ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Abbott Ireland Diagnostics Division
Lisnamuck - Longford
Co. Longford
Ireland

has established and applies
a Quality Management System for

Design and Development,
Manufacture and Distribution of
In-Vitro Diagnostic Reagents for
Clinical Chemistry and Immunochemistry.

An audit was performed, Order No. **707120365**.

Proof has been furnished that the requirements
according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from **2023-09-01** until **2026-08-31**.

Certificate Registration No.: **12 100 60456 TMS**.

Digitally signed by Ceaicovschi Tudor
Date: 2025.04.24 12:13:17 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Head of Certification Body
Munich, 2023-06-02

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

CERTIFICATE

No. QS6 054869 0012 Rev. 04

Certificate Holder: **Abbott Ireland Diagnostics Division**
Lisnamuck
Longford
Co. Longford
IRELAND

Certification Mark:

Scope of Certificate: **Design, Development and Manufacture of In-Vitro Diagnostic Test Kits and Reagents used in the Diagnosis of Prenatal Screening, Disease Status, Cardiatic Markers, Protein Metabolism, Endocrine Disorders, Renal Dysfunction, Fertility Testing, Pregnancy Testing and for Therapeutic Drug Monitoring**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 054869 0012 Rev. 04
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F005102**
Report No.: **713319707**
Effective Date: **2024-05-28**
Expiry Date: **2026-05-30**

Date of Issue: 2024-06-05

(Renee Walker)
Director, US Certification Body, MHS

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 054869 0012 Rev. 04

Regulatory Requirements: **Audit/Certification Criteria**

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

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **Abbott Ireland Diagnostics Division**
Lisnamuck, Longford, Co. Longford, IRELAND

Facility Scopes: Design, Development and Manufacture of In-Vitro Diagnostic Test Kits and Reagents used in the Diagnosis of Prenatal Screening, Disease Status, Cardiatic Markers, Protein Metabolism, Endocrine Disorders, Renal Dysfunction, Fertility Testing, Pregnancy Testing and for Therapeutic Drug Monitoring
REPs Facility ID: F005102

Date of Issue: 2024-06-05

(Renee Walker)
Director, US Certification Body, MHS

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Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074LFD0025KM
Basic UDI-DI Name: Activated Alanine Aminotransferase
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P1824	Activated Alanine Aminotransferase	52924	W01010103

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: John Lennon
Function: Quality Manager
Signature: John Lennon
Date of Approval: 05-July-2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 02-July-2024.

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland

Date Issued: 05-July-2024
Supersedes: 30-June-2022

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 05-July-2024.

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACU0430JT
Basic UDI-DI Name: Albumin BCG2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U3020	Albumin BCG2	59071	W01010201
04U3030	Albumin BCG2	59071	W01010201

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 10 SEP 2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 09-SEP-2024

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland

Date Issued: 10 SEP 2024
Supersedes: 13-Mar 2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 10 SEP 2024

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0483K5
Basic UDI-DI Name: Alkaline Phosphatase2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8320	Alkaline Phosphatase2	52929	W01010105
04T8330	Alkaline Phosphatase2	52929	W01010105

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV Süd Product Service GmbH Zertifizierstellen, Ridlerstraße 65 • 80339 Munich Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Siobhan Wright
Function: Director Quality Assurance/Site Quality Head
Signature: Siobhan Wright
Date of Approval: 16-DEC-2021

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 16-DEC-2021

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 16-DEC-2021
Supersedes: N/A

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 16-DEC-2021

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **01R0422** Description: **Alinity c Pancreatic Amylase Reagent Kit**

EDMA: **11.01.01.08**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **01R0422** Descrizione: **Alinity c Pancreatic Amylase Reagent Kit**

EDMA: **11.01.01.08**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno 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
Ugo De Luca

Date / Data
01/12/2017

ABBOTT

Declaration of Conformity

Certificate Identification: 04T85
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8520	52941	Amylase2	**Self-declared**

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
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:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	25-OCT-20	Date of Approval:	25 OCT 2020
Date Issued:	25-OCT-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	25-OCT-20

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074LGF0007LN
Basic UDI-DI Name: Activated Aspartate Aminotransferase
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P2324	Activated Aspartate Aminotransferase	52954	W01010110

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: John Lennon
Function: Quality Manager
Signature: John Lennon
Date of Approval: 05-July-2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 03-July-2024

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland

Date Issued: 05-July-2024
Supersedes: 30-June-2022

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 05-July-2024

CE DECLARATION OF CONFORMITY

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**BIOKIT, S.A.** **Av. Can Montcau, 7** **08186 Lliçà d'Amunt** **Barcelona** **Spain**

Biokit hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Biokit erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Biokit declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Biokit déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Biokit dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Biokit declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Biokit erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Biokit bekräftar härmed att nedan uppräknade produkt(er) är förenlig(a) med de EU-direktiv och standarder som identifieras i denna deklaration

Η Biokit με το παρόν δηλώνει ότι το προϊόν(–τα) που αναφέρονται κατωτέρω συμμορφώνονται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που παρατίθενται στην παρούσα δήλωση.

