Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACU0405JU
Basic UDI-DI Name: Total Bilrubin2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U0520	Total Bilirubin2	53229	W01010203

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 Münich, 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.** 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 Assurance/ Site Quality Head	Function:	Manager Regulatory Affairs
Signature:		Signature:	
Date of Approval:	26 APR 2024	Date of Approval:	24APR2024

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

Date Issued:	26 APR 2024	Place Issued:	Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	16-Dec-2021	Effective (Date or Lot Number):	26 APR 2024

Digitally signed by Ceaicovschi Tudor
Date: 2025.09.05 10:37:56 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

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: 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**

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

ABBOTT

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**

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

Abbott

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

Abbott

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

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: [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

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:	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:	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

ABBOTT

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:	Siobhan Wright	Signature:	
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Thomas Breslin**
Position:	**Director Quality Assurance/ Site Quality Head**	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 HDLReagent Kit	53391	W01010215
07P7530	Alinity c Ultra HDLReagent 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: Claudia Becker
Function: Director Quality Assurance
Signature: C. Becker
Date of Approval: 12 Oct 2023

Full Name: Susanne Ulrich
Function: Assoc. Director Regulatory Affairs
Signature: Susanne Ulrich
Date of Approval: 12/Oct/2023

Signed for, and on behalf of: Abbott GmbH, Wiesbaden, Germany

Date Issued: 12 Oct 2023
Place Issued: 65205 Wiesbaden, Germany

Supersedes: 08-Jul-2022
Effective (Date or Lot Number): 12-Oct-2023

SEKISUI DIAGNOSTICS
Because every result matters™

DECLARATION OF CONFORMITY

Manufacturer:

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

European Representative:

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

Product:

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

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

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

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

A favor de/*In favour of*:

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

Para el producto/*For the product*:

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

Elaborado en/*In the facilities*:

Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)

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. Mª 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

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 91 822.57.87 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

ANEXO Nº/*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 nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2003 12 0393 ED	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

A favor de/*In favour of*:

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

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. Mª Jesús Lamas Díaz

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 91 822.57.87 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318