Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARU0445RB
Basic UDI-DI Name: Albumin BCP2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U4520	Albumin BCP2	59071	W01010201
04U4530	Albumin BCP2	59071	W01010201

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: 10 SEP 2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 09-SEP-2024.

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

Date Issued: 10 SEP 2024
Supersedes: 18-May-2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 10 SEP 2024

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARS0487R5
Basic UDI-DI Name: Alkaline Phosphatase2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04S8720	Alkaline Phosphatase2	52929	W01010105
04S8730	Alkaline Phosphatase2	52929	W01010105

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 Zertifizierstellen, 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 054869/0015
Common Specifications (CS)	N/A	

Digitally signed by Ceaicovschi Tudor
Date: 2025.12.11 15:14:10 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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: Siobhan Wright
Function: Director Quality Assurance/Site Quality Head
Signature: Siobhan Wright
Date of Approval: 16-DEC-2021

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 16-DEC-2021

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

Date Issued: 16-DEC-2021
Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Supersedes: N/A
Effective (Date or Lot Number): 16-DEC-2021

ABBOTT

Declaration of Conformity

Certificate Identification: 04S88
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
04S8820	52925	Alanine Aminotransferase2	**Self-declared**
04S8830	52925	Alanine Aminotransferase2	**Self-declared**

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

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

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

Signature:	Siobhan Wright	Signature:	
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Thomas Breslin**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Manager Regulatory Affairs**
Date of Approval:	17-SEP-2021	Date of Approval:	17-SEP-2021
Date Issued:	17-SEP-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	*Effective Date:*	17-SEP-2021

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARS0489R9
Basic UDI-DI Name: Amylase2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04S8920	Amylase2	52940	W01010107

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.** 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: John Lennon
Function: Quality Manager
Signature: John Lennon
Date of Approval: 18-June-2025

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 18-JUNE-2025

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

Date Issued: 18-June-2025
Supersedes: 19 Feb 2024

Place Issued: Lisnamuck, Longford, Co. Longford Ireland
Effective (Date or Lot Number): 18-June-2025

ABBOTT

Declaration of Conformity

Certificate Identification: 04S90
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
04S9020	52954	Aspartate Aminotransferase2	**Self-declared**
04S9030	52954	Aspartate Aminotransferase2	**Self-declared**

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

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

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

Signature:	Siobhan Wright	Signature:	
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Thomas Breslin**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Manager Regulatory Affairs**
Date of Approval:	17-SEP-2021	Date of Approval:	17-SEP-2021
Date Issued:	17-SEP-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	17-SEP-2021

ABBOTT

Declaration of Conformity

Certificate Identification: 07K61
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
7K61-25 7K61-35	60779	ARCHITECT B12 Reagent Kit	**Self-declared**
7K61-01	41337	ARCHITECT B12 Calibrators	**Self-declared**
7K61-10	41338	ARCHITECT 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 and transposed Irish Regulation S.I. No 304 of 2001 and to the EC Directive 98/79/EC as it is 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
Full Name: **Siobhan Wright**
Position: **Director Quality Assurance/Site Quality Head**
Date of Approval: 24-APR-19
Date Issued: 24-APR-19
Supersedes: 12 OCT 2018

Signature: Lorraine Whitney
Full Name: **Lorraine Whitney**
Position: **Senior Manager Regulatory Affairs/**
Date of Approval: 19 APR 2019
Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 24-APR-19

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARS0491QU
Basic UDI-DI Name: Calcium2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04S9120	Calcium2	45789	W01010303
04S9130	Calcium2	45789	W01010303

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: John Lennon
Function: Quality Manager
Signature: John Lennon +
Date of Approval: 27-May-2024

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. McEntire
Date of Approval: 27 May 2024.

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

Date Issued: 27-May-2024
Supersedes: N/A

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 27 May 2024

+ Refer to QA Director Delegation
John Lennon
John Lennon
27-May-2024

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

For *in vitro* diagnostic medical devices (IVD) – Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy – Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry and immunochemistry, coagulation and rapid tests for immunology and serology" declares, under its own responsibility that the below listed devices comply with all essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (Legislative Decree nr. 322/2000).

