEROL HDL SL 2G	53391
IIGA-0400	IgA IP	53760
IIGA-6125	IgA IP	53760
IIGA-5025	IgA IP	53760
IIGG-0400	IgG IP	53787
IIGG-6125	IgG IP	53787
IIGG-5025	IgG IP	53787
IIGM-0400	IgM IP	53795
IIGM-6125	IgM IP	53795
IIGM-5025	IgM IP	53795
LDLL-0011	CHOLESTEROL LDL 2G CALIBRATOR	41728
LDLL-0041	CHOLESTEROL LDL 2G CALIBRATOR	41728
LDLL-0230	CHOLESTEROL LDL SL 2G	53395
LDLL-0380	CHOLESTEROL LDL SL 2G	53395
LDLL-0390	CHOLESTEROL LDL SL 2G	53395
LXCR-0112	CRP LATEX	53707
MAGX-0230	MAGNESIUM XYLIDYL	46795
MAGX-0600	MAGNESIUM XYLIDYL	46795

VitalScientific
Zone industrielle
61500 Sées - France
www.vitalscientific.com

VitalScientific
Diagnostics for Life

EU DECLARATION OF CONFORMITY

According to Annex IV of the regulation 2017/746 on *in vitro* diagnostic medical devices

	Manufacturer	VitalScientific Zone Industrielle, 61500 SEES, France
SRN	**Single Registration Number**	FR-MF-000004722

We, as the manufacturer of the devices take sole responsibility for and hereby declare that products mentioned in Annex I meet the provisions of:

☒ Regulation EU 2017/746 on *in vitro* diagnostic medical devices

Risk class :
☐ A ☒ B ☐ C ☐ D

Conformity route:

☐ Conformity assessment based on self-declaration, Annex II : Technical Documentation.

☐ Conformity assessment based on self-declaration, Annex III : Technical documentation on post-market Surveillance.

☒ Conformity assessment based on a quality management system and on assessment of technical documentation according to Annex IX chapters I and III with assessment of the technical documentation by sampling according to section 4.

Other :
Common Specifications: Not applicable

Notified Body*:*

EU CERTIFICAT NUMBER:	**39658 rev.5 issued on May 21st, 2025**
Name of Notified Body:	**GMED SAS**
Adress of Notified Body :	**1, rue Gaston Boissier, 75724 PARIS, France**
Notified Body Identification :	**0459**
Expiry date :	**April 2nd, 2029**

EU QMS Certificate :

NF EN ISO 13485 :	**2016**
Certificate number :	**10462 rev. 10 issued on May 21st, 2025**
Expiry date :	**July 27th, 2026**

☒ Only for Electrodes*:* Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, including Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

VitalScientific
Zone industrielle
61500 Sées - France
www.vitalscientific.com

VitalScientific
Diagnostics for Life

DÉCLARATION DE CONFORMITÉ UE

Conformément à l'annexe IV du règlement 2017/746 relatif aux dispositifs médicaux de diagnostic *in vitro*

	Fabricant	VitalScientific Zone Industrielle, 61500 SEES, France
SRN	**Numéro d'enregistrement unique**	FR-MF-000004722

Nous, en tant que fabricant des dispositifs, nous assumons l'entière responsabilité et déclarons par la présente que les produits mentionnés à l'annexe I satisfont aux:

☒ Règlement (UE) 2017/746 relatif aux dispositifs médicaux de diagnostic *in vitro*

Classe de risque:
☐ A ☒ B ☐ C ☐ D

Parcours de conformité:

☐ Evaluation de la conformité sur la base d'une auto-déclaration, Annexe II : Documentation Technique.

☐ Evaluation de la conformité sur la base d'une auto-déclaration, Annexe III : Documentation technique relative à la surveillance après commercialisation.

☒ Evaluation de la conformité sur la base d'un système de gestion de la qualité et de l'évaluation de la documentation technique selon Annexe IX, chapitres I et III avec une évaluation de la documentation technique par échantillonnage selon la section 4.

