Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 9001:2015

Cliff Muckleroy - Area Operations Manager Americas

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

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018
Expiry date: 12 October 2021
Certificate identity number: 10155324

Original approval(s):
ISO 9001 – 3 December 2017

Approval number(s): ISO 9001 – 0015681

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

Digitally signed by Ceaicovschi Tudor
Date: 2021.08.17 14:34:28 EEST
Reason: MoldSign Signature
Location: Moldova

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Certificate identity number: 10155324

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 9001:2015 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 9001:2015 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 9001:2015 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS

001

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016

Cliff Muckleroy - Area Operations Manager Americas

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

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018
Expiry date: 12 October 2021
Certificate identity number: 10155326

Original approval(s):

ISO 13485 – 7 December 2017

Approval number(s): ISO 13485 – 0015680

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS

001

Certificate Schedule

Certificate identity number: 10155326

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 13485:2016 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 13485:2016 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS

001

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

MDSAP Facility Identifier: 079226220

has been audited by LRQA 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
PMD Act

United States:
21 CFR 820
21 CFR 803
21 CFR 806

Cliff Muckleroy - Area Operations Manager Americas
Issued By: Lloyd's Register Quality Assurance, Inc.

Certificate Approval Number: UQA 00000846
Effective Date: 2018 October 13
Expiry Date: 2021 October 12
Certificate Issue Number: 10155325

Original Approval:
MDSAP/ ISO 13485 – 2017 December 7

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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

Certificate Schedule

Certificate Issue Number: 10155325

Approval Number: MDSAP – 0015682

The scope of this approval is applicable to:

Design and Manufacture of In Vitro Diagnostic Medical Devices, used in the Screening of Blood Donor Units for Transmissible Diseases. Design and Manufacture of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring. Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems. Manufacture, Design / Development of In Vitro Diagnostic Products including Instruments, Reagents, and Accessories for Hematology.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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

Issued By: Lloyd's Register Quality Assurance, Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States

Certificate Schedule

Certificate Issue Number: 10155325

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	MDSAP 2017 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States MDSAP Facility Identifier: 079226220-002	MDSAP 2017 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States MDSAP Facility Identifier: 079226220-003	MDSAP 2017 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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

Issued By: Lloyd's Register Quality Assurance, Inc., 1330 Enclave Parkway, Suite 200, Houston, Texas 77077, United States

ABBOTT

Declaration of Conformity

Certificate Identification: 6K01

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

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

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

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

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

Signature: Diana Romero

Full Name: Diana Romero

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 11, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

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

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

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D53-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
7D53-24	53599	Albumin BCG	**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_____

ABBOTT

Declaration of Conformity

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

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

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

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

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

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

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

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D58-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
7D58-22 7D58-42	52941	Amylase	**Self-declared**

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

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

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

Signature: 

Full Name: **Erik Muegge**

Position: **Mgr. Quality Operations Assurance**

Date of Approval: _26-FEB-2018_____

Signature: 

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: _26-FEB-2018_____

Date Issued: _26-FEB-2018_____

Place Issued: 65205 Wiesbaden, Germany

Supersedes: Not Applicable

Effective (Date or Lot Number): _26-FEB-2018_____

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D81-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
7D81-22	52954	Aspartate Aminotransferase	**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_____

Abbott

Declaration of Conformity

Certificate Identification: DOC-1E66-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
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
1E66-05	41830	Bilirubin Calibrator	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Microgenics Corporation 46500 Kato Road Fremont, CA 94538 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: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 23 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 15-Jun-2021
Date Issued: 23-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 23-Jun-2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-3L79-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
3L79-22 3L79-32 3L79-42	45789	Calcium	**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 Appplicable

Effective (Date or Lot Number): _26-FEB-2018_____

Abbott

Declaration of Conformity

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, Texas 75038, 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: Diana Romero
Full Name: **Diana Romero**
Position: **Director Quality Assurance**
Date of Approval: 22-MAY-2017

Signature:
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 22-MAY-2017
Date Issued: 22-MAY-2017
Place Issued: 65205 Wiesbaden, Germany
Supersedes: Not applicable
Effective (Date or Lot Number): 22-MAY-2017

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D56-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
7D56-22	52925	Alanine Aminotransferase	**Self-declared**

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

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

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

Signature: 

Full Name: **Erik Muegge**

Position: **Mgr. Quality Operations Assurance**

Date of Approval: _26-FEB-2018_____

Signature: 

