

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:
Nom de l'Organisme Notifié:
Adresse de l'Organisme Notifié:
Numéro d'identification:
Valable jusqu'au:

39658 rev.5 établi le 21 mai 2025
GMED SAS
1, rue Gaston Boissier, 75724 PARIS, France
0459
02 avril 2029

Certificat UE du système de management de la Qualité :

NF EN ISO 13485 :
Numéro de certificat :
Valable jusqu'au:

2016
10462 rev. 10 établi le 21 mai 2025
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
Tél. : +33(0)2 33 81 21 00
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




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