Autre:
Spécifications communes: Non applicable

Organisme Notifié:

NUMERO DU CERTIFICAT UE:	**39658 rev.5 établi le 21 mai 2025**
Nom de l'Organisme Notifié:	**GMED SAS**
Adresse de l'Organisme Notifié:	**1, rue Gaston Boissier, 75724 PARIS, France**
Numéro d'identification:	**0459**
Valable jusqu'au:	**02 avril 2029**

Certificat UE du système de management de la Qualité :

NF EN ISO 13485 :	**2016**
Numéro de certificat :	**10462 rev. 10 établi le 21 mai 2025**
Valable jusqu'au:	**27 Juillet 2026**

☒ Seulement pour les Electrodes: Directive 2011/65/UE du parlement européen et du conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques incluant la DIRECTIVE DÉLÉGUÉE (UE) 2015/863 DE LA COMMISSION du 31 mars 2015 modifiant l'annexe II de la directive 2011/65/UE du Parlement européen et du Conseil en ce qui concerne la liste des substances soumises à limitations.

VitalScientific
Zone industrielle
61500 Sées - France
www.vitalscientific.com

VitalScientific
Diagnostics for Life

DECLARACION DE CONFORMIDAD DE LA EU

Según el Anexo IV del reglamento 2017/746 sobre productos sanitarios para diagnóstico *in vitro*

	Fabricante	VitalScientific Zone Industrielle, 61500 SEES, France
SRN	**Número de registro único**	FR-MF-000004722

Nosotros, como fabricante de los dispositivos, asumimos la responsabilidad exclusiva y declaramos que los productos mencionados en el Anexo I cumplen con:

☒ Reglamento EU 2017/746 sobre productos sanitarios para diagnóstico *in vitro*

Clase de riesgo:
☐ A ☒ B ☐ C ☐ D

Vía de conformidad :

☐ Evaluación de la conformidad basada en auto declaración, Anexo II : Documentación Técnica.

☐ Evaluación de la conformidad basada en auto declaración, Anexo III : Documentación técnica sobreseguimiento poscomercialización.

☒ Evaluación de la conformidad basada en un sistema de gestión de la calidad y en la evaluación de la documentación técnica según el Anexo IX capítulos I y III con evaluación de la documentación técnica por muestreo según la sección 4.

Otro:
Especificaciones comunes: No aplicable

Organismo Notificado:

NUMERO DE CERTIFICADO UE:	**39658 rev.5 establecido el 21 de mayo de 2025**
Nombre del Organismo Notificado :	**GMED SAS**
Dirección del Organismo Notificado:	**1, rue Gaston Boissier, 75724 PARIS, France**
Identificación del Organismo Notificado:	**0459**
fecha de caducidad:	**02 de abril de 2029**

Certificado del sistema de gestión de calidad de la UE:

NF EN ISO 13485 :	**2016**
Número certificado:	**10462 rev. 10 establecido el 21 de mayo de 2025**
fecha de caducidad:	**27 de julio de 2026**

☒ Solamente para Electrode: Directiva 2011/65/UE del parlamento europeo y del consejo de 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos incluyendo la directiva delegada (UE) 2015/863 de la comisión de 31 de marzo de 2015 por la que se modifica el anexo II de la Directiva 2011/65/UE del Parlamento Europeo y del Consejo en cuanto a la lista de sustancias restringidas

Sées, 13 juin 2025

VitalScientific
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00
SIRET 318 365 228 00036

