



EU Declaration of Conformity

Basic UDI-DI: 038074ACT0496KE
Basic UDI-DI Name: Gamma-Glutamyl Transferase2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9620	Gamma-Glutamyl Transferase2	53027	W01010116
04T9630	Gamma-Glutamyl Transferase2	53027	W01010116

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 No. 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.
		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

Full Name: Rosemary McEntire

Function: Director Quality/Site Quality Head

Function: Manager Regulatory Affairs

Signature:

Signature:

Date of Approval: 19 Aug 2025

Date of Approval: 19 August 2025

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

Date Issued: 19 Aug 2025

Place Issued: Lisnamuck, Longford, Co. Longford Ireland

Supersedes: 22 May 2024

Effective (Date or Lot Number): 19 AUG 2025

Declaration of Conformity

Certificate Identification: DOC-07P5520, 07P5530-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
07P5520	53301	Alinity c Glucose Reagent Kit	Self-declared
07P5530	53301	Alinity c Glucose Reagent Kit	

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: 13-Oct-2017

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

**Abbott****IVDD Declaration of Conformity Attribute Update Letter**Number: 1

List Number and Size Code	Name and Descriptions of Devices	GMDN Code
08P4321	Alinity c Hemoglobin A1c Reagent Kit	59090

Legal Manufacturer (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
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.

This letter must be used in conjunction with the Declaration of Conformity issued in accordance with In Vitro Diagnostic Directive 98/79/EC.

IVD Directive 98/79/EC Declaration of Conformity Identification	DoC-08P4320, 08P4301, 08P4310-SD DLK TPM – Date of Approval 02-Feb-2022
Description of updated attributes from IVD Directive 98/79/EC Declaration of Conformity	Create new size code for Alinity c Hemoglobin A1c Reagent Kit (LN 08P4321) for logistical reasons to implement the REACH change to meet the requirements of the REACH Restriction relating to Dimethylformamide (DMF).

This letter documents that the device listed above continues to comply with the In Vitro Diagnostic Directive 98/79/EC and meets the applicable transitional provisions of Regulation (EU) 2022/112 of the European Parliament and the Council of 25 January 2022 and is considered a non-significant change per MDCG 2022-6 (Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR).

Full Name: Claudia BeckerFunction: Director Quality AssuranceSignature: C. BeckerDate of Approval: 26 Jul 2023Date Issued: 26 Jul 2023Full Name: Susanne UlrichFunction: Associate Director Regulatory AffairsSignature: Susanne UlrichDate of Approval: 26 Jul 2023Place Issued: WiesbadenEffective (Date or Lot Number): 26 Jul 2023

Declaration of Conformity

Certificate Identification: DOC-08P4320, 08P4301, 08P4310-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
08P4320	59090	Alinity c Hemoglobin A1c Reagent Kit	Self-declared
08P4301	53315	Alinity c Hemoglobin A1c Calibrators	Self-declared
08P4310	44435	Alinity c Hemoglobin A1c Controls	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:

02 Feb 2022

Signature:

Tiffini Jenkins

Full Name:

Tiffini Jenkins

Position:

Manager Regulatory Affairs

Date of Approval:

1-Feb-2022

Date Issued:

02 Feb 2022

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

12-Feb-2019

Effective (Date or Lot Number):

02 Feb 2022



EU Declaration of Conformity

Basic UDI-DI: 038074ACT0498KJ
Basic UDI-DI Name: Iron2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9820	Iron2	54758	W01010216

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, Certification Body, Ridlerstraße 65, 80339 Munich Germany Notified Body Number 0123		
Conformity Assessment Procedure	Quality Management System	EU Certificate No.	
	Annex IX Chapters I and III,	No. V12 054869 0013	
	Including an assessment of the technical documentation for devices concerned on the basis of representative samples		
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
Director Quality Assurance/Site Quality

Function: Head

Signature: 

Date of Approval: 21 Nov 2023

Signed for, and on

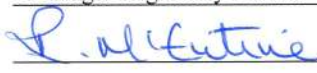
behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 21 Nov 2023
09 December 2021

Supersedes:

Full Name: Rosemary McEntire

Function: Manager Regulatory Affairs

Signature: 

Date of Approval: 21 Nov 2023

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland

Effective (Date

or Lot Number):

