Abbott

Declaration of Conformity

Certificate Identification: DOC-07P90-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
07P9020	58348	Alinity i AFP Reagent Kit	**Self-declared**
07P9030	58348	Alinity i AFP Reagent Kit	**Self-declared**
07P9010	54063	Alinity i AFP Controls	**Self-declared**
07P9001	54062	Alinity i AFP Calibrators	**Self-declared**

Authorized European Representative (name and address)	N/A
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 III 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:	27 Sep 19	Date of Approval:	26 Sept 2019
Date Issued:	27 SEP 2019	Place Issued:	AIDD, Sligo
Supersedes:	27 Nov 2017	Effective (Date or Lot Number):	27 SEP 2019

Digitally signed by Ceaicovschi Tudor
Date: 2025.12.13 09:35:09 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA
EUROPEANĂ

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-00009849	
Authorized Representative (Name and Address)	Not Applicable	
Authorized Representative SRN	Not Applicable	
Produced by (Site of Manufacture) (Name and Address)	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
Function: Associate Director Regulatory Affairs
Signature:
Date of Approval: 23 OCT 2024

Full Name: Joe Murray
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 23 Oct 2024

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

Date Issued: 23 OCT 2024
Supersedes: 28 September 2021

Place Issued: Sligo Ireland
Effective (Date or Lot Number): 23 OCT 2024

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	

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: 038074AIP0851LE
Basic UDI-DI Name: Alinity i CA 15-3
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P5120	Alinity i CA 15-3 Reagent Kit (2 x 100 Tests)	60975	W0102030102
08P5130	Alinity i CA 15-3 Reagent Kit (2 x 500 Tests)	60975	W0102030102
08P5101	Alinity i CA 15-3 Calibrators	38223	W0102152205
08P5110	Alinity i CA 15-3 Controls	38222	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 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: 06 Jun 2024

Full Name: Susanne Ulrich
Function: Assoc. Director Regulatory Affairs
Signature: Susanne Ulrich
Date of Approval: 05/Jun/2024

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

Date Issued: 06 Jun 2024
Place Issued: 65205 Wiesbaden, Germany

Supersedes: 04-Jul-2023
Effective (Date or Lot Number): 06 Jun 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	Full Name:	Susanne Ulrich
Function:	Director Quality Assurance	Function:	Assoc. Director Regulatory Affairs
Signature:	C. Becker	Signature:	Susanne Ulrich
Date of Approval:	16 Jul 2024	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

Declaration of Conformity

Certificate Identification: DOC-07P62-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
07P6220	54615	Alinity i CEA Reagent Kit	**Self-declared**
07P6230	54615	Alinity i CEA Reagent Kit	**Self-declared**
07P6210	38173	Alinity i CEA Controls	**Self-declared**
07P6201	38174	Alinity i CEA Calibrators	**Self-declared**

Authorized European Representative (name and address)	N/A
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 III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Joe Murray	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	30 Apr 18	Date of Approval:	27 April 2018
Date Issued:	30 Apr 18	Place Issued:	AIDD, Sligo
Supersedes:	11 Jan 2017	Effective (Date or Lot Number):	30 Apr 18

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

Declaration of Conformity

Certificate Identification: DOC_08P33_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
08P3320	54125	Alinity i Cortisol Reagent Kit	**Self-declared**
08P3330	54125	Alinity i Cortisol Reagent Kit	**Self-declared**
08P3301	54126	Alinity i Cortisol Calibrators	**Self-declared**

Authorized European Representative (name and address)	NA
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland and Fisher Diagnostics, A Div. of Fisher Scientific Company, LLC A Part of Thermo Fisher Scientific, Inc. 8365 Valley Pike, Middletown VA 22645 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:		Signature:	
Full Name:	Joe Murray	Full Name:	Noel Haren
Position:	Director, Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	17 May 19	Date of Approval:	15 May 2019
Date Issued:	17 MAY 2019	Place Issued:	AIDD, Sligo
Supersedes:	12 Jul 2018	Effective (Date or Lot Number:)	17 MAY 2019

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

Declaration of Conformity

Certificate Identification:	07P50
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
07P5020 07P5030	60979	Alinity i Estradiol Reagent Kit	**Self-declared**
07P5001	38249	Alinity i Estradiol Calibrators	**Self-declared**
07P5010	38248	Alinity i Estradiol Controls	**Self-declared**
07P5040	58208	Alinity i Estradiol Manual Diluent	**Self-declared**