It therefore declares and assures, under its own responsibility, that the devices:

1. comply with the applicable provisions of the Directive
2. are not included in the list A and B of Annex II of the Directive
3. are designed, manufactured and placed on the market according to the company certified quality system, in compliance with ISO 9001 and ISO 13485 as per indication expressed in Annex III of the Directive.

DICHIARAZIONE DI CONFORMITÀ CE

per dispositivi medico diagnostici *in vitro* IVD) – Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia – Via Robert Koch 2, fabbricante dei dispositivi appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che i dispositivi sotto elencati soddisfano i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che i dispositivi:

1. soddisfano le disposizioni applicabili della Direttiva
2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
3. sono progettati, fabbricati ed immessi in commercio nell'ambito dell'applicazione di un sistema di qualità aziendale dichiarato conforme e certificato secondo le norme ISO 9001 e ISO 13485 come descritto dall'Allegato III della Direttiva.

Code/Codice	Product Description/Nome prodotto
6K26-30	CRP Vario
6K26-41	CRP Vario
6K26-10	CRP Calibrator Set
6K26-12	CRP Calibrator WR
6K26-14	CRP Calibrator HS
6K26-21	CRP Control HS
6K89-30	Ammonia Ultra
6K91-30	Ceruloplasmin
4P79-30	UIBC Liquid
8L24-31	Creatinine (Enzymatic)
8L24-41	Creatinine (Enzymatic)
8L25-30	Lithium
6K89-20	Ammonia Controls
6K30-10	Clin Chem Cal
6K31-10	Plasmaproteins Cal 3x
1P93-30	Cystatin C
1P93-10	Cystatin C Calibrator

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

SENTINEL
DIAGNOSTICS

Code/Codice	Product Description/Nome prodotto
1P93-20	Cystatin C Control Set
6K25-10	CK-MB Calibrator
6K25-20	CK-MB Control
6K30-20	Clin Chem Control 1
6K30-21	Clin Chem Control 2
6K32-20	Immuno Control 1
6K32-21	Immuno Control 2
6K32-22	Immuno Control Set
6K90-20	Bile Acids Controls
6K98-10	Fructosamine Control 1
6K98-20	Fructosamine Control 2
4P80-30	Lambda Light Chains
6K24-30	Cholinesterase
6K25-30	CK-MB
6K22-30	Pancreatic Amylase
6K96-30	Kappa Light Chains
6K23-30	HBDH
6K90-30	Bile Acids
6K92-30	Dibucaine CHE
6K93-30	Copper
6K94-30	Fructosamine
6K95-30	Iron
6K95-41	Iron

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten (10) years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione delle Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo almeno di dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel Ch. SpA
A Legal Representative
Un Legale Rappresentante
Dr. Filippo De Luca

Date/Data
19/06/2015

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARS0492QW
Basic UDI-DI Name: Cholesterol2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04S9220	Cholesterol2	53359	W01010205
04S9230	Cholesterol2	53359	W01010205

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: 31 OCT 2024

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. McEntire
Date of Approval: 31 Oct 2024

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

Date Issued: 31 OCT 2024
Place Issued: Lisnamuck, Longford Co. Longford Ireland
Supersedes: 25-Sep-2023
Effective (Date or Lot Number): 31 OCT 2024

Abbott

Declaration of Conformity

Certificate Identification: DOC-7D63-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D63-22 7D63-42	53006	Creatine Kinase	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division 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: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 10 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 9 JUN 2021
Date Issued: 10-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 10-Jun-2021

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARS0495R4
Basic UDI-DI Name: Creatininc2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04S9520	Creatinine2	53251	W01010207

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

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 10 SEP 2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 09- SEP- 2024

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

Date Issued: 10 SEP 2024
Supersedes: 13-Mar-2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 10 SEP 2024

