Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0790LK
Basic UDI-DI Name: Alinity i AFP
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P9020	Alinity i AFP Reagent Kit	58348	W0102039001
07P9030	Alinity i AFP Reagent Kit		
07P9022	Alinity i AFP Reagent Kit	58348	W0102039001
07P9032	Alinity i AFP Reagent Kit		
07P9001	Alinity i AFP Calibrators	54062	W0102152205
07P9010	Alinity i AFP Controls	54063	W0102152005

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland	
Manufacturer SRN	IE-MF-000009849	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo 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.** V12 001922 0024
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: Noel Haren
Associate Director Regulatory Affairs

Digitally signed by Ceaicovschi Tudor
Date: 2026.03.31 11:53:17 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Full Name: Joe Murray
Director Quality Assurance

Function:		Function:	
Signature:		Signature:	
Date of Approval:	10 Mar 2025	Date of Approval:	07 Mar 2025

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued:	10 Mar 2025	Place Issued:	Sligo, Ireland
Supersedes:	03 OCT 2024	Effective (Date or Lot Number):	Reagent size codes 07P9022 and 07P9032 lots 75031FZ00 and 75035FZ01; and all lots manufactured with commodity numbers G71264R05 (Reagent size codes 07P9020 and 07P9030), G71262R05 (Calibrators) and G71263R04 (Controls), or higher.

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0934LK
Basic UDI-DI Name: Alinity i Anti-Tg
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
09P3420	Alinity i Anti-Tg Reagent Kit	58728	W0102100303
09P3401	Alinity i Anti-Tg Calibrators	55199	W0102100303
09P3410	Alinity i Anti-Tg Controls	55200	W0102100303

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland	
Manufacturer SRN	IE-MF-000009849	
Authorized Representative (Name and Address)	Not Applicable	
Authorized Representative SRN	Not Applicable	
Produced by (Site of Manufacture) (Name and Address)	**Reagents:** Bulk: Fisher Diagnostics, A Div. of Fisher Scientific Company, LLC A Part of Thermo Fisher Scientific, Inc. 8365 Valley Pike, Middletown VA 22645 USA Fill/Finish: Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland	**Calibrators, Controls:** Fisher Diagnostics, A Div. of Fisher Scientific Company, LLC A Part of Thermo Fisher Scientific, Inc. 8365 Valley Pike, Middletown VA 22645 USA
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.** V12 001922 0024
Common Specifications (CS)	Not Applicable	

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:	Noel Haren	Full Name:	Joe Murray
Function:	Associate Director Regulatory Affairs	Function:	Director Quality Assurance/ Site Quality Head
Signature:		Signature:	
Date of Approval:	26 Feb 2025	Date of Approval:	24 Feb 2025
Signed for, and on behalf of:	Abbott Ireland Diagnostics Division, Sligo		
Date Issued:	26 Feb 2025	Place Issued:	Sligo Ireland
Supersedes:	23 October 2024	Effective (Date or Lot Number):	26 Feb 2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0935LM
Basic UDI-DI Name: Alinity i Anti-TPO
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
09P3522	Alinity i Anti-TPO Reagent Kit	58729	W0102100301
09P3501	Alinity i Anti-TPO Calibrators	55210	W0102152211
09P3510	Alinity i Anti-TPO Controls	55211	W0102152011

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland	
Manufacturer SRN	IE-MF-000009849	
Authorized Representative (Name and Address)	Not Applicable	
Authorized Representative SRN	Not Applicable	
Produced by (Site of Manufacture) (Name and Address)	**Reagents:** Bulk: Fisher Diagnostics, A Div. of Fisher Scientific Company, LLC A Part of Thermo Fisher Scientific, Inc. 8365 Valley Pike, Middletown VA 22645 USA Fill/Finish: Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland	**Calibrators, Controls:** Fisher Diagnostics, A Div. of Fisher Scientific Company, LLC A Part of Thermo Fisher Scientific, Inc. 8365 Valley Pike, Middletown VA 22645 USA
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.** V12 001922 0024
Common Specifications (CS)	Not Applicable	