21 Nov 2023



EU Declaration of Conformity

Basic UDI-DI: 038074ACP0914HX
Basic UDI-DI Name: Alinity c Lipid Multiconstituent Calibrator
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
09P1403	Alinity c Lipid Multiconstituent Calibrator Kit	53356	W0102152203

Manufacturer (Name and Address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany		
Manufacturer SRN	DE-MF-000009455		
Authorized Representative (Name and Address)	N/A		
Authorized Representative SRN	N/A		
Produced by (Site of manufacture) (Name and Address)	Randox Laboratories Limited 55 Diamond Road Crumlin, County Antrim BT29 4QY, United Kingdom		
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 010051 0137	
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: Claudia Becker	Full Name: Bridget Norton
Function: Director Quality Assurance	Function: Assoc. Director Regulatory Affairs
Signature: 	Signature: 
Date of Approval: 25 Apr 2025	Date of Approval: 25 April 2025
Signed for, and on behalf of: Abbott GmbH, Wiesbaden, Germany	
Date Issued: 25 Apr 2025	Place Issued: 65205 Wiesbaden, Germany
Supersedes: 30-Jan-2024	Effective (Date or Lot Number): 25 Apr 2025

 Biokit A Werfen Company	CE DECLARATION OF CONFORMITY	DRC-726
		Edition 5
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DECLARATION OF CONFORMITY

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

 Biokit A Werfen Company	CE DECLARATION OF CONFORMITY	DRC-726
		Edition 5
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Notified Body:

Benannte Stelle Organismo Notificado Organisme Notifié Organismo Notificato Organismo Notificado Teknisk Kontrollorgan
Anmält Organ Κοινοποιημένος Οργανισμός

Name: Other Devices	Code: N/A
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- Certificate N°: 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)	Produto(s)
Producto(s)	Produkt(er)
Produit(s)	Produkt(er)
Prodotto(i)	Προϊόν(-τα)
P/N	
01R1420	Alinity c Lp(a) Reagent Kit
01R1401	Alinity c Lp(a) Calibrators
01R1410	Alinity c Lp(a) Control Kit



Signature
Pau Planas
CEO
Biokit, S.A

August 28th, 2018

Date

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: **04Y85-20**Description: **Lipase NG OC Reagent Kit**EDMA: **11.01.01.23**

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: **04Y85-20**Descrizione: **Lipase NG OC Reagent Kit**EDMA: **11.01.01.23**

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'adeguata procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA

A Legal Representative

Un Legale Rappresentante

Ugo De Luca

Date / Data

28/02/2019

Declaration of Conformity

Certificate Identification: 08P19
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
08P1925 08P1934	46795	Magnesium	Self-declared

Authorized European Representative (name and address)	N/A
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: <u><i>Siobhan Wright</i></u> Full Name (printed): Siobhan Wright Position: Director Quality Assurance/ Site Quality Head Date of Approval: <u>20 JAN 2021</u> Date Issued: <u>20 JAN 2021</u> Supersedes: 13 July 2020	Signature: <u><i>Lorraine Whitney</i></u> Full Name (printed): Lorraine Whitney Position: Director Regulatory Affairs Date of Approval: <u>20 JAN 2021</u> Place Issued: AIDD, Longford Effective (Date): <u>20 JAN 2021</u>
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Declaration of Conformity

Certificate Identification: DOC-08P6001-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
08P6001	47868	Alinity c Multiconstituent Calibrator 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:

02 Feb 2022

Signature:

Tiffini Jenkins

Full Name:

Tiffini Jenkins

Position:

Manager Regulatory Affairs

Date of Approval:

1-Feb-2022

Date Issued:

02 Feb 2022

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

19-Aug-2019

Effective (Date or Lot Number):

02 Feb 2022



EU Declaration of Conformity

Basic UDI-DI: 038074ACU0403JQ
Basic UDI-DI Name: Phosphorus2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U0320	Phosphorus2	59123	W01010307
04U0330	Phosphorus2	59123	W01010307

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 Certification Body, 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	Full Name: Sandra Gallagher
Function: Director Quality Assurance/ Site Quality Head	Function: Manager Regulatory Affairs
Signature:	Signature:
Date of Approval: 17 Apr 2023	Date of Approval: 17-APR-2023
Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland	
Date Issued: 17 Apr 2023	Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Supersedes: N/A	Effective (Date or Lot Number): 17 Apr 2023