EU Directive:
EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-Direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998)

Standard(s):
Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπο(-α)

ISO 13485

Notified Body:
Benannte Stelle Organismo Notificado Organisme Notifié Organismo Notificato Organismo Notificado Teknisk Kontrollorgon Anmält Organ Κοινοποιημένος Οργανισμός

Name: *Other Devices*	Code: *N/A*

- Certificate Nº: N/A Annex III

Product(s):
Produkt(e) Producto(s) Produit(s) Prodotto(i) Produto(s) Produkt(er) Produkt(er) Προϊόν(-τα)

Product(s) *Produkt(e)* *Producto(s)* *Produit(s* *Prodotto(i)*	*Produto(s)* *Produkt(er)* *Produkt(er)* *Προϊόν(-τα)*
P/N	
01R0620	**Alinity c ASO Reagent (300 test)**
01R0630	**Alinity c ASO Reagent (780 test)**
01R0601	**Alinity c ASO Standard**

Signature
Pau Planas
CEO
Biokit, S.A

August 28th, 2018
Date

Abbott

Declaration of Conformity

Certificate Identification:	DOC-07P9720-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
07P9720	53236	Alinity c Direct Bilirubin Reagent Kit	**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: C. Becker

Full Name: **Claudia Becker**

Position: **Director Quality Assurance**

Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins

Full Name: **Tiffini Jenkins**

Position: **Manager Regulatory Affairs**

Date of Approval: 11-Jul-2021

Date Issued: 22-Jul-2021

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 19-Feb-2019

Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-04V5121, 04V5131-SD DELK
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
04V5121	53229	Alinity c Total Bilirubin Reagent Kit	**Self-declared**
04V5131	53229	Alinity c Total Bilirubin Reagent Kit	**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: _____

Full Name: **Joerg Amborn**

Position: **Director, Quality Assurance**

Date of Approval: 2020-06-09

Signature: _____

Full Name: **Noah Lermer**

Position: **Director Regulatory Affairs**

Date of Approval: 12-Jun-20

Date Issued: 12-Jun-20

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 27-Feb-2019

Effective (Date or Lot Number): 12-Jun-20

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0487KD
Basic UDI-DI Name: Calcium2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8720	Calcium2	45789	W01010303
04T8730	Calcium2	45789	W01010303

Manufacturer (Name and Address)	Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339, Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: John Lennon
Function: Quality Manager
Signature: John Lennon +
Date of Approval: 27-May-2024

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. McEntire
Date of Approval: 27 May 2024.

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 27-May-2024
Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Supersedes: N/A
Effective (Date or Lot Number): 27 May 2024

+ Refer to QA Director delegation
John Lennon
John Lennon 27-May-2024

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fremstillingssted) (navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume şi adresă)	SRN reprezentant autorizat	Produs de către (locaţie producţie) (nume şi adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Notified Body (Name and Identification Number)	Conformity Assessment Procedure
BG	Нотифициран орган (име и идентификационен номер)	Процедура за оценка на съответствието
CS	Oznámený subjekt (název a identifikační číslo)	Postup posuzování shody
DA	Bemyndiget organ (navn og identifikationsnummer)	Overensstemmelsesvurderingsprocedure
DE	Benannte Stelle (Name und Identifikationsnummer)	Konformitätsbewertungsverfahren
EL	Κοινοποιημένος Οργανισμός (Όνομα και Αριθμός ταυτοποίησης)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Organismo Notificado (nombre y número de identificación	Procedimiento de evaluación de la conformidad
ET	Teavitatud asutus (nimi ja identifitseerimisnumber)	Vastavushindamismenetlus
FR	Organisme notifié (nom et numéro d'identification)	Procédure d'évaluation de la conformité
HR	Prijavljeno tijelo (naziv i identifikacijski broj)	Postupak ocjenjivanja sukladnosti
HU	Bejelentett szervezet (név és azonosító szám)	Megfelelőségértékelési eljárás
IT	Organismo notificato (nome e numero di identificazione)	Procedura di valutazione della conformità
LV	Pilnvarotā iestāde (nosaukums un identifikācijas numurs)	Atbilstības novērtēšanas procedūra
LT	Notifikuotoji įstaiga (pavadinimas ir identifikacinis numeris)	Atitikties vertinimo procedūra
NO	Meldt organ (navn og identifikasjonsnummer)	Framgangsmåte for samsvarsvurdering
PL	Jednostka notyfikowana (nazwa i numer identyfikacyjny)	Procedura oceny zgodności
PT	Organismo Notificado (Nome e Número de Identificação)	Procedimento de avaliação da conformidade
RO	Organism notificat (nume şi număr de identificare)	Procedură de evaluare a conformităţii
SK	Notifikovaný orgán (Názov a identifikačné číslo)	Postup posudzovania zhody
SV	Anmält organ (namn och identifikationsnummer)	Förfarande för bedömning av överensstämmelse
TR	Onaylanmış Kuruluş (İsim ve Tanım Numarası)	Uygunluk Değerlendirme Prosedürü