Abbott

EU Declaration of Conformity

Basic UDI-DI:	038074ARG0863M7
Basic UDI-DI Name:	ARCHITECT Direct Bilirubin
Risk Class:	Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
8G63-22	Direct Bilirubin	53233	W01010203

Manufacturer (Name and Address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
Manufacturer SRN	DE-MF-000009455	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of manufacture) (Name and Address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH 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:	Hannah Delille	Full Name:	Bridget Norton
Function:	Director Quality Assurance	Function:	Assoc. Director Regulatory Affairs
Signature:	Hannah Delille	Signature:	Bridget Norton
Date of Approval:	20. Oct. 2025	Date of Approval:	20/Oct/2025
Signed for, and on behalf of:	Abbott GmbH, Wiesbaden, Germany		
Date Issued:	20-Oct-2025	Place Issued:	65205 Wiesbaden, Germany
Supersedes:	31-Oct-2024	Effective (Date or Lot Number):	20-Oct-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARK0759NP
Basic UDI-DI Name: Ferritin
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
7K59-25 7K59-30 7K59-35	ARCHITECT Ferritin Reagent Kit	61078	W0102070102
7K59-01	ARCHITECT Ferritin Calibrators	41927	W0102152206
7K59-10	ARCHITECT Ferritin Controls	41928	W0102152006

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: 23 JAN 2025

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 23-JAN-2025

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

Date Issued: 23 JAN 2025
Place Issued: Lisnamuck, Longford Co. Longford Ireland
Supersedes: 30 Nov 2023
Effective (Date or Lot Number): 23 JAN 2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARP0174PC
Basic UDI-DI Name: Folate
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
1P74-25 1P74-35	ARCHITECT Folate Reagent Kit	60982	W0102070103
1P74-40	ARCHITECT Folate RBC Lysis Diluent	54455	W01029003
1P74-50	ARCHITECT Folate Manual Diluent	58237	W01029003
1P74-01	ARCHITECT Folate Calibrators	41931	W0102152206
1P74-10	ARCHITECT Folate Controls	41932	W0102152006
3P21-60	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
Function: Director Quality Assurance/Site Quality Head
Signature: 
Date of Approval: 23 JAN 2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
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

EU Declaration of Conformity

Basic UDI-DI: 038074ART0400QA
Basic UDI-DI Name: Gamma-Glutamyl Transferase2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T0020	Gamma-Glutamyl Transferase2	53027	W01010116
04T0020	Gamma-Glutamyl Transferase2	53027	W01010116

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

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality/Site Quality Head
Signature:
Date of Approval: 19 AUG 2025

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. Mc Entire
Date of Approval: 19 August 2025

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

Date Issued: 19 AUG 2025
Supersedes: 22 May 2024

Place Issued: Lisnamuck, Longford, Co. Longford Ireland
Effective (Date or Lot Number): 19 AUG 2025

Abbott

Declaration of Conformity

Certificate Identification: DoC-3L82-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L82-22 3L82-42	53301	Glucose	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 22-Jul-2021

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ART0402QE
Basic UDI-DI Name: Iron2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T0220	Iron2	54758	W01010216
04T0230	Iron2	54758	W01010216

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland.	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland.	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** 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: 21 Nov 2023

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature:
Date of Approval: 21 NOV 2023

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

Date Issued: 21 Nov 2023
Supersedes: 09 December 2021

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 21 Nov 2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ART0403QG
Basic UDI-DI Name: Lactate Dehydrogenase2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T0320	Lactate Dehydrogenase2	53072	W01010119
04T0330	Lactate Dehydrogenase2	53072	W01010119

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: [signature]
Date of Approval: 13 Oct 2025

Full Name: Rosemary McEntire
Function: Associate Director, Regulatory Affairs
Signature: [signature]
Date of Approval: 13 Oct 2025

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

Date Issued: 13 Oct 2025
Supersedes: 14 Dec 2021

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 13 Oct 2025

Abbott

Declaration of Conformity

Certificate Identification: 7D80
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D80-31	53114	Lipase	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: _____

