ITALCERT

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

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 ed 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. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici 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. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

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*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 008 C
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Digitally signed by Ceaicovschi Tudor
Date: 2022.06.06 16:41:48 EEST
Reason: MoldSign Signature
Location: Moldova

Serum tubes with Gel Separator & Clot Activator are suitable for analysis of Clinical Chemistry, Immunohematology and Microbiological Serology.

Les tubes pour extraction de sérum avec Gel Separateur & Activateur de Coagulation sont appropriés pour l'analyse de la Biochimie, Immuno-Hématologie et Sérologie Microbiologique.

Provette con Gel Separatore & Attivatore di Coagulazione idonee per analisi di Chimica Clinica, Immunoematologia e Sierologia microbiologica.

GEL SEPARATOR + CLOT ACTIVATOR TUBES
TUBES À ESSAI AVEC GEL SEPARATEUR ET ACTIVATEUR DE COAGULATION
PROVETTE CON GEL SEPARATORE + ATTIVATORE DI COAGULAZIONE

cod.
30011

CE IVD

3,5 ml

VacuAptaca® Ø13x75 mm vacuum test tube, in PET, with Gel Separator + Clot Activator, for 3.5 ml of blood, red cap and red rubber, sterile.

Tube à prélèvement sous vide VacuAptaca® Ø13x75 mm, en PET, avec Gel Séparateur + Activateur de Coagulation, pour 3,5 ml de sang, bouchon rouge et le caoutchouc rouge, stérile.

Provetta sottovuoto VacuAptaca® Ø13x75 mm, in PET, con Gel Separatore + Attivatore di Coagulazione, per 3,5 ml di sangue, tappo rosso e gomma rossa, sterile.

cod.
30012

CE IVD

5 ml

VacuAptaca® Ø13x100 mm vacuum test tube, in PET, with Gel Separator + Clot Activator, for 5 ml of blood, red cap and red rubber, sterile.

Tube à prélèvement sous vide VacuAptaca® Ø13x100 mm, en PET, avec Gel Séparateur + Activateur de Coagulation, pour 5 ml de sang, bouchon rouge et le caoutchouc rouge, stérile.

Provetta sottovuoto VacuAptaca® Ø13x100 mm, in PET, con Gel Separatore + Attivatore di Coagulazione, per 5 ml di sangue, tappo rosso e gomma rossa, sterile.

cod.
30013

CE IVD

8 ml

VacuAptaca® Ø16x100 mm vacuum test tube, in PET, with Gel Separator + Clot Activator, for 8 ml of blood, red cap and red rubber, sterile.

Tube à prélèvement sous vide VacuAptaca® Ø16x100 mm, en PET, avec Gel Séparateur + Activateur de Coagulation, pour 8 ml de sang, bouchon rouge et le caoutchouc rouge, stérile.

Provetta sottovuoto VacuAptaca® Ø16x100 mm, in PET, con Gel Separatore + Attivatore di Coagulazione, per 8 ml di sangue, tappo rosso e gomma rossa, sterile.

Test tubes containing anticoagulant K_2 EDTA or K_3 EDTA suitable for analysis in Hematology and Immunohematology.

Tubes à essai contenant anticoagulant K_2 EDTA ou K_3 EDTA appropriés à l'analyse en Hématologie et Immuno-Hématologie.

Provette contenenti anticoagulante K_2 EDTA o K_3 EDTA idonee per analisi in Ematologia e in Immunoematologia.

HEMATOLOGY TUBES
TUBES À ESSAI POUR HÉMATOLOGIE
PROVETTE PER EMATOLOGIA

K_3 EDTA

cod.
30200

CE IVD

2 ml

VacuAptaca® Ø13x75 mm vacuum test tube, in PET, with K_3 EDTA, for 2 ml of blood, purple cap, sterile.

Tube à prélèvement sous vide VacuAptaca® Ø13x75 mm, en PET, avec K_3 EDTA, pour 2 ml de sang, bouchon violet, stérile.

Provetta sottovuoto VacuAptaca® Ø13x75 mm, in PET, con K_3 EDTA, per 2 ml di sangue, tappo viola, sterile.

cod.
30201

CE IVD

3 ml

VacuAptaca® Ø13x75 mm vacuum test tube, in PET, with K_3 EDTA, for 3 ml of blood, purple cap, sterile.

Tube à prélèvement sous vide VacuAptaca® Ø13x75 mm, en PET, avec K_3 EDTA, pour 3 ml de sang, bouchon violet, stérile.