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: _26-FEB-2018_____

Date Issued: _26-FEB-2018_____

Place Issued: 65205 Wiesbaden, Germany

Supersedes: Not Applicable

Effective (Date or Lot Number): _26-FEB-2018_____

Abbott

Declaration of Conformity

Certificate Identification: 2J94

Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division

Legal Manufacturer's Address: 100 Abbott Park Road
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
2J94-22	59058	Detergent B	Self-Declared

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

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

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

Signature: Thomas Creel

Full Name: Thomas Creel

Position: Director, Instrument Quality

Date of Approval: 15-Nov-2019

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Assoc. Director, Regulatory Affairs

Date of Approval: 18-NOV-2019

Date Issued: 18-NOV-2019

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

Supersedes:

Effective (Date or Lot Number): 18-NOV-2019

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D62-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
7D62-22	53362	Cholesterol	**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.

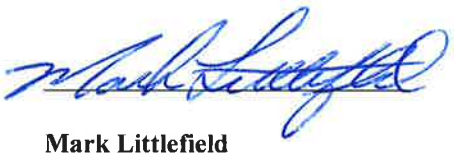
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

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_____

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D63-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
7D63-22 7D63-42	53006	Creatine Kinase	**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_____

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

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

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

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

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

DICHIARAZIONE DI CONFORMITÀ CE

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

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

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

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

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

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

SENTINEL
DIAGNOSTICS

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

Furthermore, the manufacturer declares to:

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

Il fabbricante dichiara inoltre di:

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

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

Date/Data
19/06/2015

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

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

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

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

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

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

DICHIARAZIONE DI CONFORMITÀ CE

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

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

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

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

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

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
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www.sentineldiagnostics.com

SENTINEL
DIAGNOSTICS

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

Furthermore, the manufacturer declares to:

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

Il fabbricante dichiara inoltre di:

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

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

Date/Data
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SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

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

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

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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).

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2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
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Code/Codice	Product Description/Nome prodotto
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6K26-41	CRP Vario
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6K26-21	CRP Control HS
6K89-30	Ammonia Ultra
6K91-30	Ceruloplasmin
4P79-30	UIBC Liquid
8L24-31	Creatinine (Enzymatic)
8L24-41	Creatinine (Enzymatic)
8L25-30	Lithium
6K89-20	Ammonia Controls
6K30-10	Clin Chem Cal
6K31-10	Plasmaproteins Cal 3x
1P93-30	Cystatin C
1P93-10	Cystatin C Calibrator

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

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

Furthermore, the manufacturer declares to:

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

Il fabbricante dichiara inoltre di:

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

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

Date/Data
19/06/2015

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www.sentineldiagnostics.com

Abbott

Declaration of Conformity

Certificate Identification: DoC-3L81-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
3L81-23 3L81-33 3L81-42	53251	Creatinine	**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

ABBOTT

Declaration of Conformity

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

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

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

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

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

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

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

Abbott

Declaration of Conformity

Certificate Identification: DoC-8G63-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
8G63-22	53236	Direct Bilirubin	**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.

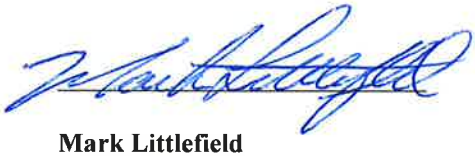
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

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_____

SEKISUI DIAGNOSTICS
Because every result matters™

DECLARATION OF CONFORMITY

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

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

Place of Issue: Prince Edward Island, Canada

Signature: _____ 06-May-2019

Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

Date

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

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D65-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
7D65-22 7D65-42	53030	Gamma-Glutamyl Transferase	**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.

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

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

Abbott

Declaration of Conformity

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

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

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

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

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

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

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

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

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

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

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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).

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Code/Codice	Product Description/Nome prodotto
6K26-30	CRP Vario
6K26-41	CRP Vario
6K26-10	CRP Calibrator Set
6K26-12	CRP Calibrator WR
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6K89-20	Ammonia Controls
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SENTINEL
DIAGNOSTICS

Code/Codice	Product Description/Nome prodotto
1P93-20	Cystatin C Control Set
6K25-10	CK-MB Calibrator
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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
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6K93-30	Copper
6K94-30	Fructosamine
6K95-30	Iron
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Furthermore, the manufacturer declares to:

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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

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