Declaration of Conformity

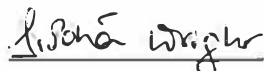
Certificate Identification: 04T81
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8120	53989	Total Protein2	Self-declared
04T8130	53989	Total Protein2	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: 
Full Name (printed): **Siobhan Wright**
Position: **Director Quality Assurance/
Site Quality Head**

Signature: 
Full Name (printed): **Lorraine Whitney**
Position: **Director Regulatory Affairs**

Date of Approval: 22-01-20

Date of Approval: 22 OCT 2020

Date Issued: 22-01-20

Place Issued: Abbott Ireland Diagnostics Division,
Lisnamuck, Longford, Co. Longford, Ireland.

Supersedes: Not Applicable

Effective Date: 22-01-20

Declaration of Conformity

Certificate Identification: DOC-08P6201-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
08P6201	30505	Alinity c Specific Proteins Multiconstituent Calibrator 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:



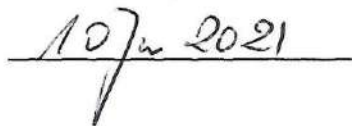
Full Name:

Claudia Becker

Position:

Director Quality Assurance

Date of Approval:



Signature:



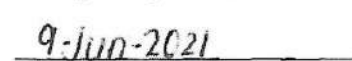
Full Name:

Tiffini Jenkins

Position:

Manager Regulatory Affairs

Date of Approval:



Date Issued:



Place Issued:

65205 Wiesbaden, Germany

Supersedes:

08-Jan-2018

Effective (Date or Lot Number):



Declaration of Conformity

Certificate Identification: 04U06
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
04U0620	53462	Triglyceride2	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: 
 Full Name (printed): Siobhan Wright
 Position: Director Quality Assurance/
 Site Quality Head

Signature: 
 Full Name (printed): Thomas Breslin
 Position: Manager Regulatory Affairs

Date of Approval: 24-JUN-2021

Date of Approval: 25-JUNE-2021

Date Issued: 24-JUN-2021

Place Issued: Abbott Ireland Diagnostics Division,
Lisnamuck, Longford, Co. Longford, Ireland.

Supersedes: Not Applicable

Effective Date: 25-JUNE-2021

EU Declaration of Conformity

Basic UDI-DI: 038074ACP0775J9
Basic UDI-DI Name: Alinity c Ultra HDL
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P7520	Alinity c Ultra HDL Reagent Kit	53391	W01010215
07P7530	Alinity c Ultra HDL Reagent Kit	53391	W01010215

Manufacturer (Name and Address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
Manufacturer SRN	DE-MF-000009455	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of manufacture) (Name and Address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65, 80339 München, 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 010051 0137
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: <u>Claudia Becker</u> Function: <u>Director Quality Assurance</u> Signature: <u>C. Becker</u> Date of Approval: <u>12 Oct 2023</u> Signed for, and on behalf of: <u>Abbott GmbH, Wiesbaden, Germany</u>	Full Name: <u>Susanne Ulrich</u> Function: <u>Assoc. Director Regulatory Affairs</u> Signature: <u>Susanne Ulrich</u> Date of Approval: <u>12 Oct 2023</u>
Date Issued: <u>12 Oct 2023</u>	Place Issued: <u>65205 Wiesbaden, Germany</u>
Supersedes: <u>08-Jul-2022</u>	Effective (Date or Lot Number): <u>12 Oct - 2023</u>

Declaration of Conformity

Certificate Identification: DOC-08P1620, 08P1630-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
08P1620	53590	Alinity c Urea Nitrogen Reagent Kit	Self-declared
08P1630	53590	Alinity c Urea Nitrogen 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: 05-Jan-2018

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

Declaration of Conformity

Certificate Identification: 04U09
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
04U0920	53583	Uric Acid2	Self-declared
04U0930	53583	Uric Acid2	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: 
Full Name (printed): Siobhan Wright
Position: Director Quality Assurance/
Site Quality Head

Signature: 
Full Name (printed): Lorraine Whitney
Position: Director Regulatory Affairs

Date of Approval: 18-Nov-20

Date of Approval: 18 Nov 2020

Date Issued: 18-Nov-20

Place Issued: Abbott Ireland Diagnostics Division,
Lisnamuck, Longford, Co. Longford, Ireland.

Supersedes: Not Applicable

Effective Date: 18-Nov-20