CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Sergiu Sorocovici

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

ARCHITECT c8000 & RSH Service

March 6th – 14th, 2018

Ali Güntekin

TRAINER NAME

ABBOTT DIAGNOSTICS

14.03.2018

DATE DD.MM.YYYY

TRAINER SIGNATURE

gale,

Germany - Delkenheim

Abbott

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Alexei Legun

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

ARCHITECT c8000 Service & c8000 RSH

November 27th- December 5th, 2018

TRAINER SIGNATURE

05.12.2018

DATE DD.MM.YYYY

TURE

Vlassis Tsompanidis
TRAINER NAME
ABBOTT DIAGNOSTICS



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:

Signature:

Full Name:

Erik Muegge

Full Name:

Mark Littlefield

Position:

QA Manager Ops

Position:

Assoc. Director Regulatory Affairs

Date of Approval:

Date of Approval:

8-SEP-2017 8-SEP-2017

Date Issued:

Abbott Laboratories

1921 Hurd Drive

Place Issued:

Irving, TX 75038

Supersedes:

_September 3, 2015

Effective (Date or

Lot Number):

8-SEP-2017



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 Creek

Signature:

Mark Littlefield

Full Name:
Position:

Director, Site QA

Full Name:
Position:

Assoc. Director Regulatory Affairs

Date of Approval:

15-12-1-018

Date of Approval:

1/5

Date Issued:

Abbott Laboratories

1921 Hurd Drive

Place Issued:

Irving, TX 75038

Supersedes:

08-SEP-2017

Effective (Date or

Lot Number):

15-00 T-2018



Certificate Identification:

DoC-7D55-SD DELK

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
7D55-22	52929	Alkaline Phosphatase	Self-declared
7D55-32	52929	Alkaline Phosphatase	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories 1921 Hurd Drive Irving Toyon 75029 LICA
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 Homeco

Signature:

Mark Littlefield

Full Name:

Diana Romero

Full Name:

Mark Littleffeld

Position:

Director Quality Assurance

Position:

Assoc. Director Regulatory Affairs

Date of Approval:

22-MAY-2017

Date Issued:

Date of Approval:

22-MAY-2017 22-MAY-2017

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

Not applicable

Effective (Date or

Lot Number):

22-MAY-2017

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\equiv	- 1	10.0	12	u .			
-	1-3		10			_	

Certificate Identification: Legal Manufacturer's Name: 7D53

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
	horized European Representative ame and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany	
	ge site of technical documentation ame and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs	
Harm	onized 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: Diana Bomero

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:

roval: 9-3-2015

Abbott Laboratories

Place Issued: 1921 Hurd Drive

Irving, TX 75038

Effective (Date or

Lot Number):

9-3-2015

Certificate Identification:

7D58

Legal Manufacturer's Name:

THE RESERVE OF THE PARTY OF THE

Abbott Laboratories Diagnostics Division

Abbott Park, Illinois 60064 USA

and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification	
7D58-21 52941		Amylase	Self-declared	
The state of the s	horized European Representative ame and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany		
104.5	ge site of technical documentation ame and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs		
Harm	onized 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

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

9-3-2015 Date Issued:

Supersedes: November 5, 2014

Signature:

Full Name:

Position:

Mark Littlefield

9-3-2015

Associate Director, Regulatory Affairs

Date of Approval:

Place Issued:

Abbott Laboratories 1921 Hurd Drive

Irving, TX 75038

Effective (Date or

Lot Number):

9-3-2015



Certificate Identification:

7D81

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

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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:

Signature:

Full Name:

Thomas Creel

Full Name:

Mark Littlefield

Position:

Director, Site QA

Position:

Assoc. Director Regulatory Affairs

Date of Approval:

Date of Approval:

12-007-2018

Date Issued:

12-0-1-2018

Abbott Laboratories

Place Issued:

1921 Hurd Drive Irving, TX 75038

Supersedes:

September 8,2017

Effective (Date or

Lot Number):