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

Annex I

REF	PRODUCT NAME	BASIC UDI
3918-004	Sodium Electrode (Na+)	370170083918-00407ZC
3918-005	Potassium Electrode (K+)	370170083918-00507ZH
3918-006	Chloride Electrode (Cl-)	370170083918-00607ZN
3918-003	Carbon Dioxide Electrode (CO2)	370170083918-00307Z7
3918-002	Reference Electrode (REF)	370170083918-00207Z2
ALBU-0250	ALBUMIN	37017008ALBU006C
ALBU-5220	ALBUMIN	37017008ALBU006C
ALBU-0600	ALBUMIN	37017008ALBU006C
ALBU-5600	ALBUMIN	37017008ALBU006C
ALBU-0700	ALBUMIN	37017008ALBU006C
ALBU-5700	ALBUMIN	37017008ALBU006C
ALBU-M830	ALBUMIN	37017008ALBU016E
ALBU-5M30	ALBUMIN	37017008ALBU016E
ALPI-0230	ALP IFCC	37017008ALPI037Q
ALPI-5100	ALP IFCC	37017008ALPI037Q
ALPI-6050	ALP IFCC	37017008ALPI037Q
ALSL-0250	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-5220	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-6050	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-0410	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-5415	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-6255	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-0430	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-0510	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-5515	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-6615	ALT/GPT 4+1 SL	37017008ALSL008N
ALSL-M490	ALT/GPT	37017008ALSL018Q
ALSL-5M90	ALT/GPT	37017008ALSL018Q
ALSL-6M30	ALT/GPT	37017008ALSL018Q
AMSL-0230	AMYLASE SL	37017008AMSL008Z
AMSL-5220	AMYLASE SL	37017008AMSL008Z
AMSL-0390	AMYLASE SL	37017008AMSL008Z
AMSL-5405	AMYLASE SL	37017008AMSL008Z
AMSL-0400	AMYLASE SL	37017008AMSL008Z
AMSL-M430	AMYLASE	37017008AMSL0193
AMSL-5M30	AMYLASE	37017008AMSL0193
ASSL-0250	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-5220	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-6050	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-0410	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-5415	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-6255	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-0430	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-0510	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-5515	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-6615	AST/GOT 4+1 SL	37017008ASSL00B3
ASSL-M490	AST/GOT	37017008ASSL01B5
ASSL-5M90	AST/GOT	37017008ASSL01B5
ASSL-6M30	AST/GOT	37017008ASSL01B5
AUML-0250	URIC ACID MONO SL	37017008AUML00AF
AUML-5220	URIC ACID MONO SL	37017008AUML00AF
AUML-0420	URIC ACID MONO SL	37017008AUML00AF
AUML-5405	URIC ACID MONO SL	37017008AUML00AF
AUML-0427	URIC ACID MONO SL	37017008AUML00AF
AUML-0497	URIC ACID MONO SL	37017008AUML00AF
AUML-5505	URIC ACID MONO SL	37017008AUML00AF
AUML-0500	URIC ACID MONO SL	37017008AUML00AF
AUML-0507	URIC ACID MONO SL	37017008AUML00AF
AUML-0707	URIC ACID MONO SL	37017008AUML00AF
AUML-5710	URIC ACID MONO SL	37017008AUML00AF
AUML-M830	URIC ACID	37017008AUML01AH
AUML-5M30	URIC ACID	37017008AUML01AH
AUSL-0250	URIC ACID SL	37017008AUSL00BR
AUSL-5220	URIC ACID SL	37017008AUSL00BR
AUSL-6050	URIC ACID SL	37017008AUSL00BR
BIDI-0250	BILIRUBIN DIRECT 4+1	37017008BIDI004H
BIDI-5220	BILIRUBIN DIRECT 4+1	37017008BIDI004H
BIDI-6050	BILIRUBIN DIRECT 4+1	37017008BIDI004H
BIDI-0500	BILIRUBIN DIRECT	37017008BIDI004H
BIDI-5600	BILIRUBIN DIRECT	37017008BIDI004H
BITD-6250	BILIRUBIN DIRECT	37017008BITD006Z
BIDI-M430	DIRECT BILIRUBIN	37017008BIDI014C
BIDI-5M30	DIRECT BILIRUBIN	37017008BIDI014C
BIDI-6M10	DIRECT BILIRUBIN	37017008BIDI014C
BITO-0250	BILIRUBIN TOTAL 4+1	37017008BITO008Q
BITO-5220	BILIRUBIN TOTAL 4+1	37017008BITO008Q
BITO-6050	BILIRUBIN TOTAL 4+1	37017008BITO008Q
BITO-0600	BILIRUBIN TOTAL 4+1	37017008BITO008Q
BITO-5600	BILIRUBIN TOTAL 4+1	37017008BITO008Q
BITD-6400	BILIRUBIN TOTAL 4+1	37017008BITD006Z
BITO-M430	TOTAL BILIRUBIN	37017008BITO018S
BITO-5M30	TOTAL BILIRUBIN	37017008BITO018S
BITO-6M10	TOTAL BILIRUBIN	37017008BITO018S
CALA-0250	CALCIUM ARSENAZO	37017008CALA002F
CALA-5220	CALCIUM ARSENAZO	37017008CALA002F
CALA-0600	CALCIUM ARSENAZO	37017008CALA002F
CALA-5600	CALCIUM ARSENAZO	37017008CALA002F
CALA-M430	CALCIUM ARSENAZO	37017008CALA012H
CALA-5M30	CALCIUM ARSENAZO	37017008CALA012H
CALI-0550	ELICAL 2	37017008CALI043X
CALI-1550	ELICAL 2	37017008CALI043X
CHDL-0250	HDL CHOLESTEROL	37017008CHDL004T
CHDL-5021	HDL CHOLESTEROL	37017008CHDL004T
CHDL-6014	HDL CHOLESTEROL	37017008CHDL004T
CHDL-0600	HDL CHOLESTEROL	37017008CHDL004T
CHDL-5090	HDL CHOLESTEROL	37017008CHDL004T
CHDL-6060	HDL CHOLESTEROL	37017008CHDL004T
CHDL-M330	HDL CHOLESTEROL	37017008CHDL014V
CHDL-5M30	HDL CHOLESTEROL	37017008CHDL014V
CHDL-6M30	HDL CHOLESTEROL	37017008CHDL014V
CHEB-0250	CHOLINESTERASE	37017008CHEB033N
CHEB-5008	CHOLINESTERASE	37017008CHEB033N