Provetta sottovuoto VacuAptaca® Ø13x75 mm, in PET, con K_3 EDTA, per 3 ml di sangue, tappo viola, sterile.

cod.
30202

CE IVD

4 ml

VacuAptaca® Ø13x75 mm vacuum test tube, in PET, with K_3 EDTA, for 4 ml of blood, purple cap, sterile.

Tube à prélèvement sous vide VacuAptaca® Ø13x75 mm, en PET, avec K_3 EDTA, pour 4 ml de sang, bouchon violet, stérile.

Provetta sottovuoto VacuAptaca® Ø13x75 mm, in PET, con K_3 EDTA, per 4 ml di sangue, tappo viola, sterile.

cod.
30203

CE IVD

6 ml

VacuAptaca® Ø13x100 mm vacuum test tube, in PET, with K_3 EDTA, for 6 ml of blood, purple cap, sterile.

Tube à prélèvement sous vide VacuAptaca® Ø13x100 mm, en PET, avec K_3 EDTA, pour 6 ml de sang, bouchon violet, stérile.

Provetta sottovuoto VacuAptaca® Ø13x100 mm, in PET, con K_3 EDTA, per 6 ml di sangue, tappo viola, sterile.

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE No. **4264/5**

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

GRUPPO VACUTEST KIMA

Sede / *Head Office*
Via dell'Industria,12 – 35020 Arzergrande (PD) - Italia
Unità Operative / *Operative Units*
MEUS S.r.l. - Via Leonardo da Vinci, 24B – 26 – 28 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
MEUS S.r.l. - Via dell'Industria, 2 - 16 – 35020 Arzergrande (PD) - Italia
ROLL S.R.L. - Via Leonardo Da Vinci, 24A – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
KIMA S.R.L. - Via Leonardo da Vinci, 22 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
VACUTEST KIMA S.r.l. - Via dell'Industria,12 – 35020 Arzergrande (PD) – Italia
VACUTEST KIMA S.r.l. - Via L. Da vInci, 22 Zona Industriale Tognana – 35028 Piove di Sacco (PD) – Italia
VACUTEST KIMA S.r.l. - Via del Lavoro s.n.c. - 31040 Nervesa Della Battaglia (TV) - Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 17 - 19 - 29 - 35

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali. Sterilizzazione per irraggiamento raggi Beta.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices. Sterilization by Beta irradiation.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE 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.

0449CM_03_IT

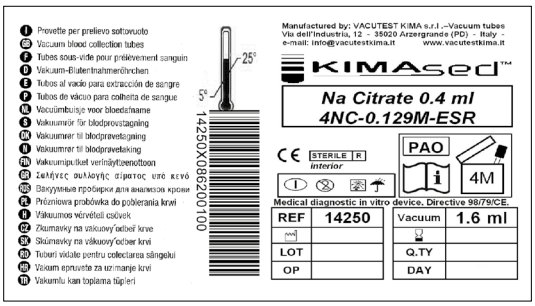
KIMASED TUBES (ESR)
KIMASED PROVETTE (VES)

STERILE R

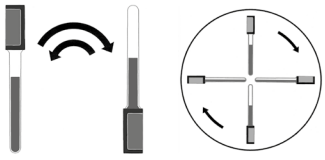
CODE *codice*	SIZE *dimensioni*	DESCRIPTION *descrizione*	DRAWING *aspirazione*	VOLUME *volume*	COLOUR *colore*	SHELF-LIFE *scadenza*	PACKAGING *confezion.*
14250	9/12,2x118 mm	Sodium citrate 3,8% *Sodio citrato 3,8%*	1,6 ml	2 ml (1,6 ml+0,4 ml)	Black *Nero*	18 months *mesi*	100 / 500

* KIMASED is supplied in aluminium bags which preserve the shelf life for **18 months**. Once the tubes are taken from the bag must be used in 4 months **(PAO)**. If tubes are kept in the bags **closed again** and **sealed** the shelf life is guaranteed for 18 months.

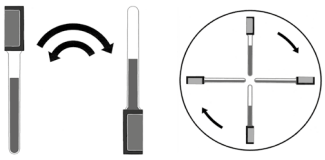
** KIMASED viene fornito in sacchetti d'alluminio per garantire la validità della provetta fino a **18 mesi**. Una volta che le provette vengono prelevate dal sacchetto, devono essere usate entro 4 mesi. Se le provette vengono tenute nei sacchetti **richiusi** e **sigillati** la validità è garantita fino a 18 mesi.*



Recommended use
Mixing indications:
1 - immediately after blood collection gently invert the sample 8-10 times.
2 - before testing mix again manually or mechanically for 3-5 minutes.