12-007-2018



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:	Elle-	Signature:	Mark Felle fle
Full Name:	Erik Muegge	Full Name:	Mark Littlefield
Position:	QA Manager Ops	Position:	Assoc. Director Regulatory Affair
Date of Approval:	8-SEP-2017	Date of Approval:	8-SEP-2017
		Date Issued:	8-5EP-2017
		Place Issued;	Abbott Laboratories 1921 Hurd Drive Irving, TX 75038
		Supersedes:	_September 3, 2015
		Effective (Date or Lot Number):	8-5EP-2017

Certificate Identification: Legal Manufacturer's Name: 1E66

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
	horized European Representative ame 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	
Harm	onized 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

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: November 5, 2014

November 5, 2014

Date Issued:

Supersedes: September 28, 2006 Signature:

Full Name: Mark Littlefield

Associate Director, Regulatory Affairs Position:

Date of Approval: November 5, 2014

Abbott Laboratories Place Issued:

1921 Hurd Drive

Irving, TX 75038

Effective (Date or

November 17, 2014 Lot Number):

Certificate Identification: Legal Manufacturer's Name: 3L79

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
	norized European Representative ame 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	
		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:

Diana Some

Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature:

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



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:

Same

Signature:

M. T !441 - 67 - 1 - 3

Full Name:

Erik Muegge

Full Name:

Mark Littlefield

Position:

QA Manager Ops

Position:

Assoc. Director Regulatory Affairs

Date of Approval:

8-5EP-2017

Date of Approval:

8-SEP-2017

8-SEP-2017

Date Issued:

Abbott Laboratories 1921 Hurd Drive

Place Issued:

Irving, TX 75038

Supersedes:

9-3-2015

Effective (Date or

Lot Number):

8-SEP-2017



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
- 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
- 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 Adids
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:

- 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 postvendita richiesta dalla Direttiva.

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

Date/Data 소염/06/20소5

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
nate (c	norized European Representative ame and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany	
Storage site of technical documentation (Name and Address)		1921 Hurd Drive Irving, TX 75038	
Harm	onized Standards	Department - Regulatory Affairs ed 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

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

Signature:

Site Director, Quality Assurance

Signature:

Mark Littlefield

Full Name: Position:

Diana Romero

Full Name:

Position:

Associate Director, Regulatory Affairs

Date of Approval:

November 5, 2014

Date of Approval:

November 5, 2014

Date Issued:

11-5-2014

Abbott Laboratories

Place Issued:

1921 Hurd Drive

Irving, TX 75038

Supersedes: July 16, 2013

Effective (Date or Lot Number):

November 17, 2014



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

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:

Signature:

Mark Littlefield

Full Name:

Erik Muegge

Full Name:

Position:

Assoc. Director Regulatory Affairs

Position:

QA Manager Ops

Date of Approval:

8-567-2017

Date of Approval:

8-527-2017

Date Issued:

8-SEP-2017

Abbott Laboratories 1921 Hurd Drive

Place Issued:

Irving, TX 75038

Supersedes:

_November 17, 2014

Effective (Date or

Lot Number):

8-5EP-2017

List Numbers

and Size Code

Declaration of Conformity

Certificate Identification:

7D65

Legal Manufacturer's Name:

GMDN Code

Abbott Laboratories Diagnostics Division

Abbott Park, Illinois 60064 USA

of Devices 7D65-21 7D65-41	53030	Gamma-Glutamyl Transferase	Self-declared
1	horized European Representative ame and Address)	Max-Planck-Ring 2	
Storage site of technical documentation (Name and Address)			

Names and Description of Devices

Listed in the Technical Documentation Harmonized Standards

Department - Regulatory Affairs

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

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

Signature:

Iana Romero

Site Director, Quality Assurance

Signature:

Mark Littlefield

Full Name: Position:

Diana Romero

Full Name: Position:

Associate Director, Regulatory Affairs

Classification

Date of Approval:

9-3-2015

Date of Approval:

9-3-2015

Abbott Laboratories

Date Issued:

9-3-2015

Place Issued:

1921 Hurd Drive Irving, TX 75038

Supersedes:

November 5, 2014

Effective (Date or

Lot Number):