REF	PRODUCT NAME	BASIC UDI
CHEB-6005	CHOLINESTERASE	37017008CHEB033N
CHSL-0250	CHOLESTEROL SL	37017008CHSL0084
CHSL-5220	CHOLESTEROL SL	37017008CHSL0084
CHSL-0497	CHOLESTEROL SL	37017008CHSL0084
CHSL-5505	CHOLESTEROL SL	37017008CHSL0084
CHSL-0500	CHOLESTEROL SL	37017008CHSL0084
CHSL-0507	CHOLESTEROL SL	37017008CHSL0084
CHSL-0700	CHOLESTEROL SL	37017008CHSL0084
CHSL-5710	CHOLESTEROL SL	37017008CHSL0084
CHSL-0707	CHOLESTEROL SL	37017008CHSL0084
CHSL-M690	CHOLESTEROL	37017008CHSL0186
CHSL-5M90	CHOLESTEROL	37017008CHSL0186
CHSL-5M30	CHOLESTEROL	37017008CHSL0186
CKMB-0900	CK-MB CONTROL	37017008CKMB056K
CKMB-1030	CK-MB CONTROL	37017008CKMB056K
CKSL-0230	CK NAC SL	37017008CKSL0095
CKSL-5220	CK NAC SL	37017008CKSL0095
CKSL-6050	CK NAC SL	37017008CKSL0095
CKSL-0410	CK NAC SL	37017008CKSL0095
CKSL-5405	CK NAC SL	37017008CKSL0095
CKSL-6255	CK NAC SL	37017008CKSL0095
CKSL-M230	CK NAC	37017008CKSL0197
CKSL-5M30	CK NAC	37017008CKSL0197
CKSL-6M10	CK NAC	37017008CKSL0197
CLDL-0250	LDL CHOLESTEROL	37017008CLDL0067
CLDL-5021	LDL CHOLESTEROL	37017008CLDL0067
CLDL-6014	LDL CHOLESTEROL	37017008CLDL0067
CLDL-M330	LDL CHOLESTEROL	37017008CLDL0169
CLDL-5M30	LDL CHOLESTEROL	37017008CLDL0169
CLDL-6M30	LDL CHOLESTEROL	37017008CLDL0169
CMSL-0230	CK-MB	37017008CMSL039Z
CMSL-5220	CK-MB	37017008CMSL039Z
CMSL-6220	CK-MB	37017008CMSL039Z
CMSL-WR	CK-MB	37017008CMSL039Z
CMSL-0410	CK-MB SL	37017008CMSL009T
CMSL-5405	CK-MB SL	37017008CMSL009T
CMSL-6255	CK-MB SL	37017008CMSL009T
CONT-0060	ELITROL I	37017008CONT05AY
CONT-1060	ELITROL I	37017008CONT05AY
CONT-0160	ELITROL II	37017008CONT05AY
CONT-1160	ELITROL II	37017008CONT05AY
CRCO-0600	CREATININE JAFFE	37017008CRCO008H
CRCO-5600	CREATININE JAFFE	37017008CRCO008H
CRCO-6600	CREATININE JAFFE	37017008CRCO008H
CRSL-0250	CREATININE PAP SL	37017008CRSL00BJ
CRSL-5221	CREATININE PAP SL	37017008CRSL00BJ
CRSL-6070	CREATININE PAP SL	37017008CRSL00BJ
CRSL-0630	CREATININE PAP SL	37017008CRSL00BJ
CRSL-5505	CREATININE PAP SL	37017008CRSL00BJ
CRSL-6470	CREATININE PAP SL	37017008CRSL00BJ
CRSL-M490	CREATININE PAP	37017008CRSL01BL
CRSL-5M90	CREATININE PAP	37017008CRSL01BL
CRSL-6M30	CREATININE PAP	37017008CRSL01BL
FEFE-0230	IRON FERENE	37017008FEFE004C