Raccomandazioni d'uso
Indicazioni per miscelare:
1 - dopo il prelievo agitare il campione 8-10 volte per inversione lenta.
2 - prima del test ripetere la miscelazione manualmente o meccanicamente per 3-5 minuti.



Sample preservation: at room temperature (maximum 4 hours).

Storage temperatures	Up to 24 °C	at 2-4 °C
Maximum preservation time	4 hours	≤ 24 hours

Conservazione del campione: *a temperatura ambiente (massimo 4 h).*

Temperature di conservazione	*Fino a 24°C*	*a 2-4 °C*
Tempo massimo di conservazione	*4 ore*	≤ 24 ore

For further information related to ESR test see CLSI document (ex NCCLS) H02-A5.

Per ulteriori informazioni relative al test della VES consultare il documento CLSI (ex NCCLS) H02-A5.

Please contact our sales department for the relevant codes for variants of the above product

Contattare l'ufficio commerciale per altri codici disponibili

Abbott

Declaration of Conformity

Certificate Identification: DoC-3L82-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L82-22 3L82-42	53301	Glucose	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:
Full Name: **Erik Muegge**
Position: **Mgr. Quality Operations Assurance**
Date of Approval: _26-FEB-2018_____

Signature: 
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: _26-FEB-2018_____
Date Issued: _26-FEB-2018_____
Place Issued: 65205 Wiesbaden, Germany
Supersedes: Not Applicable
Effective (Date or Lot Number): __26-FEB-2018_____

Abbott

Declaration of Conformity

Certificate Identification: 6L45
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6L45-21	53229	Total Bilirubin	Self-declared
6l45-41	53229	Total Bilirubin	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Thomas Creel

Full Name: **Thomas Creel**

Position: **Director, Site QA**

Date of Approval: 28-June-2019

Signature: Mark Littlefield

Full Name: **Mark Littlefield**

Position: **Associate Director, Regulatory Affairs**

Date of Approval: 28-JUN-2019

Date Issued: 28-JUN-2019

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: October 12, 2018

Effective (Date or Lot Number): 28-JUN-2019

Abbott

Declaration of Conformity

Certificate Identification: 8G63
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8G63-21	53236	Direct Bilirubin	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:
Full Name: **Erik Muegge**
Position: **QA Manager Ops**
Date of Approval: 8-SEP-2017

Signature:
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: September 3, 2015
Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 1E66

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E66-04	41830	Bilirubin Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: September 28, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

Abbott

Declaration of Conformity

Certificate Identification:	7D56
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D56-21	52925	Alanine Aminotransferase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: _____

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature: _____

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: September 3, 2015

Effective (Date or Lot Number): 8-SEP-2017

Abbott

Declaration of Conformity

Certificate Identification: 7D81
Legal Manufacturer's Name: Abbott Laboratories Diagnostic Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D81-21	52954	Aspartate Aminotransferase	**Self-declared**

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Thomas Creel

Full Name: **Thomas Creel**

Position: **Director, Site QA**

Date of Approval: 15-Oct-2018

Signature:

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 15-OCT-2018

Date Issued: 15-OCT-2018

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: 08-SEP-2017

Effective (Date or Lot Number): 15-OCT-2018

ABBOTT

Declaration of Conformity

Certificate Identification: 7D65
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D65-21 7D65-41	53030	Gamma-Glutamyl Transferase	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 7D58
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D58-21	52941	Amylase	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

Abbott

Declaration of Conformity

Certificate Identification: 7D80
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D80-31	53114	Lipase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: _____

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature: _____

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: November 17, 2014

Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 7D75
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D75-21 7D75-31	53590	Urea Nitrogen	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 3L81

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L81-22; 3L81-32; 3L81-41	53251	Creatinine	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: July 16, 2013

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 3P39

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3P39-21; 3P39-41	53583	Uric Acid	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 7D73
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D73-21	53989	Total Protein	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories, 1921 Hurd Drive, Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 7D53
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D53-23	53599	Albumin BCG	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 7D55
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D55-21 7D55-31	52929	Alkaline Phosphatase	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 6, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

Abbott

Declaration of Conformity

Certificate Identification:	7D56
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D56-21	52925	Alanine Aminotransferase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: _____

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature: _____

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: September 3, 2015

Effective (Date or Lot Number): 8-SEP-2017

Abbott

Declaration of Conformity

Certificate Identification:	7D62
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D62-21	53362	Cholesterol	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature:

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: 9-3-2015

Effective (Date or Lot Number): 8-SEP-2017

Abbott

Declaration of Conformity

Certificate Identification: 7D74
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D74-21	53462	Triglyceride	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:
Full Name: **Erik Muegge**
Position: **QA Manager Ops**
Date of Approval: 8-SEP-2017

Signature:
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: 9-3-2015
Effective (Date or Lot Number): 8-SEP-2017

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

For *in vitro* diagnostic medical devices (IVD) – Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy – Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry and immunochemistry, coagulation and rapid tests for immunology and serology" declares, under its own responsibility that the below listed devices comply with all essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (Legislative Decree nr. 322/2000).