9-3-2015

Certificate Identification: Legal Manufacturer's Name:

3K33

Abbott Laboratories

Diagnostics Division

Abbott Park, Illinois 60064 USA

GMDN Code	Names and Description of Devices	Classification
30169	Ultra HDL	Self-declared
Representative	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany	
documentation	Abbott 1921 Hurd Drive Irving, TX 75038	·
onized Standards	Listed in the Technical Documentation	
	30169 horized European Representative ame and Address) ge site of technical	30169 Ultra HDL horized European Representative ame and Address) ge site of technical documentation ame and Address) Irving, TX 75038 Department - Regulatory Affairs

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

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

Signature:

Site Director, Quality Assurance

Signature:

Full Name:

Mark Littlefield

Full Name: Position:

Diana Romero

Position:

Associate Director, Regulatory Affairs

Date of Approval:

November 5, 2014

Date of Approval:

November 5, 2014

Date Issued:

November 5, 2014

Place Issued:

Abbott Laboratories

1921 Hurd Drive

Irving, TX 75038

Effective (Date or Lot Number):

November 17, 2014

Supersedes:

April 4, 2013



DECLARATION OF CONFORMITY

Manufacturer:

Sekisul 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

Sekisul Diagnostics PEI Inc.

06-May-2019 Date

Sekisul Diagnostics P.E.I. Inc. 70 Walts Avenue Charlotteltown, Prince Edward Island C1E 289 Canada Tei: 902-665-1396 Fax: 902-628-5504 www.sekisulsisonostics.com

Certificate Identification:

5P56

Legal Manufacturer's Name:

Abbott Laboratories

Diagnostics Division

Department - Regulatory Affairs Listed in the Technical Documentation

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
	horized European Representative ame 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	

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

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

Signature:

Harmonized Standards

Signature:

Full Name:

Diana Romero

Full Name:

Mark Littlefield

Position:

Site Director, Quality Assurance

Position:

Associate Director, Regulatory Affairs

Date of Approval:

November 5, 2014

Date of Approval:

November 5, 2014 Abbott Laboratories

Place Issued:

1921 Hurd Drive

Date Issued:

11-5-2014

Irving, TX 75038

Supersedes:

January 30, 2014

Effective (Date or Lot Number):

November 17, 2014



Certificate Identification:

DoC-4P5220, 4P5201, 4P5211-SD DELK

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
4P52-20	59090	Hemoglobin A1c Reagent	Self-declared
4P52-01	53315	Hemoglobin A1c Calibrator	Self-declared
4P52-11	44435	Hemoglobin A1c Controls	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical	
	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:

Mana morrene

Signature:

Mark Littlefield

Full Name:

Diana Romero

Full Name:

Position:

Position:

Director, Site QA

Date of Approval:

Assoc. Director, Regulatory Affairs

17-200-2017

Date of Approval:

17-NOV-2017

Date Issued:

17-100-2017

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

N/A

Effective (Date or

Lot Number):

17-Nov-2017



EC DECLARATION OF CONFORMITY

For in vitra diagnostic medical devices (IVD) - Directive 98/79/EC

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). 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 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

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

- comply with the applicable provisions of the Directive
- are not included in the list A and B of Annex II of the Directive
- 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

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 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, 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:

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

Code/Codice	Product Description / Name products
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



ISO 9001:2008 - 150 13485:2003 - EN ISO 13485:2012 - 150 13485;2003 CMDCAS - 85 OHSAS 18801:2887 - ISO 14001:2084

WWW.Sextline



6K95-41	6K95-30	6K94-30	6K93-30	6K92-30	6K90-30	6K23-30	6K96-30	6K22-30	6K25-30	6K24-30	4P80-30	6K98-20	6K98-10	6K90-20	6K32-22	6K32-21	6K3Z-20	6K30-21	6K30-20	6K25-20	6K25-10	1P93-20	Code/Codice
Iron	Iron	Fructosamine	Copper	Dibucaine CHE	Bile Acids	HBDH	Kappa Light Chains	Pancreatic Amylase	CK-MB	Cholinesterase	Lambda Light Chains	Fructosamine Control 2	Fructosamine Control 1	Bile Acids Controls	Immuno Control Set	Immuno Control 2	Immuno Control 1	Clin Chem Control 2	Clin Chem Control 1	CK-MB Control	CK-MB Calibrator	Cystatin C Control Set	Product Description/Nome prodotto