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:	Thomas McDonagh	Full Name:	Joe Murray
Function:	Associate Director Regulatory Affairs	Function:	Director Quality Assurance/ Site Quality Head
Signature:		Signature:	
Date of Approval:	26 Nov 2024	Date of Approval:	26 Nov 2024
Signed for, and on behalf of:	Abbott Ireland Diagnostics Division, Sligo		
Date Issued:	26 Nov 2024	Place Issued:	Sligo Ireland
Supersedes:	16 March 2023	Effective (Date or Lot Number):	26 Nov 2024

Abbott

Declaration of Conformity

Certificate Identification:	07P67
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
07P6722 07P6732	60779	Alinity i B12 Reagent Kit	**Self-declared**
07P6701	41337	Alinity i B12 Calibrators	**Self-declared**
07P6710	41338	Alinity i B12 Controls	**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:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name:	Siobhan Wright	Full Name:	Lorraine Whitney
Position:	Director Quality Assurance/ Site Quality Head	Position:	Senior Manager Regulatory Affairs
Date of Approval:	24-APR-19	Date of Approval:	19 APR 2019
Date Issued:	24-APR-19	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	16-Mar-2018	Effective (Date or Lot Number):	24-APR-19

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0849LT
Basic UDI-DI Name: Alinity i CA 125 II
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P4920	Alinity i CA 125 II Reagent Kit (2 x 100 Tests)	54588	W0102030106
08P4930	Alinity i CA 125 II Reagent Kit (2 x 500 Tests)	54588	W0102030106
08P4901	Alinity i CA 125 II Calibrators	38231	W0102152205
08P4910	Alinity i CA 125 II Controls	38230	W0102152005

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)	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, PA 19355 USA	
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 0100510137**
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: 15 Mar 2024

Full Name: Susanne Ulrich
Function: Assoc. Director Regulatory Affairs
Signature: Susanne Ulrich
Date of Approval: 12/Mar/2024

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

Date Issued: 15 Mar 2024
Place Issued: 65205 Wiesbaden, Germany

Supersedes: 03-Mar-2023
Effective (Date or Lot Number): 15 Mar 2024

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0832LA
Basic UDI-DI Name: Alinity i CA 19-9XR
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P3220	Alinity i CA 19-9XR Reagent Kit	60976	W0102030103
08P3230	Alinity i CA 19-9XR Reagent Kit	60976	W0102030103
08P3201	Alinity i CA 19-9XR Calibrators	38225	W0102152205
08P3210	Alinity i CA 19-9XR Controls	38224	W0102152205

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)	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, PA 19355 USA	
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 0100510137**
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: 16 Jul 2024

Full Name: Susanne Ulrich
Function: Assoc. Director Regulatory Affairs
Signature: Susanne Ulrich
Date of Approval: 15 Jul 2024

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

Date Issued: 16 Jul 2024
Place Issued: 65205 Wiesbaden, Germany

Supersedes: 16-Nov-2022
Effective (Date or Lot Number): 16 Jul 2024

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0762LE
Basic UDI-DI Name: Alinity i CEA
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P6220	Alinity i CEA Reagent Kit	54615	W0102030112
07P6230	Alinity i CEA Reagent Kit	54615	W0102030112
07P6201	Alinity i CEA Calibrators	38174	W0102152205
07P6210	Alinity i CEA Controls	38173	W0102152005

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland	
Manufacturer SRN	IE-MF-000009849	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo 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.** V12 001922 0024
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:	Noel Haren	Full Name:	John Lennon
Function:	Associate Director Regulatory Affairs	Function:	Director Quality Assurance
Signature:		Signature:	
Date of Approval:	18 Mar 2026	Date of Approval:	18 MAR 2026

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued:	18-MAR-2026	Place Issued:	Sligo, Ireland
Supersedes:	18 December 2024	Effective (Date or Lot Number):	18-MAR-2026

Abbott

Declaration of Conformity

Certificate Identification: DoC-08P06 -AII 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
08P0623	48366	Alinity i Anti-HCV Reagent Kit (2 x 100 Tests)	**Annex II List A**
08P0633	48366	Alinity i Anti-HCV Reagent Kit (2 x 500 Tests)	**Annex II List A**
08P0602	41972	Alinity i Anti-HCV Calibrator	**Annex II List A**
08P0611	41973	Alinity i Anti-HCV Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
Notified Body number	TÜV SÜD: 0123
Approval Certificate No.	TÜV SÜD: V7 010051 0112
Storage site of technical documentation (name and address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany.
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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C Becker

Full Name: **Claudia Becker**

Position: **Director Quality Systems**

Date of Approval: 28 Apr 2022

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 28/Apr/2022

Date Issued: 28-APRIL-2022

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 03-Aug-2021

Effective (Date or Lot Number): 28/Apr/2022.