Full Name: **Erik Muegge**

Position: **QA Manager Ops**

Date of Approval: 8-SEP-2017

Signature: _____

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: November 17, 2014

Effective (Date or Lot Number): 8-SEP-2017

ABBOTT

Declaration of Conformity

Certificate Identification: 3E16
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3E16-02	53109	Lipase Calibrator	Self-declared

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 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: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

Abbott

Declaration of Conformity

Certificate Identification: 03P68
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
03P6824	46795	Magnesium	Self-declared
03P6834	46795	Magnesium	Self-declared

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:	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:	20-JAN-2021	Date of Approval:	20 JAN 2021
Date Issued:	20-JAN-2021	Place Issued:	AIDD Longford
Supersedes:	27 April 2020	Effective (Date)	20-JAN-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-1E65-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E65-06	47868	Multiconstituent Calibrator	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Microgenics Corporation, 46500 Kato Road, Fremont, CA, 94538 USA .
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 10 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 9-Jun-2021
Date Issued: 10-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 16-May-2019
Effective (Date or Lot Number): 10-Jun-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-1E66-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E66-05	41830	Bilirubin Calibrator	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Microgenics Corporation 46500 Kato Road Fremont, CA 94538 USA
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 23 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 15-Jun-2021
Date Issued: 23-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 23-Jun-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-1E78-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E78-04	30505	Specific Proteins Multiconstituent Calibrator	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	NITTOBO MEDICAL CO., LTD. MEDICAL DEVELOPMENT CENTER, 1 Shiojima, Fukuhara, Fukuyama-Machi, Koriyama- City, Fukushima-Pref. 963-8061 Japan.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 13-Sep-2019
Effective (Date or Lot Number): 22-Jul-2021

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARV0002QG
Basic UDI-DI Name: Consolidated Chemistry Calibrator
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04V1501	Consolidated Chemistry Calibrator	47868	W0101050399

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)	Randox Science Park 30 Randalstown Road, Antrim BT41 4FL United Kingdom	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body No. 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Joe Murray
Function: Director Quality/Site Quality Head
Signature: Joe Murray
Date of Approval: 04 Nov 2025

Full Name: Rosemary McEntire
Function: Associate Director Regulatory Affairs
Signature: R. McEntire
Date of Approval: 04 Nov 2025

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

Date Issued: 04 Nov 2025
Place Issued: Lisnamuck, Longford, Co. Longford, Ireland

Supersedes: 19 December 2024
Effective (Date or Lot Number): 04 Nov 2025

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 S Plus	Unassayed/single level	05P79-10
Multichem S Plus	Unassayed/single level	05P79-11
Multichem S Plus	Unassayed/single level	05P79-12
Multichem S Plus	Assayed/single level	05P78-10
Multichem S Plus	Assayed/single level	05P78-11
Multichem S Plus	Assayed/single level	05P78-12

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2016
QMS Certification No.:	Q51038520004 Rev 01
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	12 February 2025

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 18 **(Day)** FEB **(Month)** 2022 **(Year)**

TECHNOPATH
CLINICAL DIAGNOSTICS

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

B. Hass.

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

Ballina, Co.Tipperary 18-FEB-2022.
Place and Date of Issue

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 vitro diagnostic medical devices – statistical aspects
ISO 14971:2019	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

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 S Plus	Unassayed/single level	05P79-10
Multichem S Plus	Unassayed/single level	05P79-11
Multichem S Plus	Unassayed/single level	05P79-12
Multichem S Plus	Assayed/single level	05P78-10
Multichem S Plus	Assayed/single level	05P78-11
Multichem S Plus	Assayed/single level	05P78-12

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2016
QMS Certification No.:	Q51038520004 Rev 01
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	12 February 2025

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 18 **(Day)** FEB **(Month)** 2022 **(Year)**

TECHNOPATH
CLINICAL DIAGNOSTICS

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

B. Hass.

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

Ballina, Co.Tipperary 18-FEB-2022.
Place and Date of Issue

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 vitro diagnostic medical devices – statistical aspects
ISO 14971:2019	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

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	05P76-10

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: 038074ART0407QQ
Basic UDI-DI Name: Phosphorus2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T0720	Phosphorus2	59123	W01010307
04T0730	Phosphorus2	59123	W01010307

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV Süd Product Service GmbH Certification Body, Ridlerstraße 65 • 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 17 APR 2023

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 17-APR-2023.