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
- have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoitre di:

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

Sentinei Ch. SpA
A Legal Representative
Urr Legale Rappresentante Dr. Filippo De Luca

> 3 FC2/30/5F Date/Data

[SQ 9601:2008 - ISO 12485:2008 - EN ISO 13485:2012 - ISO 12485:2003 CMDCAS - BS OHSAS 18001:2007 - ISO 14001:2004

1901 SOS

Certificate Identification: Legal Manufacturer's Name:

2P56

Abbott Laboratories

Diagnostics Division

Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2P56÷21 2P56÷41	53072	Lactate Dehydrogenase	Self-declared

	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany	
Storage site of technical documentation (Name and Address)	1921 Hurd Drive	3.9.()
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

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: November 5, 2014

> November 5, 2014 Date Issued:

Supersedes: December 31, 2012 Signature:

Full Name: Mark Littlefield

Associate Director, Regulatory Affairs Position:

Date of Approval: November 5, 2014

Abbott Laboratories

Place Issued: 1921 Hurd Drive

Irving, TX 75038

Effective (Date or

November 17, 2014 Lot Number):



Certificate Identification:

7D80

Legal Manufacturer's Name:

Abbott Laboratories Diagnostics Division

Legal Manufacturer's Address:

Abbott Park, Illinois 60064 USA

	Classification
7D80-31 53114 Lipase	Self-declared

Authorized European	Abbott GmbH & Co. KG
Representative (name and address)	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:

Signature:

Full Name:

Mark Littlefield

Full Name: Position:

QA Manager Ops

Erik Muegge

Position:

Assoc. Director Regulatory Affairs

Date of Approval:

Date of Approval:

8-5E1-2017 8-SEP-2017

Date Issued:

Abbott Laboratories 1921 Hurd Drive

Place Issued:

Irving, TX 75038

Supersedes:

_November 17, 2014

Effective (Date or

Lot Number):

8-SEP-2017

□ ABBOTT

Declaration of Conformity

Certificate Identification: Legal Manufacturer's Name: 3E16

Abbott Laboratories Diagnostics Division

Abbott Park, Illinois 60064 USA

List Numbers GMDN Code and Size Code of Devices		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	(Frankling)
Storage site of technical documentation (Name and Address)		Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs	
Harm	onized 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

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 Tomero

Signature:

Full Name:

Diana Romero

Full Name:

Mark Littlefield

Position:

Site Director, Quality Assurance

Position:

Associate Director, Regulatory Affairs

Date of Approval:

9-3-2015

Date of Approval:

9-3-2015

Date Issued:

9-3-2015

Abbott Laboratories

Place Issued:

1921 Hurd Drive Irving, TX 75038

Lot Number):

Effective (Date or

9-3-2015

Supersedes:

November 5, 2014

□ ABBOTT

Declaration of Conformity

Certificate Identification: Legal Manufacturer's Name: 7D73

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	
Цант	onized Standards	Department - Regulatory Affairs 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

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:

Diana Romero

Full Name:

Mark Littlefield

Position:

Site Director, Quality Assurance

Position:

Associate Director, Regulatory Affairs

Date of Approval:

9-3-2015

Date of Approval:

9-3-2015

9-3-2015

Lot Number):

Abbott Laboratories

Date Issued:

Place Issued:

1921 Hurd Drive

Effective (Date or

Irving, TX 75038 9-3-2015

Supersedes:

November 5, 2014



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)	
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:

- FAMOU

Signature:

Mark Littlefield

Full Name:

Erik Muegge

QA Manager Ops

Full Name:
Position:

Assoc. Director Regulatory Affairs

Position:

Date of Approval:

8-550-2017

Date of Approval:

8-SEP-2017

8-SEP-2017

Date Issued:

Abbott Laboratories

1921 Hurd Drive

Place Issued:

Irving, TX 75038

Supersedes:

9-3-2015

Effective (Date or

Lot Number):

8-SEA-2017

Certificate Identification: Legal Manufacturer's Name:

Abbott Laboratories

Diagnostics Division

Abbott Park, Illinois 60064 USA

and Size Code of Devices		Names and Description of Devices	Classification	
3P39-21; 3P39-41	53583	Uric Acid	Self-declared	
	norized European Representative ame and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany		
-	e site of technical documentation ame 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

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:

Diana Romero

Full Name:

Mark Littlefield

Position:

\$ite Director, Quality Assurance.

Position:

Associate Director, Regulatory Affairs

Date of Approval:

November 5, 2014

Date of Approval:

November 5, 2014

Date Issued:

11-5-2014

Place Issued:

Abbott Laboratories 1921 Hurd Drive

Effective (Date or

Irving, TX 75038

Supersedes:

December 31, 2012

Lot Number):

November 17, 2014

□ ABBOTT

Declaration of Conformity

Certificate Identification: Legal Manufacturer's Name: 7D75

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

	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	1921 Hurd Drive
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:

Dana Homero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: 9-3-2015

Date Issued: 9-3-20/5

Supersedes: November 5, 2014

Signature:

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: 9-3-2015

Abbott Laboratories

Place Issued: 1921 Hurd Drive

Irving, TX 75038

Effective (Date or

Lot Number): 9 - 3 - 20/5

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)	Max-Planck-Ring 2	
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038	
Harmonized Standards	Department - Regulatory Affairs 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

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

November 5, 2014

Date Issued:

Date of Approval:

November 5, 2014

Supersedes:

March 6, 2014

Signature:

Full Name:

Mark Littlefield

Position:

Associate Director, Regulatory Affairs

Date of Approval:

November 5, 2014

Abbott Laboratories

1921 Hurd Drive

Irving, TX 75038

Effective (Date or

Lot Number):

Place Issued:

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	СН103РЦА
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:

Conformity Route:

Quality Management System:

QMS Certification No.:

Issued By:

47869

Annex III Self-Declared

EN ISO 13485:2012/ ISO 13485:2003

LRQ 4008261/A

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. 24-7an-2014.

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 i 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	

Issue Date: 24th Jan 2014

Certificate Identification: Legal Manufacturer's Name:

Abbott Laboratories

Diagnostics Division

Abbott Park, Illinois 60064 USA

GMDN Code	Names and Description of Devices	Classification	
56676	Acid Wash	Self-declared	
norized European Representative ame and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany		
e site of technical documentation ame and Address)	Abbott 1921 Hurd Drive Irving, TX 75038		
	56676 norized European Representative and Address) e site of technical documentation	56676 Acid Wash lorized European Representative Max-Planck-Ring 2 lime and Address) 65205 Wiesbaden, Germany e site of technical documentation 1921 Hurd Drive	

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.

Listed in the Technical Documentation

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: November 5, 2014

> 11-5-2014 Date Issued:

Harmonized Standards

Supersedes: December 11, 2006 Signature:

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

□ 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
	horized European Representative ame and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany	
	ge site of technical documentation nme and Address)	Abbott 1921 Hurd Drive Irving, TX 75038	
Harmonized Standards		Department - Regulatory Affairs Listed in the Technical Documentation	1 11 11 11 11 11 11 11 11 11 11 11 11 1

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

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

Full Name:

Signature:

Diana Romero

Site Director, Quality Assurance Position:

5-28-2015 Date of Approval:

> 5-28-2015 Date Issued:

Supersedes: March 28, 2013 Signature:

Full Name: Mark Littlefield

Associate Director, Regulatory Affairs Position:

Date of Approval: 5-28-2015

Abbott Laboratories

Place Issued: 1921 Hurd Drive

Irving, TX 75038

Effective (Date or

Lot Number):

5-28-2015

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	1	L)	n			п

Certificate Identification: Legal Manufacturer's Name: 1J72

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
	thorized European Representative Jame and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany	
1	ge site of technical documentation (ame and Address)	Abbott 1921 Hurd Drive Irving, TX 75038	
		Department - Regulatory Affairs	
Harr	nonized 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