Abbott

IVDD Declaration of Conformity Attribute Update Letter

Number: 1

List Number and Size Code	Name and Descriptions of Devices	GMDN Code
07P5020 07P5030	Alinity i Estradiol Reagent Kit	60979
07P5001	Alinity i Estradiol Calibrators	38249
07P5010	Alinity i Estradiol Controls	38248
07P5040	Alinity i Estradiol Manual Diluent	58237

Legal Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Authorized European Representative (Name and Address)	N/A
Storage Site of Technical Documentation (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.

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	07P50_Alinity_Estradiol_EU_DOC effective date 07Jan2021
Description of updated attributes from IVD Directive 98/79/EC Declaration of Conformity	Update to GMDN Code. GMDN Code 58208 was made obsolete by GMDN. This has been replaced with new GMDN Code 58237 for 07P5040 Alinity I Estradiol Manual Diluent.

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: David Spellman

Function: Director Quality Assurance/Site Quality Head

Signature:

Date of Approval: 21 Nov 2023

Date Issued: 21 Nov 2023

Full Name: Rosemary McEntire

Function: Manager Regulatory Affairs

Signature: R. McEntire

Date of Approval: 21 NOV 2023

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

Effective (Date or Lot Number): 21 Nov 2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0769LU
Basic UDI-DI Name: Free T3
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P6920 07P6930	Alinity Free T3 Reagent Kit	54417	W01020401
07P6901	Alinity Free T3 Calibrators	38261	W0102152208
07P6910	Alinity Free T3 Controls	54418	W0102152008

Manufacturer (Name and Address)	Abbott Ireland Diagnostic Division, Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-0000100700	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostic Division, Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜD SÜD Product Service GmbH, Ridlerstraβe 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: Gillian O'Sullivan
Function: Manager Quality Assurance
Signature: Gillian O'Sullivan
Date of Approval: 02-Jul-2025

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R McEntire
Date of Approval: 02 Jul 2025

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

Date Issued: 02-Jul-2025
Supersedes: 21 Dec 2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 02-Jul-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0770LD
Basic UDI-DI Name: Free T4
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P7020 07P7030	Alinity i Free T4 Reagent Kit	54413	W01020402
07P7001	Alinity i Free T4 Calibrators	38259	W0102152208
07P7010	Alinity i Free T4 Controls	38258	W0102152008

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)		

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: Joe Murray
Function: Director Quality/Site Quality Head
Signature: Joe Murray
Date of Approval: 10 Mar 2026

Full Name: Rosemary McEntire
Function: Associate Director Regulatory Affairs
Signature: R. McEntire
Date of Approval: 10 Mar 2026

Signed for, and on behalf of: Abbott Ireland Diagnostic Division Lisnamuck, Longford Co. Longford Ireland
Date Issued: 10 Mar 2026
Supersedes: 07 Nov 2024

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 10 Mar 2026

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0749LN
Basic UDI-DI Name: FSH
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P4920 07P4930	Alinity i FSH Reagent Kit	54187	W0102050104
07P4901	Alinity i FSH Calibrators	38255	W0102152208
07P4910	Alinity i FSH Controls	38254	W0102152008

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: Joe Murray
Function: Director Quality/Site Quality Head
Signature: Joe Murray
Date of Approval: 10 Dec 2025

Full Name: Rosemary McEntire
Function: Associate Director Regulatory Affairs
Signature: R McEntire
Date of Approval: 10 Dec 2025

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland
Date Issued: 10 Dec 2025
Supersedes: 03 April 2024
Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 10 Dec 2025