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.
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:	**Director Regulatory Affairs**
Date of Approval:	07-JAN-2021	Date of Approval:	07 JAN 2021
Date Issued:	07-JAN-2021	Place Issued	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes	06 June 2019	Effective (Lot number or date)	07-JAN-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-07P65-AIDD Longford
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
07P6520	61078	Alinity i Ferritin Reagent Kit	**Self-declared**
07P6530	61078	Alinity i Ferritin Reagent Kit	**Self-declared**
07P6501	41927	Alinity i Ferritin Calibrators	**Self-declared**
07P6510	41928	Alinity i Ferritin Controls	**Self-declared**

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 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 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:	17-DEC-18	Date of Approval:	17 DEC 18
Date Issued:	17 Dec 2018	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	31 Dec 2016	Effective (Date or Lot Number):	17 DEC 18

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

Abbott

Declaration of Conformity

Certificate Identification: DoC-07P93-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
07P9320	54669	Alinity i Free PSA Reagent Kit	**Annex II List B**
07P9330	54669	Alinity i Free PSA Reagent Kit	**Annex II List B**
07P9301	38183	Alinity i Free PSA Calibrators	**Annex II List B**
07P9310	38182	Alinity i Free PSA 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:	1 N. WALSH	Signature:	
Full Name:	1 Joe Murray	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	26/Nov/19	Date of Approval:	25 Nov 2019
Date Issued:	26 Nov 2019	Place Issued:	AIDD, Sligo
Supersedes:	16 Oct 2019	Effective (Date or Lot Number):	26 Nov 2019

1 Ref attached delegation
26/Nov/19

Abbott

Declaration of Conformity

Certificate Identification: 07P69
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
07P6920 07P6930	54417	Alinity i Free T3 Reagent Kit	**Self-declared**
07P6901	38261	Alinity i Free T3 Calibrators	**Self-declared**
07P6910	54418	Alinity i Free T3 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:	01-MAY-2020	Date of Approval:	01 MAY 2020
Date Issued:	01-MAY-2020	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	24 April 2019	Effective (Date or Lot Number):	01-MAY-2020

Abbott

Declaration of Conformity

Certificate Identification: 07P70
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
07P7020 07P7030	54413	Alinity i Free T4 Reagent Kit	**Self-declared**
07P7001	38259	Alinity i Free T4 Calibrators	**Self-declared**
07P7010	38258	Alinity i Free T4 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:	02-Jun-2017	Effective (Date or Lot Number):	24-APR-19

Abbott

Declaration of Conformity

Certificate Identification: 07P49
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
07P4920 07P4930	54187	Alinity i FSH Reagent Kit	**Self-declared**
07P4901	38255	Alinity i FSH Calibrators	**Self-declared**
07P4910	38254	Alinity i FSH 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:	29-Nov-2017	Effective (Date or Lot Number):	24-APR-19

Abbott

Declaration of Conformity

Certificate Identification: DoC-07P87 -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
07P8722	48304	Alinity i Anti-HBc II Reagent Kit (2 x 100 Tests)	**Annex II List A**
07P8732	48304	Alinity i Anti-HBc II Reagent Kit (2 x 600 Tests)	**Annex II List A**
07P8701	41983	Alinity i Anti-HBc II Calibrator	**Annex II List A**
07P8710	41984	Alinity i Anti-HBc 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	TÜV SÜD: 0123
Approval Certificate No.	TÜV SÜD: V7 010051 0111
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 Assurance**
Date of Approval: 06 May 2021

Signature: Susanne Ulrich
Full Name: **Susanne Ulrich**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 04/May/2021
Date Issued: 06-May-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2020
Effective (Date or Lot Number): 06-May-2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-07P64-09P10-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
07P6422	48331	Alinity i HBeAg Reagent Kit (2 x 100 Tests)	**Annex II List A**
07P6432	48331	Alinity i HBeAg Reagent Kit (2 x 500 Tests)	**Annex II List A**
07P6401	42007	Alinity i HBeAg Calibrators	**Annex II List A**
07P6410	42008	Alinity i HBeAg Controls	**Annex II List A**
09P1001	42007	Alinity i HBeAg Quantitative Calibrators	**Annex II List A**
09P1010	42008	Alinity i HBeAg Quantitative 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 0109
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 Assurance**
Date of Approval: 14 Jun 2021

Signature: S. Veber
Full Name: **Stefan Veber**
Position: **Manager Regulatory Affairs**
Date of Approval: 2021-06-14
Date Issued: 14-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 14-Feb-2020
Effective (Date or Lot Number): 14-Jun-2021

Abbott

Declaration of Conformity

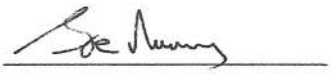
Certificate Identification: DoC-07P89-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

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-07P8942-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
07P8942	48316	Alinity i Anti-HBs Specimen Diluent	**Self-declared**

Authorized European Representative (name and address)	N/A
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 III 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:	19 July 2018	Effective (Date or Lot Number):	22 Feb 2022

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