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

Signature:

Position:

lana Homero

Signature:

Full Name: Mark Littlefield

Full Name:

Diana Romero

Position:

Associate Director, Regulatory Affairs

Date of Approval:

5-28-2015

Site Director, Quality Assurance

Date of Approval:

5-28-2015

Date Issued:

5-28-2015

Abbott Laboratories

Place Issued:

1921 Hurd Drive Irving, TX 75038

Supersedes:

March 28, 2013

Effective (Date or Lot Number):

5-28-2015

Certificate Identification: 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
	horized European Representative ame and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany	
	ge site of technical documentation ame and Address)	Abbott 1921 Hurd Drive Irving, TX 75038	
		Department - Regulatory Affairs	

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

Listed in the Technical Documentation

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:

Position:

Date of Approval:

Diana Romero

Site Director, Quality Assurance

December 4, 2014

December 4, 2014

Date Issued:

Harmonized Standards

Supersedes: New

Signature:

Full Name:

Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: December 4, 2014

Abbott Laboratories

1921 Hurd Drive

Irving, TX 75038

Effective (Date or

Lot Number):

Place Issued:

December 4, 2014

□ ABBOTT

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

Authorized European	Abbott
Representative	0
(Name and Address)	65205 Wiesbaden, Germany
Storage site of technical	Abbott
documentation	1921 Hurd Drive
(Name and Address)	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

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

Signature:

Site Director, Quality Assurance

Signature:

Mark Littlefield

Full Name: Position:

Diana Romero

Full Name: Position:

Associate Director, Regulatory Affairs

Date of Approval:

10-11-2015

Date of Approval:

6-11-2015

Abbott Laboratories

6-11-2015 Date Issued:

Place Issued:

1921 Hurd Drive Irving, TX 75038

Supersedes: March 28,2013

Effective (Date or Lot Number):

6-11-2015



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

ARCH Sys Ace LO	IRIS V3
Abbott Laboratories	
Diagnostics Division	Company of the Compan
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)	Abbat Laboratories Diagnostics División Abbatt 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:

Lauren Sieber

Signature.
Full Name:

Deborah Hinkley

Fall Name: Position:

B : 10 44

Position:

Regulatory Affairs

Product Quality Assurance Manager KM).

Director

Date of Approval-

528 2015

Date of Approval

5/29/2015

Date Issued:

06/02/2015

Place Issued

Abbott Laboratories
Dingnostics Division

Superspides:

June 13, 2013

Effective (Date or Lot Number):

Abbott Park, IL 60064 L SA 06/02/2015

19.220

MANAGEMENT SYSTEM CERTIFICATE

Certificato no./Certificate No.: 130955-2013-AHSO-ITA-ACCREDIA

Data prima emissione/Initial date: 15 febbraio 2013

Validità:/Valid: 15 febbraio 2019 - 15 febbraio 2022

Si certifica che il sistema di gestione di/This is to certify that the management system of

ATLAS FILTRI S.r.l.

Sede Legale: Via Pierobon, 32 - 35010 Limena (PD) - Italy

e i siti come elencati nell'Appendix che accompagna questo certificato / and the sites as mentioned in the appendix accompanying this certificate

È conforme ai requisiti della norma per il Sistema di Gestione della Salute e Sicurezza sui Lavoro/ has been found to conform to the Occupational Health and Safety Management System standard:

ISO 45001:2018

Questa certificazione è valida per il seguente campo applicativo: Produzione di filtri e sistemi di trattamento acque, attraverso le fasi di stampaggio ad iniezione, bobinatura elementi filtranti e, agglomerazione di micro-fibra attraverso la linea melt blown, riempimento con materiale filtrante del corpo filtro, assemblaggio e incollaggio

This certificate is valid for the following scope: Production of water filters and water treatment systems following the injection moulding process, filtering units winding and microfiber agglomeration made by a melt blown productive line. Body filters filled up with filtering material, assembling and finishing included

(EA 14)

(EA 14)

