

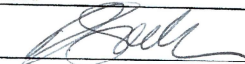
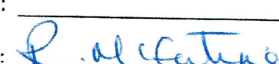


## EU Declaration of Conformity

**Basic UDI-DI:** 038074ACU0405JU  
**Basic UDI-DI Name:** Total Bilirubin2  
**Risk Class:** Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U0520	Total Bilirubin2	53229	W01010203
<b>Manufacturer (Name and Address)</b>		Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland	
<b>Manufacturer SRN</b>		IE-MF-000010070	
<b>Authorized Representative (Name and Address)</b>		N/A	
<b>Authorized Representative SRN</b>		N/A	
<b>Produced by (Site of Manufacture) (Name and Address)</b>		Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland	
<b>Notified Body (Name and Identification Number)</b>		TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany Notified Body Number 0123	
<b>Conformity Assessment Procedure</b>		<b>EU Certificate No.</b> V12 054869 0013	
		<b>Quality Management System</b> Annex IX Chapters I and III,  Including an assessment of the technical documentation for devices concerned on the basis of representative samples	
<b>Common Specifications (CS)</b>		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>David Spellman</u> Function: <u>Director Quality Assurance/ Site Quality</u> Signature: <u></u> Date of Approval: <u>26 Apr 2024</u>	Full Name: <u>Rosemary McEntire</u> Function: <u>Manager Regulatory Affairs</u> Signature: <u></u> Date of Approval: <u>24 APR 2024</u>
Signed for, and on behalf of: <u>Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland</u>	
Date Issued: <u>26 Apr 2024</u> Supersedes: <u>16-Dec-2021</u>	Place Issued: <u>Lisnamuck, Longford, Co. Longford, Ireland</u> Effective (Date or Lot Number): <u>26 Apr 2024</u>

# 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

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
<b>Harmonized Standards</b>	Listed in the Technical Documentation

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

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

Signature: 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

## Declaration of Conformity

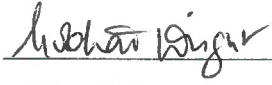
**Certificate Identification:** 04T84  
**Legal Manufacturer's Name:** Abbott Ireland Diagnostics Division  
**Legal Manufacturer's Address:** Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8420	52925	Alanine Aminotransferase2	Self-declared
04T8430	52925	Alanine Aminotransferase2	Self-declared

<b>Authorized European Representative (name and address)</b>	Not Applicable
<b>Storage of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
<b>Harmonized Standards</b>	Listed in the Technical Documentation

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

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

Signature:   
 Full Name (printed): **Siobhan Wright**  
 Position: **Director Quality Assurance/  
Site Quality Head**

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

Date of Approval: 17-SEP-2021

Date of Approval: 17-SEP-2021

Date Issued: 17-SEP-2021

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

Supersedes: **Not Applicable**

Effective Date: 17-SEP-2021

## Declaration of Conformity


**Certificate Identification:** 04T86  
**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
04T8620	52954	Aspartate Aminotransferase2	Self-declared
04T8630	52954	Aspartate Aminotransferase2	Self-declared

<b>Authorized European Representative (name and address)</b>	Not Applicable
<b>Storage of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
<b>Harmonized Standards</b>	Listed in the Technical Documentation

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

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

Signature:   
 Full Name (printed): **Siobhan Wright**  
 Position: **Director Quality Assurance/  
 Site Quality Head**

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

Date of Approval: 17-SEP-2021

Date of Approval: 17-SEP-2021

Date Issued: 17-SEP-2021

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

Supersedes: **Not Applicable**

Effective Date: 17-SEP-2021



# 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

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
<b>Harmonized Standards</b>	Listed in the Technical Documentation

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

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

Signature: *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



## EU Declaration of Conformity

Basic UDI-DI: 038074ACT0491K4  
Basic UDI-DI Name: Creatinine2  
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9120	Creatinine2	53251	W01010207
<b>Manufacturer (Name and Address)</b>	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland		
<b>Manufacturer SRN</b>	IE-MF-000010070		
<b>Authorized Representative (Name and Address)</b>	N/A		
<b>Authorized Representative SRN</b>	N/A		
<b>Produced by (Site of Manufacture) (Name and Address)</b>	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland		
<b>Notified Body (Name and Identification Number)</b>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123		
<b>Conformity Assessment Procedure</b>	<b>Quality Management System</b> Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	<b>EU Certificate No.</b> No. V12 054869 0013	
<b>Common Specifications (CS)</b>	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: 10 SEP 2024

Full Name: Sandra Gallagher

Function: Manager Regulatory Affairs

Signature: 

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

Place Issued: Lisnamuck, Longford Co. Longford Ireland

Effective (Date or Lot Number): 10 SEP 2024

Supersedes: 13-Mar-2023

## 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

<b>Authorized European Representative (name and address)</b>	Not Applicable
<b>Storage of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
<b>Harmonized Standards</b>	Listed in the Technical Documentation

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

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

**Signature:**   
**Full Name (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

## Declaration of Conformity

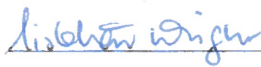
**Certificate Identification:** 04U06  
**Legal Manufacturer's Name:** Abbott Ireland Diagnostics Division  
**Legal Manufacturer's Address:** Lisnamuck, Longford, Co. Longford, Ireland.