FEFE-5140	IRON FERENE	37017008FEFE004C
FEFE-6040	IRON FERENE	37017008FEFE004C
FEFE-0600	IRON FERENE	37017008FEFE004C
FEFE-5600	IRON FERENE	37017008FEFE004C
FEFE-6400	IRON FERENE	37017008FEFE004C
FEFE-M230	IRON FERENE	37017008FEFE014E
FEFE-5M30	IRON FERENE	37017008FEFE014E
FEFE-6M10	IRON FERENE	37017008FEFE014E
GHSL-0250	GLUCOSE HK SL	37017008GHSL009Q
GHSL-5220	GLUCOSE HK SL	37017008GHSL009Q
GHSL-6050	GLUCOSE HK SL	37017008GHSL009Q
GHSL-0600	GLUCOSE HK SL	37017008GHSL009Q
GHSL-5505	GLUCOSE HK SL	37017008GHSL009Q
GHSL-6605	GLUCOSE HK SL	37017008GHSL009Q
GHSL-M490	GLUCOSE HK	37017008GHSL019S
GHSL-5M90	GLUCOSE HK	37017008GHSL019S
GHSL-6M30	GLUCOSE HK	37017008GHSL019S
GISL-0250	GAMMA-GT PLUS SL	37017008GISL00A3
GISL-5220	GAMMA-GT PLUS SL	37017008GISL00A3
GISL-6050	GAMMA-GT PLUS SL	37017008GISL00A3
GISL-0420	GAMMA-GT PLUS SL	37017008GISL00A3
GISL-5405	GAMMA-GT PLUS SL	37017008GISL00A3
GISL-6255	GAMMA-GT PLUS SL	37017008GISL00A3
GISL-M230	GAMMA-GT	37017008GISL01A5
GISL-5M30	GAMMA-GT	37017008GISL01A5
GISL-6M10	GAMMA-GT	37017008GISL01A5
GPSL-0250	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-5220	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-0497	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-5505	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-0500	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-0507	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-0700	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-5710	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-0707	GLUCOSE PAP SL	37017008GPSL00CG
GPSL-M690	GLUCOSE PAP	37017008GPSL01CJ
GPSL-5M90	GLUCOSE PAP	37017008GPSL01CJ
GPSL-5M30	GLUCOSE PAP	37017008GPSL01CJ
HBAC-0043	HbA1c CALIBRATOR SET	37017008HBAC042Y
HBAC-4301	HbA1c CALIBRATOR SET	37017008HBAC042Y
HBAC-4302	HbA1c CALIBRATOR SET	37017008HBAC042Y
HBAC-4303	HbA1c CALIBRATOR SET	37017008HBAC042Y
HBAC-4304	HbA1c CALIBRATOR SET	37017008HBAC042Y
HBAC-0049	HbA1c CONTROL L + H	37017008HBAC0532
HBAC-4605	HbA1c CONTROL L + H	37017008HBAC0532
HBAC-4705	HbA1c CONTROL L + H	37017008HBAC0532
HBAC-0240	HbA1c	37017008HBAC002Q
HBAC-5224	HbA1c	37017008HBAC002Q
HBAC-6076	HbA1c	37017008HBAC002Q
HBAC-6004	HbA1c	37017008HBAC002Q