EN	**Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples**
BG	Система за управление на качеството Приложение IX, глави I и III, включително оценка на техническата документация на съответните изделия въз основа на представителни проби
CS	Systém řízení kvality Příloha IX Kapitoly I a III, včetně posouzení technické dokumentace dotčených prostředků na základě reprezentativních vzorků
DA	Kvalitetsstyringssystem Bilag IX kapitel I og III, Herunder en vurdering af den tekniske dokumentation for relevant udstyr på baggrund af repræsentative prøver
DE	Qualitätsmanagementsystem Anhang IX Kapitel I und III, einschließlich einer Bewertung der Technischen Dokumentation für betroffene Produkte auf der Grundlage repräsentativer Stichproben
EL	Σύστημα Διαχείρισης Ποιότητας Παράρτημα IX Κεφάλαια I και III, συμπεριλαμβάνεται αξιολόγηση του τεχνικού φακέλου για προϊόντα που εξετάζονται με βάση αντιπροσωπευτικά δείγματα
ES	Sistema de Gestión de Calidad Anexo IX, capítulos I y III, se incluye una evaluación de la documentación técnica para los productos afectados sobre la base de muestras representativas
ET	Kvaliteedijuhtimissüsteem IX lisa I ja III peatükk Sealhulgas asjaomaste seadmete tehnilise dokumentatsiooni hindamist esindavate valimite põhjal
FR	Système de gestion de la qualité Annexe IX Chapitres I et III, Inclut une évaluation de la documentation technique pour les dispositifs concernés, sur la base d'échantillons représentatifs
HR	Sustav upravljanja kvalitetom Prilog IX., Poglavlja I. i III., uključujući ocjenjivanje tehničke dokumentacije za predmetne proizvode na temelju reprezentativnih uzoraka
HU	Minőségirányítási rendszer IX. melléklet, I. és III. fejezet, ideértve az érintett eszközök műszaki dokumentációjának reprezentatív minták alapján való értékelését
IT	Sistema di gestione della qualità Allegato IX Capitoli I e III, compresa una valutazione della documentazione tecnica per i dispositivi interessati sulla base di campioni rappresentativi
LV	Kvalitātes vadības sistēma IX pielikuma I un III nodaļa, tostarp attiecīgo ierīču tehniskās dokumentācijas novērtējums, pamatojoties uz reprezentatīviem paraugiem
LT	Kokybės valdymo sistema IX priedo I ir III skyriai, įskaitant atitinkamų priemonių techninės dokumentacijos vertinimą remiantis tipiniais pavyzdžiais
NO	Kvalitetsstyringssystem Vedlegg IX kapittel I og III, inkludert en vurdering av den tekniske dokumentasjonen for aktuelt utstyr på grunnlag av representative prøver
PL	System Zarządzania Jakością Załącznik IX, Rozdziały I oraz III, w tym ocena dokumentacji technicznej danych wyrobów na podstawie reprezentatywnych próbek
PT	Sistema de gestão da qualidade Anexo IX Capítulos I e III, Incluindo uma avaliação da documentação técnica para os dispositivos em questão com base em amostras representativas
RO	Sistemul de management al calității Anexa IX, Capitolele I și III inclusiv o evaluare a documentației tehnice pentru dispozitivele în cauză pe baza unor probe reprezentative.
SK	Systém riadenia kvality Príloha IX Kapitoly I a III, vrátane posúdenia technickej dokumentácie príslušných pomôcok na základe reprezentatívnych vzoriek
SV	Kvalitetsledningssystem Bilaga IX Kapitel I och III, Inklusive en bedömning av den tekniska dokumentationen för berörda produkter som grundar sig på representativa urval
TR	Kalite Yönetim Sistemi Ek IX Bölüm I ve III Temsili numuneler bazında ilgili cihazlar için teknik dokümantasyonun değerlendirilmesi dahil