It therefore declares and assures, under its own responsibility, that the devices:

1. comply with the applicable provisions of the Directive
2. are not included in the list A and B of Annex II of the Directive
3. are designed, manufactured and placed on the market according to the company certified quality system, in compliance with ISO 9001 and ISO 13485 as per indication expressed in Annex III of the Directive.

DICHIARAZIONE DI CONFORMITÀ CE

per dispositivi medico diagnostici *in vitro* IVD) – Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia – Via Robert Koch 2, fabbricante dei dispositivi appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che i dispositivi sotto elencati soddisfano i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che i dispositivi:

1. soddisfano le disposizioni applicabili della Direttiva
2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
3. sono progettati, fabbricati ed immessi in commercio nell'ambito dell'applicazione di un sistema di qualità aziendale dichiarato conforme e certificato secondo le norme ISO 9001 e ISO 13485 come descritto dall'Allegato III della Direttiva.

Code/Codice	Product Description/Nome prodotto
6K26-30	CRP Vario
6K26-41	CRP Vario
6K26-10	CRP Calibrator Set
6K26-12	CRP Calibrator WR
6K26-14	CRP Calibrator HS
6K26-21	CRP Control HS
6K89-30	Ammonia Ultra
6K91-30	Ceruloplasmin
4P79-30	UIBC Liquid
8L24-31	Creatinine (Enzymatic)
8L24-41	Creatinine (Enzymatic)
8L25-30	Lithium
6K89-20	Ammonia Controls
6K30-10	Clin Chem Cal
6K31-10	Plasmaproteins Cal 3x
1P93-30	Cystatin C
1P93-10	Cystatin C Calibrator

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

SENTINEL
DIAGNOSTICS

Code/Codice	Product Description/Nome prodotto
1P93-20	Cystatin C Control Set
6K25-10	CK-MB Calibrator
6K25-20	CK-MB Control
6K30-20	Clin Chem Control 1
6K30-21	Clin Chem Control 2
6K32-20	Immuno Control 1
6K32-21	Immuno Control 2
6K32-22	Immuno Control Set
6K90-20	Bile Acids Controls
6K98-10	Fructosamine Control 1
6K98-20	Fructosamine Control 2
4P80-30	Lambda Light Chains
6K24-30	Cholinesterase
6K25-30	CK-MB
6K22-30	Pancreatic Amylase
6K96-30	Kappa Light Chains
6K23-30	HBDH
6K90-30	Bile Acids
6K92-30	Dibucaine CHE
6K93-30	Copper
6K94-30	Fructosamine
6K95-30	Iron
6K95-41	Iron

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten (10) years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione delle Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo almeno di dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel Ch. SpA
A Legal Representative
Un Legale Rappresentante
Dr. Filippo De Luca

Date/Data
19/06/2015

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

ABBOTT

Declaration of Conformity

Certificate Identification: 3L79

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L79-21;3L79-31; 3L79-41	45789	Calcium	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 3E16
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3E16-02	53109	Lipase Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 1E65

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E65-04	30216	Multiconstituent Calibrator	Self-declared
1E65-05	30216	Multiconstituent Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: March 6, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 5P56

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
5P56-01	53356	Lipid Multiconstituent Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: January 30, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 9D29
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
9D29-20	56676	Water Bath Additive	Self-declared
9D29-21	56676	Water Bath Additive	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 6-11-2015
Date Issued: 6-11-2015
Supersedes: March 28,2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 6-11-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 6-11-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 6K01

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6K01-20	56676	Acid Wash	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 11, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 9D31
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
9D31-20	58236	Alkaline Wash	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 1J72
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1J72-20	59058	Detergent A	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 2J94

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2J94-21	59058	Detergent B	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: December 4, 2014

Date Issued: December 4, 2014

Supersedes: New

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: December 4, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): December 4, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 4P52