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

Date Issued: 17 APR 2023
Supersedes: N/A

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 17 APR 2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ART0409QU
Basic UDI-DI Name: Total Bilrubin2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T0920	Total Bilirubin2	53229	W01010203
04T0930	Total Bilirubin2	53229	W01010203

Manufacturer (Name and Address)	Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Münich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name:	David Spellman	Full Name:	Rosemary McEntire
Function:	Director Quality Assurance/ Site Quality Head	Function:	Manager Regulatory Affairs
Signature:		Signature:	
Date of Approval:	26 APR 2024	Date of Approval:	24 APR 2024

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

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

ABBOTT

Declaration of Conformity

Certificate Identification: 04U44
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
04U4420	53989	Total Protein2	**Self-declared**
04U4430	53989	Total Protein2	**Self-declared**

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

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

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

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	24-Jun-20	Date of Approval:	24 Jun 2020
Date Issued:	24-Jun-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective (Date or Lot Number):	24-Jun-20

ABBOTT

Declaration of Conformity

Certificate Identification: 04T10
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
04T1020	53462	Triglyceride2	**Self-declared**
04T1030	53462	Triglyceride2	**Self-declared**

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

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

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

Signature:	Siobhan Wright	Signature:	
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Thomas Breslin**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Manager Regulatory Affairs**
Date of Approval:	24-JUN-2021	Date of Approval:	25-JUNE-2021
Date Issued:	24-JUN-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	25-JUNE-2021

ABBOTT

Declaration of Conformity

Certificate Identification: 04T12
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
04T1220	53590	Urea Nitrogen2	**Self-declared**
04T1230	53590	Urea Nitrogen2	**Self-declared**

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

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

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

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	22-Feb-2021	Date of Approval:	22 Feb 2021
Date Issued:	22-Feb-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	23 June 2020	Effective Date:	22 Feb 2021

ABBOTT

Declaration of Conformity

Certificate Identification:	04T13
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
04T1320	53583	Uric Acid2	Self-declared
04T1330	53583	Uric Acid2	Self-declared

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

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

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

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	24-SEP-20	Date of Approval:	24 Sep 2020
Date Issued:	24-SEP-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	24-SEP-20

Abbott

Declaration of Conformity

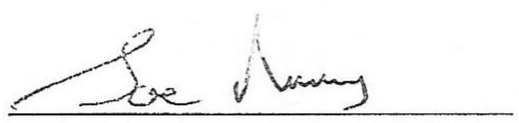
Certificate Identification:	DoC-09P08- AIDD Sligo
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09P0825	54393	TRAb Reagent Kit	**Self-declared**
09P0835	54393	TRAb Reagent Kit	**Self-declared**
09P0801	42079	TRAb Calibrators	**Self-declared**
09P0810	42080	TRAb Controls	**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:	15 Jun 2021	Date of Approval:	15 Jun 2021
Date Issued:	15 Jun 2021	Place Issued:	AIDD Sligo
Supersedes:	Not applicable	Effective (Date or Lot Number):	15 Jun 2021

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Detergent A
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
1J72-20	Detergent A	59058	W0201010185

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)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown, Prince Edward Island CANADA C1E 2B9
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: Kevin Richardson
Function: Director Good Manufacturing Practices
Signature: Kevin Richardson
Date of Approval: 19-NOV-2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 21-NOV-2025

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

Date Issued: 21-NOV-2025
Supersedes: 20-July-2023

Place Issued: Irving, TEXAS
Effective (Date or Lot Number): 21-NOV-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Detergent B
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
2J94-22	Detergent B	59058	W0201010185