EN	EU Certificate No.	Common Specifications (CS)	Full Name
BG	ЕС Сертификат №	Общи спецификации (ОС)	Пълно наименование
CS	Číslo certifikátu EU	Společné specifikace	Celý název
DA	EU-certifikatnummer	Fælles specifikationer	Fulde navn
DE	Nr. des EU-Zertifikats	Gemeinsame Spezifikationen (GS)	Vollständiger Name
EL	Αριθμός πιστοποιητικού ΕΕ	Κοινές προδιαγραφές (ΚΠ)	Πλήρης ονομασία
ES	Número certificado UE	Especificaciones comunes	Nombre completo
ET	EL-i sertifikaadi nr	Ühtsed kirjeldused	Täisnimi
FR	N° certificat UE	Spécifications communes	Nom complet
HR	EU potvrda br.	Zajedničke specifikacije („CS“)	Puni naziv
HU	EU-tanúsítvány száma	Egységes előírások	Teljes név
IT	N° del certificato UE	Specifiche comuni (SC)	Nome completo
LV	ES sertifikāta Nr.	Kopīgās specifikācijas	Pilns nosaukums
LT	ES sertifikatas Nr.	Bendrosios specifikacijos	Vardas ir pavardė
NO	EU-sertifikatnr.	Felles spesifikasjoner	Fullt navn
PL	Nr Certyfikatu UE	Wspólne specyfikacje	Imię i nazwisko
PT	Certificado UE Nº	Especificações comuns	Nome completo
RO	Nr. certificat UE:	Specificații comune (CS)	Numele complet
SK	Certifikát EÚ č.	Spoločné špecifikácie	Celý názov
SV	Nummer på EU-intyg	Gemensamma specifikationer	Fullständigt namn
TR	AB Sertifika Numarası	Genel Spesifikasyonlar (GS)	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcţia	Semnat pentru şi în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro. Toto prohlášení je v souladu s Přílohou IV nařízení IVD a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico *in vitro* descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico *in vitro*. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic *in vitro*. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici *in vitro*. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til *in vitro*-diagnostikk. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico *in vitro*. Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för *in vitro*-diagnostik. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9320** Description: **Alinity c Ceruloplasmin Reagent Kit**

EDMA: **12.01.03.02**

complies with all the 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. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:
1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9320** Descrizione: **Alinity c Ceruloplasmin Reagent Kit**

EDMA: **12.01.03.02**

soddisfa 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 il dispositivo:
1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:
1. conservare e tenere a disposizione dell'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 di almeno 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
Ugo De Luca

Date / Data
19/12/2017

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

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0488KF
Basic UDI-DI Name: Cholesterol2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8820	Cholesterol2	53359	W01010205
04T8830	Cholesterol2	53359	W01010205

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 31 OCT 2024

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature:
Date of Approval: 31 Oct 2024

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 31 OCT 2024
Supersedes: 25-Sep-2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 31 OCT 2024

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9422** Description: **Alinity c Cholinesterase Reagent Kit**

EDMA: **11.01.01.11**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9422** Descrizione: **Alinity c Cholinesterase Reagent Kit**

EDMA: **11.01.01.11**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno 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
Ugo De Luca

Date / Data
01/12/2017

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9432** Description: **Alinity c Cholinesterase Reagent Kit**

EDMA: **11.01.01.11**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9432** Descrizione: **Alinity c Cholinesterase Reagent Kit**

EDMA: **11.01.01.11**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno 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
Ugo De Luca

Date / Data
01/12/2017

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9522** Description: **Alinity c CK-MB Reagent Kit**

EDMA: **11.01.01.14**

complies with all the 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. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:
1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9522** Descrizione: **Alinity c CK-MB Reagent Kit**

EDMA: **11.01.01.14**

soddisfa 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 il dispositivo:
1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:
1. conservare e tenere a disposizione dell'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 di almeno 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
Ugo De Luca

Date / Data
24/11/2017

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9532** Description: **Alinity c CK-MB Reagent Kit**

EDMA: **11.01.01.14**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9532** Descrizione: **Alinity c CK-MB Reagent Kit**

EDMA: **11.01.01.14**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno 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
Ugo De Luca

Date / Data
24/11/2017

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9501** Description: **Alinity c CK-MB Calibrator Kit**

EDMA: **11.50.03.02**

complies with all the 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. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:
1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9501** Descrizione: **Alinity c CK-MB Calibrator Kit**

EDMA: **11.50.03.02**

soddisfa 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 il dispositivo:
1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:
1. conservare e tenere a disposizione dell'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 di almeno 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
Ugo De Luca

Date / Data
24/11/2017

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9510** Description: **Alinity c CK-MB Control Kit**

EDMA: **11.50.02.01**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9510** Descrizione: **Alinity c CK-MB Control Kit**

EDMA: **11.50.02.01**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno 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
Ugo De Luca

Date / Data
24/11/2017

Abbott

Declaration of Conformity

Certificate Identification: DOC-08P4220-SD DLK 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
08P4220	53006	Alinity c Creatine Kinase Reagent Kit	**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: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 05 May 2022

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 29-Apr-2022
Date Issued: 05 May 2022
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 31-Dec-2016
Effective (Date or Lot Number): 05-May-2022