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4P52-21	61010	Hemoglobin A1c	Self-declared
4P52-02	53315	Hemoglobin A1c Calibrators	Self-declared
4P52-10	44435	Hemoglobin A1c Controls	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: March 6, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 4P52
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4P52-21	59090	Hemoglobin A1c Reagent Kit (300 tests)	Self-declared
4P52-02	53315	Hemoglobin A1c Calibrators	Self-declared
4P52-10	44435	Hemoglobin A1c Controls	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Scott Anderson signing for Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: August 4, 2015
Date Issued: August 4, 2015
Supersedes: November 17, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: August 4, 2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): August 5, 2015

TECHNOPATH
CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY

Manufacturer
Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Category	Catalogue Number
Multichem A1c	Assayed/bi-level	04V0610

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2016
QMS Certification No.:	Q51038520004
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	12 February 2022

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 31 **(Day)** 01 **(Month)** 20 **(Year)**

Signed for and on behalf of Techno-path Manufacturing Ltd.,

B. Hass

Bernd Hass,
VP of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

Ballina, Co.Tipperary 31-01-20
Place and Date of Issue

TECHNOPATH
CLINICAL DIAGNOSTICS

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
SOR/98-282, May 7, 1998	Canada Medical Device Regulations

ABBOTT

Declaration of Conformity

Certificate Identification: 3K33

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3K33-21	30169	Ultra HDL	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: April 4, 2013

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

SEKISUI DIAGNOSTICS
Because every result matters™

DECLARATION OF CONFORMITY

Manufacturer:	Sekisui Diagnostics P.E.I. Inc 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada
European Representative:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
Product:	Direct LDL Catalogue Number 1E31-20 GMDN Code: 53395
Classification:	General IVD
Conformity Assessment Route:	Annex III, self-certified

We hereby declare that the above-mentioned products meet the provisions of the Council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documents are held by the manufacturer.

Place of Issue: Prince Edward Island, Canada

Signature: _____ 06-May-2019

Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

Date

Sekisui Diagnostics P.E.I. Inc.
70 Watts Avenue
Charlottetown, Prince Edward Island
C1E 2B9 Canada
Tel: 902-566-1396 Fax: 902-628-6504
www.sekisuidiagnostics.com

Abbott

Declaration of Conformity

Certificate Identification:	ARCH Sys Acc LC	IRIS V4
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division	
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA	

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4D18-03	56701	ARCHITECT Septum	**Self-declared**
4D19-01	56701	ARCHITECT Replacement Caps	**Self-declared**
7C14-01	56676	ARCHITECT Sample Cups	**Self-declared**
7C15-02	56676	ARCHITECT Reaction Vessels	**Self-declared**
7C15-03	56676	ARCHITECT Reaction Vessels	**Self-declared**

Authorized European Representative (Name and Address)	Abbott GmbH & Co. KG Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: [signature]

Full Name: Katerina Damjanoska

Position: Site Quality Director

Date of Approval: 5/29/2019

Date Issued: 22 July 2019

Supersedes: 02 June 2015

Signature: [signature]

Full Name: Mary Ellen Muszynski

Position: Regulatory Affairs Director

Date of Approval: 22 July 19

Place Issued: Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064 USA

Effective (Date or Lot Number): 22 July 19

TECHNOPATH
CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY

Manufacturer
Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Category	Catalogue Number
Multichem S Plus	Unassayed/single level	05P79-10
Multichem S Plus	Unassayed/single level	05P79-11
Multichem S Plus	Unassayed/single level	05P79-12
Multichem S Plus	Assayed/single level	05P78-10
Multichem S Plus	Assayed/single level	05P78-11
Multichem S Plus	Assayed/single level	05P78-12

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2016
QMS Certification No.:	Q51038520004
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	12 February 2022

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 31 **(Day)** 01 **(Month)** 20 **(Year)**

TECHNOPATH
CLINICAL DIAGNOSTICS

Signed for and on behalf of Techno-path Manufacturing Ltd.,

B. Hass

Bernd Hass,
VP of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

Ballina, Co.Tipperary 31-01-20
Place and Date of Issue

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
SOR/98-282, May 7, 1998	Canada Medical Device Regulations

Abbott

A Promise for Life

This document certifies that:

Sergiu Sorocovici

has completed

Architect i2000SR

Level1 / Level 2

Application, Operation, Troubleshooting

from 9 February 2015 to 13 February 2015

Trainer : **Athanasios Plakas**

Date: **13 Feb 2015**

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Sergiu Sorocovici

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

ARCHITECT c8000 & RSH Service

March 6th – 14th, 2018

Ali Güntekin		14.03.2018
TRAINER NAME	TRAINER SIGNATURE	DATE DD.MM.YYYY
ABBOTT DIAGNOSTICS		**Germany - Delkenheim**

Abbott