Abbott

Declaration of Conformity

Certificate Identification:	DoC-08P10-AIDD Sligo
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08P1022	48321	Alinity i HBsAg Qualitative II Reagent Kit	**Annex II List A**
08P1032	48321	Alinity i HBsAg Qualitative II Reagent Kit	**Annex II List A**
08P1001	41999	Alinity i HBsAg Qualitative II Calibrators	**Annex II List A**
08P1010	42000	Alinity i HBsAg Qualitative II Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V7 0019220015
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:	Joe Murray	Signature:	Noel Haren
Full Name:	Joe Murray	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	17 Jun 2021	Date of Approval:	17 Jun 2021
Date Issued:	17 Jun 2021	Place Issued:	AIDD, Sligo
Supersedes:	12 Oct 2020	Effective (Date or Lot Number):	17 Jun 2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-08P08-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08P0822	48321	Alinity i HBsAg Reagent Kit	**Annex II List A**
08P0832	48321	Alinity i HBsAg Reagent Kit	**Annex II List A**
08P0852	48321	Alinity i HBsAg Reagent Kit	**Annex II List A**
08P0857	48321	Alinity i HBsAg Reagent Kit	**Annex II List A**
08P0801	41999	Alinity i HBsAg Calibrators	**Annex II List A**
08P0810	42000	Alinity i HBsAg Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V7 001922 0014
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:	Joe Murray	Signature:	
Full Name:	Joe Murray	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	25 May 2022	Date of Approval:	25 May 2022
Date Issued:	25 May 2022	Place Issued:	AIDD, Sligo
Supersedes:	25 Nov 2019	Effective (Date or Lot Number):	25 May 2022

Abbott

EU Declaration of Conformity

Basic UDI-DI:	038074AIT0475ML
Basic UDI-DI Name:	Alinity i Insulin
Risk Class:	Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T7520	Alinity i Insulin Reagent Kit	54237	W0102060103
04T7501	Alinity i Insulin Calibrators	42091	W0102152202
04T7510	Alinity i Insulin Controls	42092	W0102152002

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)	**Head Office**: Denka Co., Ltd. Head Office 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo, 103-8338 Japan **Kagamida Factory**: Denka Co., Ltd. 1359-1 Kagamida, Kigoshi, Gosen-shi, Niigata, 959-1695 Japan	
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 0100510137**
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:	C. Becker	Signature:	Bridget Norton
Date of Approval:	21 Aug 2025	Date of Approval:	21 Aug 2025
Signed for, and on behalf of:	Abbott GmbH, Wiesbaden, Germany		
Date Issued:	21 Aug 2025	Place Issued:	65205 Wiesbaden, Germany
Supersedes:	08-Aug-2024	Effective (Date or Lot Number):	21 Aug 2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0791LM
Basic UDI-DI Name: LH
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P9120 07P9130	Alinity i LH Reagent Kit	54254	W0102050105
07P9101	Alinity i LH Calibrators	38270	W0102152208

Manufacturer (Name and Address)	Abbott Ireland Diagnostic Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-0000100700	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostic Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜD 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)		

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: 29-Aug-2025

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R McEntire
Date of Approval: 28 August 2025

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

Date Issued: 29-Aug-2025
Supersedes: 07 FEB 2024

Place Issued: Lisnamuck, Longford, Co. Longford Ireland
Effective (Date or Lot Number): 29-Aug-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0836LJ
Basic UDI-DI Name: Progesterone
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P3620 08P3630	Alinity i Progesterone Reagent Kit	54322	W0102050106
08P3601	Alinity i Progesterone Calibrators	54325	W0102152208
08P3610	Alinity i Progesterone Controls	54326	W0102152008
08P3640	Alinity i Progesterone Manual Diluent	58237	W01029003

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: 07 JUNE 2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 31-MAY-2024

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

Date Issued: 07 JUNE 2024
Place Issued: Lisnamuck, Longford, Co. Longford, Ireland

Supersedes: 30 November 2023
Effective (Date or Lot Number): 07 JUNE 2024

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0766LN
Basic UDI-DI Name: Prolactin
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P6620 07P6630	Alinity i Prolactin Reagent Kit	54335	W0102050108
07P6601	Alinity i Prolactin Calibrators	54337	W0102152208
07P6610	Alinity i Prolactin Controls	54338	W0102152008

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: 30 SEP 2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 27-SEP-2024

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

Date Issued: 30 SEP 2024
Supersedes: 29 June 2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 30 SEP 2024