Luogo e Data/Place and date: Vimercate (MB), 19 dicembre 2018



ACCREDIA %

Per l'Organismo di Certificazione/ For the Certification Body DNV GL – Business Assurance Via Energy Park, 14 20871 Vimercate (MB) - Italy

Zeno Beltrami Management Representative

La validità del presente Certificato è subordinatà al rispetto dalle condizioni contenute nel Contratto di Certificazione/ Lack of fulfilment of condizions as set out in the Certification Agreement may render tals Certificate invalid. DAVI di Eusherss Assurence Italia S.n.d., Vila Einergip Perb, 14 - 2.05% Vilmercute (VM) - Italio, TE; 038-65-09-004 3. soyne dinegit à

DNV.GL

Cerdificato no.:/Certificate No.: 130955-2013-AHSO-ITA-ACCREDIA Luogo e Data:/Flace and date: Vimercate (MB), 19 dicembre 2018

Appendix to Certificate

Site Name	Site Address	Site Scope Local	Site Scope
ATLAS FILTRI S.r.i. Sede Legale e Operativa	Via Pierobon, 32 - 35010 Limena (PB) - Italy	Riferimento al campo applicativo	Reference to scope
ATLAS FILTRI S.r.f. Sede Operativa	Via del Santo, 227 - 35010 Limena (PD) -	Riferimento al campo applicativo	Reference to scope

La veifald de presente conflictuée à subordinata al ficacito delle condizioni continuità nel Centratiu di Ceruficazione/ Lactor fudifinant of conditions as set autili ne cenfulazioni protentent model professioni conditionate invalo 1919 di Ber man Acumerce Dalla S.A., de Bresp Phil., de 1907, d'intervalori latte in professioni programme della

SISTEMA DI GESTIONE CERTIFICATO

Certificato n.: CERT-14951-2004-AQ-VEN-SINCERT

Data Prima Emissione: 12 ottobre 2004

Validità: 02 ottobre 2019 - 01 ottobre 2022

Si certifica che il sistema di gestione di

ATLAS FILTRI S.r.I. - Sede Legale e Operativa

Via Pierobon, 32 - 35010 Limena (PD) - Italia e i siti come elencati nell'Appendix che accompagna questo certificato

E conforme allo Standard: ISO 9001:2015

Questa certificazione è valida per il seguente campo applicativo: Progettazione, produzione, commercializzazione di filtri e sistemi-per il trattamento di acqua per uso potabile, domestico e industriale (IAF 14, 18)

Luogo e Data: Vimercate (MB), 01 settembre 2019

Olygon Will Do to' pe latent a manabarente Olygon Work proj. 1919 (1910, para e. U.; driva be te provincia a procedorente soo, 565, 561, 1914 tello del Manabaro et di proceditamente Na, Wio, UVI e. ESP. ACCREDIA 🤾

Per: Na Cal - Business Assurance Na Energy Park, 14, - 20871 Vimercate (MB) - Italy

The Bellen

Il mancato rispetto delle condizioni stabilite nei regolamento di certificazione potrebbe invalidare il certificato. UNITA ACCPENTATA, DIAV GI Business Assuranze Reise S.-L., Va Sterryy Park. 14–2007. Vanerezo: (MR) - Iraky TEL+38 6X 99 905. www.dn.cgi it

DNV.GL

Certificato n.; CERT-14951-2004-AQ-VEN-SINCERT Luogo e Data: Vimercate (MB), 01 settembre 2019

Appendice al Certificato

ATLAS FILTRI S.r.l. - Sede Legale e Operativa I siti inclusi nel certificato sono i seguenti:

Mome del cibo	Traditions del cita	Course and Landing
Monte act and	דוותוווניכת מכן פונס	Campil applicative
ATLAS FILTRI S.r.J Sede	Via Pierohon, 32 - 35010 Limena	Riferimento al campo applicativo
Legale e Operativa	(PD) - Italia	
ATLAC ELITET C. 1 - Codo	And del Courts 257 25010 (June 2)	Official contract of special contractions
ALES FLLIN S.I.I. Seue	via del Samo, 227 - SSU10 Limena Kilenmento al Campo applicativo	Klienmento al campo applicativo
Operativa	(PD) - Italia	