Annex I

REF	PRODUCT NAME	BASIC UDI
HBAC-7225	HbA1c	37017008HBAC002Q
HBAE-0043	HbA1c Enzymatic Calibrator Set	37017008HBAE043A
HBAE-4301	HbA1c Enzymatic Calibrator Set	37017008HBAE043A
HBAE-4303	HbA1c Enzymatic Calibrator Set	37017008HBAE043A
HBAE-M130	HbA1c Enzymatic	37017008HBAE0134
HBAE-5M30	HbA1c Enzymatic	37017008HBAE0134
HBAE-6M30	HbA1c Enzymatic	37017008HBAE0134
HBAE-7050	HbA1c Enzymatic	37017008HBAE0134
HLCA-0041	HDL LDL CALIBRATOR	37017008HLCA046J
HLCA-4001	HDL LDL CALIBRATOR	37017008HLCA046J
ICRP-0043	CRP IP CALIBRATOR SET	37017008ICRP049G
ICRP-4311	CRP IP CALIBRATOR SET	37017008ICRP049G
ICRP-4312	CRP IP CALIBRATOR SET	37017008ICRP049G
ICRP-4313	CRP IP CALIBRATOR SET	37017008ICRP049G
ICRP-4314	CRP IP CALIBRATOR SET	37017008ICRP049G
ICRP-4315	CRP IP CALIBRATOR SET	37017008ICRP049G
ICRP-0046	CRP IP CONTROL I	37017008ICRP059J
ICRP-4610	CRP IP CONTROL I	37017008ICRP059J
ICRP-0047	CRP IP CONTROL II	37017008ICRP059J
ICRP-4710	CRP IP CONTROL II	37017008ICRP059J
ICRP-0400	CRP IP	37017008ICRP0098
ICRP-6125	CRP IP	37017008ICRP0098
ICRP-5025	CRP IP	37017008ICRP0098
ICRP-M230	CRP IP	37017008ICRP019A
ICRP-6M30	CRP IP	37017008ICRP019A
ICRP-5M30	CRP IP	37017008ICRP019A
IFRT-0042	FERRITIN CALIBRATOR	37017008IFRT04B5
IFRT-4230	FERRITIN CALIBRATOR	37017008IFRT04B5
IFRT-0230	FERRITIN	37017008IFRT03B3
IFRT-5020	FERRITIN	37017008IFRT03B3
IFRT-6005	FERRITIN	37017008IFRT03B3
IHAP-0400	HAPTOGLOBIN IP	37017008IHAP037E
IHAP-6125	HAPTOGLOBIN IP	37017008IHAP037E
IHAP-5025	HAPTOGLOBIN IP	37017008IHAP037E
IMAL-0043	µALBUMIN IP CALIBRATOR SET	37017008IMAL048K
IMAL-4311	µALBUMIN IP CALIBRATOR SET	37017008IMAL048K
IMAL-4312	µALBUMIN IP CALIBRATOR SET	37017008IMAL048K
IMAL-4313	µALBUMIN IP CALIBRATOR SET	37017008IMAL048K
IMAL-4314	µALBUMIN IP CALIBRATOR SET	37017008IMAL048K
IMAL-4315	µALBUMIN IP CALIBRATOR SET	37017008IMAL048K
IMAL-0046	µALBUMIN IP CONTROL I	37017008IMAL058M
IMAL-4610	µALBUMIN IP CONTROL I	37017008IMAL058M
IMAL-0047	µALBUMIN IP CONTROL II	37017008IMAL058M
IMAL-4710	µALBUMIN IP CONTROL II	37017008IMAL058M
IMAL-0400	µALBUMIN IP	37017008IMAL008B
IMAL-6125	µALBUMIN IP	37017008IMAL008B
IMAL-5025	µALBUMIN IP	37017008IMAL008B
IMAL-M230	MICROALBUMIN IP	37017008IMAL018D
IMAL-6M30	MICROALBUMIN IP	37017008IMAL018D