List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04U0620	53462	Triglyceride2	Self-declared

<b>Authorized European Representative (name and address)</b>	Not Applicable
<b>Storage of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
<b>Harmonized Standards</b>	Listed in the Technical Documentation

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

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

Signature:   
 Full Name (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





Abbott

# 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

<b>Manufacturer (Name and Address)</b>	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
<b>Manufacturer SRN</b>	DE-MF-000009455	
<b>Authorized Representative (Name and Address)</b>	N/A	
<b>Authorized Representative SRN</b>	N/A	
<b>Produced by (Site of manufacture) (Name and Address)</b>	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada	
<b>Notified Body (Name and Identification Number)</b>	TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65, 80339 München, Germany Notified Body Number 0123	
<b>Conformity Assessment Procedure</b>	<b>Quality Management System</b> Annex IX Chapters I and III, including an assessment of the technical documentation for devices concerned on the basis of representative samples.	<b>EU Certificate No.</b> <b>No. V12 010051 0137</b>
<b>Common Specifications (CS)</b>	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>	Full Name: <u>Susanne Ulrich</u>
Function: <u>Director Quality Assurance</u>	Function: <u>Assoc. Director Regulatory Affairs</u>
Signature: <u><i>C. Becker</i></u>	Signature: <u><i>Susanne Ulrich</i></u>
Date of Approval: <u>12 Oct 2023</u>	Date of Approval: <u>12/ Oct / 2023</u>
Signed for, and on behalf of: <u>Abbott GmbH, Wiesbaden, Germany</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

Manufacturer: Sekisui Diagnostics P.E.I. Inc  
70 Watts Avenue Charlottetown  
Prince Edward Island  
C1E 2B9  
Canada

European Representative: MDSS GmbH  
Schiffgraben 41  
30175 Hannover  
Germany

Product:


Product Code	Name	GMDN Code
07P7120	Alinity c Direct LDL Reagent Kit	53395

Classification: General IVD

Conformity Assessment Route: Annex III, self-certified

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

Place of Issue: Prince Edward Island, Canada

Signature:   
Penny White  
Senior Manager Regulatory Affairs  
Sekisui Diagnostics PEI Inc.

29-Jun-2021  
Date



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
**de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE**

**EC DESIGN-EXAMINATION CERTIFICATE**  
**in accordance with the Annex IV, Section 4, of the Directive 98/79/EC**

<b>Certificado nº/Certificate no</b> <b>2003 12 0393 ED</b>	<b>Fecha de validez/Date of validity</b> <b>Desde/From 20-05-2022 Hasta/To 26-05-2025</b>	<b>ON nº/NB no</b> <b>0318</b>
----------------------------------------------------------------	----------------------------------------------------------------------------------------------	-----------------------------------

**A favor de/In favour of:**

<b>Fabricante/Manufacturer:</b> <b>Nombre/Name: DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.</b> <b>Dirección/Address: Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)</b> <b>Representante autorizado ante la UE/Authorized EU representative: Idem</b>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

**Para el producto/For the product:**

<b>Categoría/Category: Productos sanitarios para diagnóstico "in vitro"/ In vitro diagnostic medical devices</b> <b>Grupo genérico/ Generic group: Diagnóstico de enfermedades infecciosas / Diagnostic of infectious diseases</b> <b>Tipo/Type: Especificado en el Anexo de este Certificado/Specified in Annex to this Certificate</b>
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**Elaborado en/In the facilities:**

<b>Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)</b>
----------------------------------------------------------------------

**Fecha inicial/ Initial date: 11/12/2003**

**Fecha de prórroga anterior/ Previous extension date: 19/11/2018**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total nº: 2003 12 0388 CT. / *This certificate must be accompanied by the EC Full Quality Assurance System Certificate no: 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva / *This certificate is issued on the assessment of the design documentation contained in dossier no 2003 05 0240 and guarantees that the design of the described products fulfils the requirements of the Directive.*

Madrid, 19 de mayo de 2022

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 19/05/2022

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://localizador.aemps.es>

CSV: ZZLVQP3967



CORREO ELECTRÓNICO  
on0318@aemps.es

Página 1 de 2

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28022 MADRID  
Tel.: (+34) 91 822.57.87 / (+34) 91.822.59.97  
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318



ANEXO N°/ANNEX NO: I

**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
**de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE**  
**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with the Annex IV, Section 4, of the Directive 98/79/EC*

Certificado n°/Certificate no <b>2003 12 0393 ED</b>	Fecha de validez/Date of validity Desde/From <b>20-05-2022</b> Hasta/To <b>26-05-2025</b>	ON n°/NB no <b>0318</b>
---------------------------------------------------------	----------------------------------------------------------------------------------------------	----------------------------

**A favor de/In favour of:**

<b>Fabricante/Manufacturer:</b> Nombre/Name: <b>DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.</b> Dirección/Address: <b>Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)</b> <b>Representante autorizado ante la UE/Authorized EU representative: Idem</b>
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**Tipo de producto/ Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.**

**Clasificación/ Classification: Lista A del Anexo II/ List A, Annex II**

**Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis D, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis D infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]**

**HDV Ab**

ELISA cualitativo / *ELISA qualitative*

- DAB.CE (96 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 19 de mayo de 2022

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de  
medicamentos y  
productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 19/05/2022

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://localizador.aemps.es>

CSV: Z Z L V Q P 3 9 6 7



CORREO ELECTRÓNICO  
on0318@aemps.es

Página 2 de 2

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ORGANISMO NOTIFICADO 0318