

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 Reglamentarios



VitalScientific

Zone Industrielle
61500 SEES - France
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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

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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.

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.

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

Valérie LAMBERT,

Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Zone Industrielle
61500 SEES - France

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SIRET 318 365 228 00036

Cécile GOUBAULT,

Directeur Général Délégué
Managing Director
Directora General

Société par actions simplifiée au capital de 5.663.754,36 € – SIREN : 318 365 228 – RCS ALENCON

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

Annex I

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
GPST-0250	GLUCOSE PAP SL	37017008GPST00CG
GPST-5220	GLUCOSE PAP SL	37017008GPST00CG
GPST-0497	GLUCOSE PAP SL	37017008GPST00CG
GPST-5505	GLUCOSE PAP SL	37017008GPST00CG
GPST-0500	GLUCOSE PAP SL	37017008GPST00CG
GPST-0507	GLUCOSE PAP SL	37017008GPST00CG
GPST-0700	GLUCOSE PAP SL	37017008GPST00CG
GPST-5710	GLUCOSE PAP SL	37017008GPST00CG
GPST-0707	GLUCOSE PAP SL	37017008GPST00CG
GPST-M690	GLUCOSE PAP	37017008GPST01CJ
GPST-5M90	GLUCOSE PAP	37017008GPST01CJ
GPST-5M30	GLUCOSE PAP	37017008GPST01CJ
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

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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

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

Vla
G

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

VitalScientific

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

**VitalScientific,
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

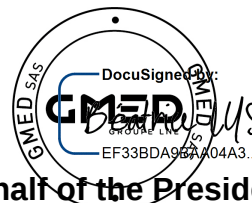
Début de validité / Effective date **May 21st, 2025 (included)**

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

Etabli le / Issued on : **May 21st, 2025**



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



On behalf of the President
Béatrice LYS
Technical Director

GMED N° 10462-10

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

Modifie le certificat 10462-9

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Instrument Training

Vital Scientific BV hereby declares that the participant has attended a four days seminar for service engineers and the participant is now a certified engineer for the declared instruments.

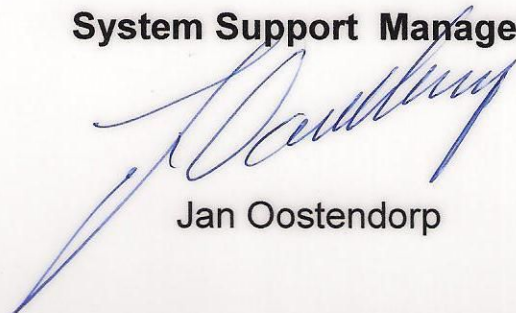
Participant: Mr. A. Legun

Company: Global Biomarketing Group-Moldova SRL
Moldova

Instrument: Vitalab: XL Series
E Series
Junior Series
Dry ISE
Micro Series
ProXS

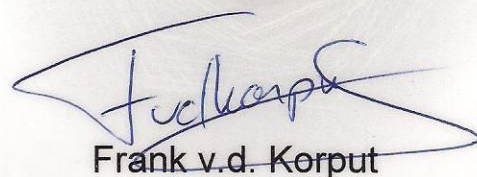
Date of training: April 20th – April 23rd, 2010

System Support Manager:



Jan Oostendorp

System Support Engineer:



Frank v.d. Kerput