IMAL-5M30	MICROALBUMIN IP	37017008IMAL018D
IORO-0400	OROSOMUCOID IP	37017008IORO03DD
IORO-6125	OROSOMUCOID IP	37017008IORO03DD
IORO-5025	OROSOMUCOID IP	37017008IORO03DD
IPAL-0400	PREALBUMIN IP	37017008IPAL039J
IPAL-6125	PREALBUMIN IP	37017008IPAL039J
IPAL-5025	PREALBUMIN IP	37017008IPAL039J
IPRO-0043	PROTEIN IP CALIBRATOR SET	37017008IPRO04DS
IPRO-4311	PROTEIN IP CALIBRATOR SET	37017008IPRO04DS
IPRO-4312	PROTEIN IP CALIBRATOR SET	37017008IPRO04DS
IPRO-4313	PROTEIN IP CALIBRATOR SET	37017008IPRO04DS
IPRO-4314	PROTEIN IP CALIBRATOR SET	37017008IPRO04DS
IPRO-4315	PROTEIN IP CALIBRATOR SET	37017008IPRO04DS
IRCT-0046	RHEUMATOLOGY CONTROL I	37017008IRCT05C2
IRCT-4610	RHEUMATOLOGY CONTROL I	37017008IRCT05C2
IRCT-0047	RHEUMATOLOGY CONTROL II	37017008IRCT05C2
IRCT-4710	RHEUMATOLOGY CONTROL II	37017008IRCT05C2
IRFA-0042	RF CALIBRATOR	37017008IRFA049N
IRFA-4220	RF CALIBRATOR	37017008IRFA049N
IRFA-0230	RHEUMATOID FACTOR	37017008IRFA009E
IRFA-5020	RHEUMATOID FACTOR	37017008IRFA009E
IRFA-6005	RHEUMATOID FACTOR	37017008IRFA009E
IRON-0600	IRON FERENE	37017008IRON00DE
IRON-5600	IRON FERENE	37017008IRON00DE
IRON-6400	IRON FERENE	37017008IRON00DE
IRON-0250	IRON FERENE	37017008IRON00DE
IRON-5024	IRON FERENE	37017008IRON00DE
IRON-6013	IRON FERENE	37017008IRON00DE
IRON-M230	IRON FERENE	37017008IRON01DG
IRON-5M30	IRON FERENE	37017008IRON01DG
IRON-6M30	IRON FERENE	37017008IRON01DG
ISCA-0250	ISE CALIBRATORS	37017008ISCA049C
ISCA-4221	ISE CALIBRATORS	37017008ISCA049C
ISCA-4222	ISE CALIBRATORS	37017008ISCA049C
LACI-0250	LACTATE	37017008LACI035K
LACI-5008	LACTATE	37017008LACI035K
LACI-6005	LACTATE	37017008LACI035K
LITH-0230	LITHIUM	37017008LITH03BV
LITH-5008	LITHIUM	37017008LITH03BV
LITH-0048	LITHIUM CONTROL	37017008LITH05BZ
LITH-4080	LITHIUM CONTROL	37017008LITH05BZ
LLSL-0230	LDH-L SL	37017008LLSL00D5
LLSL-5220	LDH-L SL	37017008LLSL00D5
LLSL-6050	LDH-L SL	37017008LLSL00D5
LLSL-0400	LDH-L SL	37017008LLSL00D5
LLSL-5400	LDH-L SL	37017008LLSL00D5
LLSL-6250	LDH-L SL	37017008LLSL00D5
LLSL-M230	LDH IFCC	37017008LLSL01D7
LLSL-5M30	LDH IFCC	37017008LLSL01D7
LLSL-6M10	LDH IFCC	37017008LLSL01D7
LPSL-0250	LIPASE	37017008LPSL03EP
LPSL-5088	LIPASE	37017008LPSL03EP
LPSL-6061	LIPASE	37017008LPSL03EP
MGXB-0250	MAGNESIUM XB	37017008MGXB00BC