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)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown, Prince Edward Island CANADA C1E 2B9
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: Kevin Richardson
Function: Director Good Manufacturing Practices
Signature: Kevin Richardson
Date of Approval: 19-NOV-2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 21-Nov-2025

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

Date Issued: 21-NOV-2025
Supersedes: 20-May-2022

Place Issued: Irving, Texas
Effective (Date or Lot Number): 21-NOV-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Acid Wash
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
6K01-20	ARCHITECT Acid Wash	56676	W0201010185

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)	Fisher Diagnostics 8365 Valley Pike Middletown, VA 22645 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. **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: Kevin Richardson
Function: Director Good Manufacturing Practices
Signature: Kevin Richardson
Date of Approval: 19-NOV-2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 21-Nov-2025

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

Date Issued: 21-Nov-2025
Supersedes: 20-July-2023

Place Issued: Irving, Texas
Effective (Date or Lot Number): 21-Nov-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Water Bath Additive
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
9D29-20	Water Bath Additive	56676	W0201010185

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)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown, Prince Edward Island CANADA C1E 2B9
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: Kevin Richardson
Function: Director Good Manufacturing Practices
Signature: Kevin Richardson
Date of Approval: 19-NOV-2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 21-Nov-2025

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

Date Issued: 21-NOV-2025
Supersedes: 20-May-2022

Place Issued: Irving, Texas
Effective (Date or Lot Number): 21-Nov-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Alkaline Wash
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
9D31-20	ARCHITECT Alkaline Wash	**58236**	**W0201010185**

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)	Fisher Diagnostics 8365 Valley Pike Middletown, VA 22645 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. **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: Kevin Richardson
Function: Director Good Manufacturing Practices
Signature: Kevin Richardson
Date of Approval: 19-NOV-2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 21-Nov-2025

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

Date Issued: 21-Nov-2025
Supersedes: 20-July-2023

Place Issued: Irving, Texas
Effective (Date or Lot Number): 21-Nov-2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074SLI0002T5
Basic UDI-DI Name: ARCHITECT Probe Conditioning Solution
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
1L56-40	ARCHITECT 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: 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: ARCHITECT Septum
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
4D18-03	ARCHITECT Septum	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)	MGS Germantown A division of MGS Group NA, Inc. N117 W19125 Fulton Drive Germantown Wisconsin 53022 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: David Birdbow
Function: Manager Good Manufacturing Practices
Signature: D Birdbow
Date of Approval: 12 SEP 2025

Full Name: Melissa Vaughan
Function: Director Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: 12 Sept 2025

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Dr, Irving, TX 75038 USA
Date Issued: 17 Aug, 2025
Supersedes:

Place Issued: Abbott Laboratories 1915 Hurd Drive, Irving, TX 75038
Effective (Date or Lot Number): 12 Sept 2025

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074SLI0002T5
Basic UDI-DI Name: ARCHITECT Concentrated Wash Buffer
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
6C54-58	ARCHITECT Concentrated Wash Buffer	58236	W0201020185
6C54-82	ARCHITECT Concentrated Wash Buffer	58236	W0201020185
6C54-88	ARCHITECT ARM 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. 2e
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
Place Issued: Sligo, Ireland
Supersedes: 23 May 2022
Effective (Date or Lot Number): 15 Jul 2022

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074SLI0002T5
Basic UDI-DI Name: ARCHITECT Trigger Solution
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
6C55-63	ARCHITECT Trigger Solution	58793	W0201020185
6C55-85	ARCHITECT 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:
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: 038074SLI0002T5
Basic UDI-DI Name: ARCHITECT Pre-Trigger Solution
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
6E23-65	ARCHITECT Pre-Trigger Solution	61163	W0201020185
6E23-82	ARCHITECT 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: 038074DAL0005FW
Basic UDI-DI Name: ARCHITECT Reaction Vessels
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
7C15-03	ARCHITECT Reaction Vessels	**56676**	**W0201020185**

Manufacturer (Name and Address)	Abbott Laboratories I 915 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
02 Sep, 2022
Supersedes:

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