Abbott

EU Declaration of Conformity

Basic UDI-DI:	038074AIP0768LS
Basic UDI-DI Name:	Alinity i 2nd Generation Testosterone
Risk Class:	Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P6822	Alinity i 2nd Generation Testosterone Reagent Kit	61077	W0102050110
07P6832	Alinity i 2nd Generation Testosterone Reagent Kit	61077	W0102050110
07P6801	Alinity i 2nd Generation Testosterone Calibrators	58381	W0102152202
07P6810	Alinity i 2nd Generation Testosterone Controls	58380	W0102152002

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)	Axis-Shield Diagnostics Ltd, Luna Place, The Technology Park, Dundee DD2 1XA, UK	
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 0100510137**
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:	Susanne Ulrich
Function:	Director Quality Assurance	Function:	Associate Director Regulatory Affairs
Signature:	C. Becker	Signature:	Susanne Ulrich
Date of Approval:	04 Jul 2024	Date of Approval:	04 Jul 2024
Signed for, and on behalf of:	Abbott GmbH, Wiesbaden, Germany		
Date Issued:	04-Jul-2024	Place Issued:	65205 Wiesbaden, Germany
Supersedes:	11-Apr-2023	Effective (Date or Lot Number):	04-Jul-2024

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0792LP
Basic UDI-DI Name: Alinity i Total PSA
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P9220	Alinity i Total PSA Reagent Kit	54665	W0102030113
07P9230	Alinity i Total PSA Reagent Kit	54665	W0102030113
07P9201	Alinity i Total PSA Calibrators	38208	W0102152205
07P9210	Alinity i Total PSA Controls	38207	W0102152005

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland	
Manufacturer SRN	IE-MF-000009849	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park Sligo 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.** V12 001922 0024
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: Noel Haren
Function: Associate Director Regulatory Affairs
Signature: [signature]
Date of Approval: 20 Jan 2026

Full Name: John Lennon
Function: Director Quality Assurance
Signature: [signature]
Date of Approval: 19 - JAN - 2026

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued: 20 Jan 2026

Place Issued: Sligo, Ireland

Supersedes: 08 March 2023

Effective (Date or Lot Number): 20 Jan 2026

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0794LT
Basic UDI-DI Name: Total T3
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P9420 07P9430	Alinity i Total T3 Reagent Kit	58330	W01020405
07P9401	Alinity i Total T3 Calibrators	58333	W0102152208
07P9440	Alinity i Total T3 Manual Diluent	58237	W01029003

Manufacturer (Name and Address)	Abbott Ireland Diagnostic Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-0000100700	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostic Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraβe 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: Joe Murray
Function: Director Quality/Site Quality Head
Signature: Joe Murray
Date of Approval: 29 Oct 2025

Full Name: Rosemary McEntire
Function: Associate Director Regulatory Affairs
Signature: R. McEntire
Date of Approval: 29 Oct 2025

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

Date Issued: 29 Oct 2025
Supersedes: 21 Dec 2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 29 Oct 2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0795LV
Basic UDI-DI Name: Total T4
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P9520 07P9530	Alinity i Total T4 Reagent Kit	58322	W01020407
07P9501	Alinity i Total T4 Calibrators	58324	W0102152208
07P9510	Alinity i Total T4 Controls	58325	W0102152008

Manufacturer (Name and Address)	Abbott Ireland Diagnostic Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-0000100700	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostic 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: Joe Murray
Function: Director Quality/Site Quality Head
Signature: Joe Murray
Date of Approval: 06 Nov 2025

Full Name: Rosemary McEntire
Function: Associate Director Regulatory Affairs
Signature: R McEntire
Date of Approval: 06 Nov 2025

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

Date Issued: 06 Nov 2025
Supersedes: 05-July-2024

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 06 Nov 2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0748LL
Basic UDI-DI Name: Alinity i TSH
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P4820 07P4830	Alinity i TSH Reagent Kit	54386	W01020410
07P4801	Alinity i TSH Calibrators	38272	W0102152202
07P4810	Alinity i TSH Controls	38271	W0102152002

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
Function: Director Quality Assurance/Site Quality Head
Signature:
Date of Approval: 26 Oct 2023

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 20-OCT-2023

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

Date Issued: 26 Oct 2023
Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Supersedes: 30-Aug-2022
Effective (Date or Lot Number): 26 Oct 2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0787LW

Basic UDI-DI Name: Alinity i Anti-HBc II

Risk Class: Class D

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P8722	Alinity i Anti-HBc II Reagent Kit	48304	W0105020208
07P8732	Alinity i Anti-HBc II Reagent Kit	48304	W0105020208
07P8701	Alinity i Anti-HBc II Calibrator	41983	W0105080902
07P8710	Alinity i Anti-HBc II Controls	41984	W0105080802

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)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
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	**EU Certificate No.** **V10 010051 0150**
	Technical Documentation Assessment Annex IX Chapter II	**EU Certificate No.** **V70 010051 0163**
Common Specifications (CS)	COMMISSION IMPLEMENTING REGULATION (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council.	