Il mancato rispetto delle condizioni stabilità nei regolamento di cerdificazione potrebbe invalidare il cendificato.
UNITA ACCREDITATA: DAV GL. Businetti Assurando Italie B. F. L. Vai Energy Frah, 34 - 25871. Vinerrato (VIB) - Italy, TEL:169 68 99 905. www.dnv.gh.c.
Pagina 1 of 1

MANAGEMENT SYSTEM CERTIFICATE

Certificato no./Certificate No.: 130911-2013-AE-ITA-ACCREDIA

Data prima emissione/Initial date: 26 febbraio 2013

Validītà:/Valid: 17 ottobre 2018 - 26 febbraio 2022

Si certifica che il sistema di gestione di/This is to certify that the management system of

ATLAS FILTRI S.r.l.

Sede Legale: Via Pierobon, 32 - 35010 Limena (PD) - Italy, estimated in the sites as mentioned in the appendix accompanying this certificate.

È conforme ai requisiti della norma per il Sistema di Gestione Ambientale/ Has been found to conform to the Environmental Management System standard.

ISO 14001:2015

Valutato secondo le prescrizioni del Regolamento Tecnico RT-09/ Evaluated according to the requirements of Technical Regulations RT-09

Questa certificazione è valida per il seguente campo applicativo: Produzione di filtri e sistemi di trattamento acque, attraverso le fasi di stampaggio ad inicatone, bobinatura elementi filtranti e, aggiomerazione di micro-fibra attraverso la linea melt blown, riempimento con materiale filtrante del corpo filtro, assemblaggio e incollaggio.

This certificate is valid for the following scope:

Production of water filters and water treatment systems following the injection moulding process, filtering units winding and microfiber agglomeration made by a melt blown productive line. Body filters filled up with filtering material, assembling and finishing included

(EA: 14)

Luogo e Data/Place and date: Vimercate (MB), 17 ottobre 2018

ACCREDIA %

Per l'Organismo di Certificazione/ For the Certification Body DNV GL. Business Assurance Via Energy Park, 14 - 20871 Vimercate (MB) - Italy

Zeno Beltrami Management Representative

La volidità del presente Cartificato è subordinata al rispetto delle condizioni contenute nel Contratto di Cardi cazione/ Leks di fulfiment di condistans sa set out in the Cardiciade Agrement may randori his Cardiciate (haulis). Uni di Levorievi Assureca Italia III - 1º di Entropi Pars, 14 - 7.212 I Primocule (1981), Iluny, Illi 109 de 39 1915, www. divupi II

DNV.GL

Certificato no.:/Certificate No.: 130911-2013-AE-1TA-ACCREDIA Luogo e Data:/Place and date: Vimercate (MB), 17 ottobre 2018

Appendix to Certificate

Site Name	Site Address	Site Scope Local	Site Scope
ATLAS FLITRI S.r.L Sede Legale e Operativa	Via Pierobon, 32 - 35010 Limena (PD) - Italy	Attività di assemblaggio filtri e sistemi di trattamento acque, Imballaggio e magazzino	Activity of assembling filters and water treatment systems, packaging and warehouse
Sede Operativa	Via dei Santo, 227 - 35010 Limena (PD) - Italy	Riferimento al campo applicativo	Reference to scope
ATLAS FILTRI S.r.I Sito Operativo e Magazzino	Via Unità d'Italia, 8C - 35010 Limena (PD) - Italy	Attività di assemblaggio filtri e sistemi di trattamento acque, imballaggio e magazzino	Activity of assembling filters and water treatment systems, packaging and

La validità del presente Cerificabo è subordinata al rispetto delle condizioni contenute nel Contratto di Cerultazione/ Laced fulfilmente di condizione asse doi in the Cerification aggenenti man prender tible Cerification invalidi DNV GL ben mas Assurano Malla San, Livei inergi Pere, Lei - 20/21 infrancost (Prig.) – Italia (ELOS) sió 59 395, svrave drugil E