V6

Annex I

REF	PRODUCT NAME	BASIC UDI
MGXB-5220	MAGNESIUM XB	37017008MGXB00BC
MGXB-0600	MAGNESIUM XB	37017008MGXB00BC
MGXB-5600	MAGNESIUM XB	37017008MGXB00BC
MGXB-M430	MAGNESIUM XB	37017008MGXB01BE
MGXB-5M30	MAGNESIUM XB	37017008MGXB01BE
PASL-0230	ALP (DEA) SL	37017008PASL00AY
PASL-5220	ALP (DEA) SL	37017008PASL00AY
PASL-6050	ALP (DEA) SL	37017008PASL00AY
PASL-0400	ALP (DEA) SL	37017008PASL00AY
PASL-5405	ALP (DEA) SL	37017008PASL00AY
PASL-6255	ALP (DEA) SL	37017008PASL00AY
PASL-0420	ALP (DEA) SL	37017008PASL00AY
PHOS-0230	PHOSPHORUS	37017008PHOS00DL
PHOS-5220	PHOSPHORUS	37017008PHOS00DL
PHOS-0600	PHOSPHORUS	37017008PHOS00DL
PHOS-5600	PHOSPHORUS	37017008PHOS00DL
PHOS-M430	PHOSPHORUS	37017008PHOS01DN
PHOS-5M30	PHOSPHORUS	37017008PHOS01DN
PROB-0250	TOTAL PROTEIN PLUS	37017008PROB00ED
PROB-5220	TOTAL PROTEIN PLUS	37017008PROB00ED
PROB-0600	TOTAL PROTEIN PLUS	37017008PROB00ED
PROB-5600	TOTAL PROTEIN PLUS	37017008PROB00ED
PROB-0700	TOTAL PROTEIN PLUS	37017008PROB00ED
PROB-5700	TOTAL PROTEIN PLUS	37017008PROB00ED
PROB-M830	TOTAL PROTEIN	37017008PROB01EF
PROB-5M30	TOTAL PROTEIN	37017008PROB01EF
PRTU-0600	MICROPROTEIN PLUS	37017008PRTU00JF
PRTU-5600	MICROPROTEIN PLUS	37017008PRTU00JF
PRTU-M230	URINE PROTEIN	37017008PRTU01JH
PRTU-5M30	URINE PROTEIN	37017008PRTU01JH
PRTU-4020	MICROPROTEIN Standard	37017008PRTU04JP
RHFA-M130	RHEUMATOID FACTOR	37017008RHFA019P
RHFA-5M30	RHEUMATOID FACTOR	37017008RHFA019P
RHFA-6M30	RHEUMATOID FACTOR	37017008RHFA019P
RHFA-4220	RHEUMATOID FACTOR	37017008RHFA019P
TGML-0250	TRIGLYCERIDES SL	37017008TGML00DC
TGML-5220	TRIGLYCERIDES SL	37017008TGML00DC
TGML-0425	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-5415	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-0427	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-0497	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-5515	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-0515	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-0517	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-0700	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-5710	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-0707	TRIGLYCERIDES MONO SL NEW	37017008TGML00DC
TGML-M690	TRIGLYCERIDES	37017008TGML01DE
TGML-5M90	TRIGLYCERIDES	37017008TGML01DE
TGML-5M30	TRIGLYCERIDES	37017008TGML01DE
TIBC-0250	Direct TIBC	37017008TIBC00A8
TIBC-5025	Direct TIBC	37017008TIBC00A8
TIBC-6007	Direct TIBC	37017008TIBC00A8
TIBC-M130	Direct TIBC	37017008TIBC01AA
TIBC-5M30	Direct TIBC	37017008TIBC01AA
TIBC-6M30	Direct TIBC	37017008TIBC01AA
TRF2-M230	TRANSFERRIN	37017008TRF201BR
TRF2-5M30	TRANSFERRIN	37017008TRF201BR
TRF2-6M10	TRANSFERRIN	37017008TRF201BR
URSL-0250	UREA UV SL	37017008URSL00JU
URSL-5220	UREA UV SL	37017008URSL00JU
URSL-6050	UREA UV SL	37017008URSL00JU
URSL-0420	UREA UV SL	37017008URSL00JU
URSL-5405	UREA UV SL	37017008URSL00JU
URSL-6255	UREA UV SL	37017008URSL00JU
URSL-0427	UREA UV SL	37017008URSL00JU
URSL-0500	UREA UV SL	37017008URSL00JU
URSL-5505	UREA UV SL	37017008URSL00JU
URSL-6605	UREA UV SL	37017008URSL00JU
URSL-0507	UREA UV SL	37017008URSL00JU
URSL-M830	UREA	37017008URSL01JW
URSL-5M30	UREA	37017008URSL01JW
URSL-6M10	UREA	37017008URSL01JW
VITD-0043	VITAMIN D CALIBRATOR SET	37017008VITD04FD
VITD-4311	VITAMIN D CALIBRATOR SET	37017008VITD04FD
VITD-4312	VITAMIN D CALIBRATOR SET	37017008VITD04FD
VITD-4313	VITAMIN D CALIBRATOR SET	37017008VITD04FD
VITD-4314	VITAMIN D CALIBRATOR SET	37017008VITD04FD
VITD-4315	VITAMIN D CALIBRATOR SET	37017008VITD04FD
VITD-0049	VITAMIN D CONTROL SET	37017008VITD05FF
VITD-4630	VITAMIN D CONTROL SET	37017008VITD05FF
VITD-4730	VITAMIN D CONTROL SET	37017008VITD05FF
VITD-0250	VITAMIN D	37017008VITD03FB
VITD-5021	VITAMIN D	37017008VITD03FB
VITD-6005	VITAMIN D	37017008VITD03FB