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: 24 Jun 2025

Full Name: Bridget Norton

Function: Assoc. Director Regulatory Affairs

Signature: Bridget Norton

Date of Approval: 24/June/2025

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

Date Issued: 24 Jun 2025

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 02-Aug-2024

Effective (Date or Lot Number): 24 Jun 2025

Abbott

Declaration of Conformity

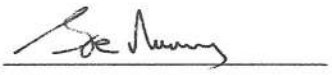
Certificate Identification: DoC-07P89-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P8922	48316	Alinity i Anti-HBs Reagent Kit	**Annex II List A**
07P8932	48316	Alinity i Anti-HBs Reagent Kit	**Annex II List A**
07P8952	48316	Alinity i Anti-HBs Reagent Kit	**Annex II List A**
07P8957	48316	Alinity i Anti-HBs Reagent Kit	**Annex II List A**
07P8901	41997	Alinity i Anti-HBs Calibrators	**Annex II List A**
07P8910	41998	Alinity i Anti-HBs Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V7 001922 0013
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:		Signature:	
Full Name:	Joe Murray	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	17 Feb 2022	Date of Approval:	22 Feb 2022
Date Issued:	22 Feb 2022	Place Issued:	AIDD, Sligo
Supersedes:	12 November 2021	Effective (Date or Lot Number):	22 Feb 2022

Abbott

Declaration of Conformity

Certificate Identification: DoC-07P42-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P4222	49713	Alinity i CMV IgG Reagent Kit	**Annex II List B**
07P4232	49713	Alinity i CMV IgG Reagent Kit	**Annex II List B**
07P4201	49716	Alinity i CMV IgG Calibrators	**Annex II List B**
07P4210	49717	Alinity i CMV IgG Controls	**Annex II List B**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V1 0019220008
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:	N. WALSH	Signature:	
Full Name:	Joe Murray	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	25 NOV 19	Date of Approval:	25 Nov 2019
Date Issued:	25 NOV 2019	Place Issued:	AIDD, Sligo
Supersedes:	16 October 2019	Effective (Date or Lot Number):	25 Nov 2019

xREF attached delegation memo 25/NOV/19

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0744LC
Basic UDI-DI Name: Alinity i CMV IgM
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P4422	Alinity i CMV IgM Reagent Kit	49724	W0105040204
07P4432	Alinity i CMV IgM Reagent Kit	49724	W0105040204
07P4401	Alinity i CMV IgM Calibrator	49727	W0105080904
07P4410	Alinity i CMV IgM Controls	38294	W0105080804

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland	
Manufacturer SRN	IE-MF-000009849	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo 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.** V12 001922 0024
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:	Noel Haren	Full Name:	John Lennon
Function:	Associate Director Regulatory A ffairs	Function:	Director Quality Assurance
Signature:		Signature:	
Date of Approval:	12 Feb 2026	Date of Approval:	12-Feb-2026

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued:	12-Feb-2026	Place Issued:	Sligo, Ireland
Supersedes:	30 July 2025	Effective (Date or Lot Number):	12-Feb-2026

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0745LE
Basic UDI-DI Name: Alinity i Toxo IgG
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P4522	Alinity i Toxo IgG Reagent Kit	52438	W0105050102
07P4532	Alinity i Toxo IgG Reagent Kit	52438	W0105050102
07P4501	Alinity i Toxo IgG Calibrators	42166	W0105080905
07P4510	Alinity i Toxo IgG Controls	42167	W0105080805

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)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
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
Function: Director Quality Assurance
Signature: C. Becker
Date of Approval: 01 Sep 2025

Full Name: Susanne Ulrich
Function: Assoc. Director Regulatory Affairs
Signature: Susanne Ulrich
Date of Approval: 28/Aug/2025

