

## Declaration of Conformity

**Certificate Identification:**  
**Legal Manufacturer's Name:**

9D29  
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

<b>Authorized European Representative (Name and Address)</b>	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (Name and Address)</b>	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
<b>Harmonized Standards</b>	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

## 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:** 3L82  
**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
3L82-21, 3L82-41	53301	Glucose	Self-declared

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

## Declaration of Conformity

**Certificate Identification:** DoC-3K33-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
3K33-22	53393	Ultra HDL	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



**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



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

## Declaration of Conformity

**Certificate Identification:** DoC-2P56-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
2P56-22 2P56-42	53072	Lactate Dehydrogenase	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, 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: 

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



## 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:



Penny White  
Senior Manager Regulatory Affairs  
Sekisui Diagnostics PEI Inc.

06-May-2019  
Date



## Declaration of Conformity

**Certificate Identification:**  
**Legal Manufacturer's Name:**

5P56  
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

<b>Authorized European Representative (Name and Address)</b>	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (Name and Address)</b>	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
<b>Harmonized Standards</b>	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



## DECLARATION OF CONFORMITY



### Manufacturer

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

Product(s):

Product Name	Catalogue Number
Multichem S Plus (Unassayed)	05P79-10
Multichem S Plus (Unassayed)	05P79-11
Multichem S Plus (Unassayed)	05P79-12
Multichem S Plus	CH100CRP
Multichem S Plus	CH101CRP
Multichem S Plus	CH102CRP
Multichem S Plus	CH103CRP
Multichem S Plus (Assayed)	05P78-10
Multichem S Plus (Assayed)	05P78-11
Multichem S Plus (Assayed)	05P78-12
Multichem S Plus (Unassayed)	CH110CRP.05
Multichem S Plus (Unassayed)	CH111CRP.05
Multichem S Plus (Unassayed)	CH112CRP.05
Multichem S Plus (Unassayed)	CH113CRP.05
Multichem S Plus	CH100PLA
Multichem S Plus	CH101PLA
Multichem S Plus	CH102PLA
Multichem S Plus	CH103PLA
Multichem S Plus (Assayed)	CH110PLA.05
Multichem S Plus (Assayed)	CH111PLA.05
Multichem S Plus (Assayed)	CH112PLA.05
Multichem S Plus (Assayed)	CH113PLA.05

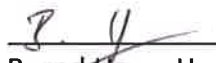


GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2012/ ISO 13485:2003
QMS Certification No.:	LRQ 4008261/A
Issued By:	Lloyds Register LRQA, 71 Fenchurch Street, London EC3M 4BS United Kingdom.

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.**

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

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

24-Jan-2014  
 Date

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

Standard	Title
EN ISO 15223-1:2012	Symbols for use in the labelling of medical devices
ISO 13485:2012 + AC:2012	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 13640:2002	Stability Testing of In vitro diagnostic reagents

## Declaration of Conformity

**Certificate Identification:**  
**Legal Manufacturer's Name:**

1E65  
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

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

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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  
Abbott Laboratories

Place Issued: 1921 Hurd Drive  
Irving, TX 75038

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



## 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

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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: Diana Romero

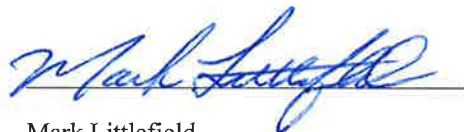
Position: Site Director, Quality Assurance

Date of Approval: 9-3-2015

Date Issued: 9-3-2015

Supersedes: November 5, 2014

Signature:



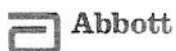
Full Name: Mark Littlefield

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



## Declaration of Conformity

Certificate Identification: ARCH Sys Acc LC IRIS V3  
Legal Manufacturer's Name: Abbott Laboratories  
Legal Manufacturer's Address: Diagnostics Division  
Abbott Park, IL 60064 USA

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

Full Name: Lauren Sieber

Position: Product Quality Assurance Manager

Date of Approval: 5/28/2015

Date Issued: 06/02/2015

Supersedes: June 13, 2013

Signature: 

Full Name: Deborah Hinkley

Position: Regulatory Affairs Director

Date of Approval: 5/29/2015

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

Effective (Date or Lot Number): 06/02/2015



# CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

**Sergiu Sorocovici**

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

**ARCHITECT c8000 & RSH Service**

**March 6<sup>th</sup> – 14<sup>th</sup>, 2018**

Ali Güntekin

TRAINER NAME

ABBOTT DIAGNOSTICS

TRAINER SIGNATURE

14.03.2018

DATE DD.MM.YYYY

Germany - Delkenheim

**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

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



## 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

# Certificate of Approval

This is to certify that the Management System of:

**Abbott GmbH**

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

**& Abbott Diagnostics GmbH**

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

has been approved by Lloyd's Register to the following standards:

ISO 9001:2015



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 17 January 2020

Expiry date: 30 September 2021

Certificate identity number: 10246646

Certificate approval number: LRQ 0925480/A

Original approval(s):

ISO 9001 – 23 September 1994

Approval number(s): ISO 9001 – 00004791

The scope of this approval is applicable to:

Design, development, manufacture, control of contract manufacturers, registration, stockholding and distribution  
of in-vitro diagnostic devices.



001

# Certificate of Approval

This is to certify that the Management System of:

**Abbott GmbH**

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

**& Abbott Diagnostics GmbH**

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 17 January 2020

Expiry date: 30 September 2021

Certificate identity number: 10246647

Certificate approval number: LRQ 0925480/A

Original approval(s):

ISO 13485 – 23 September 1994

Approval number(s): ISO 13485 – 00004790

The scope of this approval is applicable to:

Design, development, manufacture, control of contract manufacturers, registration, stockholding and distribution  
of in-vitro diagnostic devices.



001

# Certificate of Approval

This is to certify that the Management System of:

**Abbott GmbH**

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

MDSAP Facility Identifier: F003705

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

**ISO 13485:2016**

**Australia:**

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1  
(Excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil:**

RDC ANVISA n. 16/2013

RDC ANVISA n. 23/2012

RDC ANVISA n. 67/2009

**Canada:**

Medical Devices Regulations – Part 1- SOR 98/282

**Japan:**

MHLW Ministerial Ordinance 169, Article 4 to Article 68

**United States:**

21 CFR 803

21 CFR 806

21 CFR 807 – Subparts A to D

21 CFR 820



Clifford Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

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MDSAP/ISO 13485 – 2018 October 1

Approval number: MDSAP – 0079011

The scope of this approval is applicable to:

Design, development, manufacture, control of contract manufacturers, registration, stockholding and  
distribution of in-vitro diagnostic devices.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

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