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

Date Issued: 01 Sep 2025
Place Issued: 65205 Wiesbaden, Germany

Supersedes: 29-Nov-2023
Effective (Date or Lot Number): 01 Sep 2025

Abbott

EU Declaration of Conformity

Basic UDI-DI:	038074AIP0747LJ
Basic UDI-DI Name:	Alinity i Toxo IgM
Risk Class:	Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P4722	Alinity i Toxo IgM Reagent Kit	52442	W0105050103
07P4732	Alinity i Toxo IgM Reagent Kit	52442	W0105050103
07P4701	Alinity i Toxo IgM Calibrator	42163	W0105080905
07P4710	Alinity i Toxo IgM Controls	42164	W0105080805

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)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
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:	Lisa-Marie Herzig	Full Name:	Ursula Koehl
Function:	Manager Quality Systems	Function:	Senior Manager Regulatory Affairs
Signature:	L. Herzig	Signature:	U. Koehl
Date of Approval:	2025-11-11	Date of Approval:	11-Nov-2025
Signed for, and on behalf of:	Abbott GmbH, Wiesbaden, Germany		
Date Issued:	11-Nov-2025	Place Issued:	65205 Wiesbaden, Germany
Supersedes:	30-April 2024	Effective (Date or Lot Number):	11-Nov-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074AIP0814L8
Basic UDI-DI Name: Folate
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P1422 08P1432	Alinity i Folate Reagent Kit	60982	W0102070103
08P1440	Alinity i Folate RBC Lysis Diluent	54455	W01029003
08P1460	Alinity i Folate Manual Diluent	58237	W01029003
08P1401	Alinity i Folate Calibrators	41931	W0102152206
08P1410	Alinity i Folate Controls	41932	W0102152006
08P1542	Alinity i Folate Lysis Reagent	54455	W01029003

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:	S. Gallagher
Date of Approval:	23 JAN 2024	Date of Approval:	19-JAN-2024

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

Date Issued:	23 JAN 2024	Place Issued:	Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	30 Nov 2022	Effective (Date or Lot Number):	23 JAN 2024

TECHNOPATH
CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY

Manufacturer
Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Category	Catalogue Number
Multichem IA Plus	Assayed/tri-level	08P86-10

GMDN:	47869
Classification:	Annex II List B
Conformity Route:	Annex IV
Quality Management System:	EN ISO 13485:2016
QMS/CE Certification No.:	V11038520001
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	26 May 2024
Notified Body Number:	0123

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 31 **(Day)** 01 **(Month)** 20 **(Year)**

Signed for and on behalf of Techno-path Manufacturing Ltd.,

B Hass

Bernd Hass,
VP of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

Ballina, Co.Tipperary 31-01-20
Place and Date of Issue

TECHNOPATH
CLINICAL DIAGNOSTICS

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
SOR/98-282, May 7, 1998	Canada Medical Device Regulations

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074SLI0001T3
Basic UDI-DI Name: Alinity i-series Concentrated Wash Buffer
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
06P1368	Alinity i-series Concentrated Wash Buffer	58236	W0201020185

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Manufacturer SRN	IE-MF-000009849
Authorized Representative (Name and Address)	N/A
Authorized Representative SRN	N/A
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Conformity Assessment Procedure	**Annex II and III**

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: Noel Haren
Function: Manager Regulatory Affairs
Signature: N. Haren
Date of Approval: 15 Jul 2022

Full Name: Joe Murray
Function: Director Quality Assurance
Signature: Joe Murray
Date of Approval: 15 Jul 2022

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued: 15 Jul 2022
Supersedes: 23 May 2022

Place Issued: Sligo, Ireland
Effective (Date or Lot Number): 15 Jul 2022

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074SLI0001T3
Basic UDI-DI Name: Alinity Pre-Trigger Solution
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
06P1270	Alinity Pre-Trigger Solution	61163	W0201020185

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Manufacturer SRN	IE-MF-000009849
Authorized Representative (Name and Address)	N/A
Authorized Representative SRN	N/A
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Conformity Assessment Procedure	**Annex II and III**

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: Noel Haren
Function: Manager Regulatory Affairs
Signature: N. Haren
Date of Approval: 15 Jul 2022

Full Name: Joe Murray
Function: Director Quality Assurance
Signature: Joe Murray
Date of Approval: 15 Jul 2022

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued: 15 Jul 2022
Supersedes: 23 May 2022

Place Issued: Sligo, Ireland
Effective (Date or Lot Number): 15 Jul 2022

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074SLI0001T3
Basic UDI-DI Name: Alinity i-series Probe Conditioning Solution
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
01R5840	Alinity i-series Probe Conditioning Solution	59058	W0201020185

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Manufacturer SRN	IE-MF-000009849
Authorized Representative (Name and Address)	N/A
Authorized Representative SRN	N/A
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Conformity Assessment Procedure	**Annex II and III**

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: Noel Haren
Function: Manager Regulatory Affairs
Signature:
Date of Approval: 15 Jul 2022

Full Name: Joe Murray
Function: Director Quality Assurance
Signature:
Date of Approval: 15 Jul 2022

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued: 15 Jul 2022
Supersedes: 23 May 2022

Place Issued: Sligo, Ireland
Effective (Date or Lot Number): 15 Jul 2022

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0003FS
Basic UDI-DI Name: Alinity Reaction Vessels
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
06P1401	Alinity Reaction Vessels	56676	W0201020185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Abbott Laboratories Abbott Park, Illinois 60064 USA
Conformity Assessment Procedure	**Annex II and III**

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 and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states. **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: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 18-July-2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 18-July-2025

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Dr. Irving, TX 75038 USA

Date Issued: 18-July-2025
Supersedes: 17 Nov, 2022

Place Issued: Abbott Laboratories 1915 Hurd Drive, Irving, TX 75038
Effective (Date or Lot Number): 18-July-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074SLI0001T3
Basic UDI-DI Name: Alinity Trigger Solution
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
06P1170	Alinity Trigger Solution	58793	W0201020185

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Manufacturer SRN	IE-MF-000009849
Authorized Representative (Name and Address)	N/A
Authorized Representative SRN	N/A
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Conformity Assessment Procedure	**Annex II and III**

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: Noel Haren
Function: Manager Regulatory Affairs
Signature: N. Hen
Date of Approval: 15 Jul 2022

Full Name: Joe Murray
Function: Director Quality Assurance
Signature: Joe Murray
Date of Approval: 15 Jul 2022

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued: 15 Jul 2022
Supersedes: 23 May 2022

Place Issued: Sligo, Ireland
Effective (Date or Lot Number): 15 Jul 2022

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0003FS
Basic UDI-DI Name: Alinity ci-series Sample Cups
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
01R3801	Alinity ci-series Sample Cups	56676	W0201020185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Nypro Chicago 955 Tri-State Parkway Gurnee, IL 60031 USA
Conformity Assessment Procedure	**Annex II and III**

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 and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states. **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: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 18-July-2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 19-July-2025

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Dr. Irving TX 75038 USA
Date Issued: 18-July-2025
Supersedes: 17 Nov, 2022

Place Issued: Abbott Laboratories 1915 Hurd Drive, Irving, TX 75038
Effective (Date or Lot Number): 19-July-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0003FS
Basic UDI-DI Name: Alinity Reagent Replacement Caps
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04R4701 Caps	Alinity Reagent Replacement Caps	**56676**	**W0201020185**

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Abbott Laboratories Abbott Park, Illinois 60064 USA
Conformity Assessment Procedure	**Annex II and III**

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 and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states. **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: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 18-July-2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 18-July-2025

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Dr. Irving, TX 75038 USA
Date Issued: 18-July-2025
17 Nov, 2022
Supersedes:

Place Issued: Abbott Laboratories 1915 Hurd Drive, Irving, TX 75038
Effective (Date or Lot Number): 18-July-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0003FS
Basic UDI-DI Name: Alinity ci-series Calibrator/Control Replacement Caps
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04R1001	Alinity ci-series Calibrator/Control Replacement Caps	56676	W0201020185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Abbott Laboratories Abbott Park, IL 60064 USA
Conformity Assessment Procedure	**Annex II and III**

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; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 17 Nov 2022

Full Name: Amanda Peoples
Function: Project Manager, Regulatory Affairs
Signature: Amanda Peoples
Date of Approval: 17 Nov 2022

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038 USA

Date Issued: 15-Nov-2022
Supersedes: 02 September 2022

Place Issued: Irving, Texas
Effective (Date or Lot Number): 17-Nov-2022