

Declaration of Conformity

Certificate Identification: DOC-08P6101-SD DLK 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
08P6101	41830	Alinity c Bilirubin Calibrator Kit	Self-declared

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

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

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

Signature: C. Becker

Full Name: **Claudia Becker**

Position: **Director Quality Assurance**

Date of Approval: 02 Feb 2022

Signature: Tiffini Jenkins

Full Name: **Tiffini Jenkins**

Position: **Manager Regulatory Affairs**

Date of Approval: 1-Feb-2022

Date Issued: 02 Feb 2022

Place Issued: **65205 Wiesbaden, Germany**

Supersedes: **05-April-2017**

Effective (Date or Lot Number): 02 Feb 2022



EU Declaration of Conformity

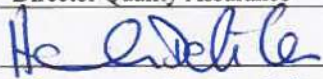
Basic UDI-DI: 038074ACP0797JK
Basic UDI-DI Name: Alinity c Direct Bilirubin
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P9720	Alinity c Direct Bilirubin Reagent Kit	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

Function: Director Quality Assurance

Signature: 

Date of Approval: 20 Oct. 2025

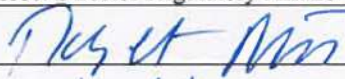
Signed for, and on behalf of: Abbott GmbH, Wiesbaden, Germany

Date Issued: 20-Oct-2025

Supersedes: 31-Oct-2024

Full Name: Bridget Norton

Function: Assoc. Director Regulatory Affairs

Signature: 

Date of Approval: 20/10/2025

Place Issued: 65205 Wiesbaden, Germany

Effective (Date or Lot Number): 20-Oct-2025



EU Declaration of Conformity

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

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U0520	Total Bilirubin2	53229	W01010203
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 München, Germany Notified Body Number 0123		
Conformity Assessment Procedure	Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	EU Certificate No. 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



EU Declaration of Conformity

Basic UDI-DI: 038074ACT0487KD
Basic UDI-DI Name: Calcium2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8720	Calcium2	45789	W01010303
04T8730	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,	EU Certificate No. No. V12 054869 0013	
	Including an assessment of the technical documentation for devices concerned on the basis of representative samples		
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:

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

Full Name: Rosemary McEntire

Function: Manager Regulatory Affairs

Signature:

Date of Approval: 27 May 2024

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

Effective (Date or Lot Number): 27 May 2024

+ Refer to QA Director Delegation

John Lennon 27 May 2024



EU Declaration of Conformity

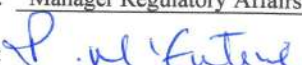
Basic UDI-DI: 038074ACT0488KF
Basic UDI-DI Name: Cholesterol2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8820	Cholesterol2	53359	W01010205
04T8830	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: 

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: 

Date of Approval: 31 OCT 2024

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
Effective (Date or Lot Number): 31 OCT 2024

Supersedes: 25-Sep-2023

EC DECLARATION OF CONFORMITY
for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9522**Description: **Alinity c CK-MB Reagent Kit**EDMA: **11.01.01.14**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE
per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9522**Descrizione: **Alinity c CK-MB Reagent Kit**EDMA: **11.01.01.14**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'adeguata procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA

A Legal Representative

Un Legale Rappresentante

Ugo De Luca

Date / Data

24/11/2017

EC DECLARATION OF CONFORMITY
for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9532**Description: **Alinity c CK-MB Reagent Kit**EDMA: **11.01.01.14**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE
per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9532**Descrizione: **Alinity c CK-MB Reagent Kit**EDMA: **11.01.01.14**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'adeguata procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA

A Legal Representative

Un Legale Rappresentante

Ugo De Luca

Date / Data

24/11/2017

EC DECLARATION OF CONFORMITY
for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9501**Description: **Alinity c CK-MB Calibrator Kit**EDMA: **11.50.03.02**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE
per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9501**Descrizione: **Alinity c CK-MB Calibrator Kit**EDMA: **11.50.03.02**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'adeguata procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA

A Legal Representative

Un Legale Rappresentante

Ugo De Luca

Date / Data

24/11/2017

EC DECLARATION OF CONFORMITY
for *in vitro* diagnostic medical device (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, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9510**Description: **Alinity c CK-MB Control Kit**EDMA: **11.50.02.01**

complies with all the 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. 332/2000).

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

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

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 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.

DICHIARAZIONE DI CONFORMITA' CE
per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9510**Descrizione: **Alinity c CK-MB Control Kit**EDMA: **11.50.02.01**

soddisfa 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 il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'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 di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'adeguata procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA

A Legal Representative

Un Legale Rappresentante

Ugo De Luca

Date / Data

24/11/2017



EU Declaration of Conformity

Basic UDI-DI: 038074ARV0004QL
Basic UDI-DI Name: Consolidated Chemistry Calibrator
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04V6201	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

Full Name: Rosemary McEntire

Function: Director Quality/Site Quality Head

Function: Associate Director Regulatory Affairs

Signature:

Signature:

Date of Approval: 04 Nov 2025

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	08P87-10
Multichem S Plus	Unassayed/single level	08P87-11
Multichem S Plus	Unassayed/single level	08P87-12
Multichem S Plus	Assayed/single level	08P88-10
Multichem S Plus	Assayed/single level	08P88-11
Multichem S Plus	Assayed/single level	08P88-12

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 15 (Day) 02 (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 15-02-2022,
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



EU Declaration of Conformity

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

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

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

Full Name: David Spellman
Director Quality Assurance/ Site Quality

Function: Head

Signature:

Date of Approval: 10 SEP 2024

Full Name: Sandra Gallagher

Function: Manager Regulatory Affairs

Signature:

Date of Approval: 09-SEP-2024

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

Date Issued: 10 SEP 2024

Place Issued: Lisnamuck, Longford Co. Longford Ireland

Effective (Date or Lot Number): 10 SEP 2024

Supersedes: 13-Mar-2023

Declaration of Conformity

Certificate Identification: DOC-08P4220-SD DLK 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
08P4220	53006	Alinity c Creatine Kinase Reagent Kit	Self-declared

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

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

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

Signature: C. Becker

Full Name: **Claudia Becker**

Position: **Director Quality Assurance**

Date of Approval: 05 May 2022

Signature: Tiffini Jenkins

Full Name: **Tiffini Jenkins**

Position: **Manager Regulatory Affairs**

Date of Approval: 29-Apr-2022

Date Issued: 05 May 2022

Place Issued: **65205 Wiesbaden, Germany**

Supersedes: **31-Dec-2016**

Effective (Date or Lot Number): 05-May-2022



EU Declaration of Conformity

Basic UDI-DI: 038074DAL0002FQ
Basic UDI-DI Name: Alinity c-series Detergent A
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P9670	Alinity c-series Detergent A	59058	W0201010185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-00001777
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 C1E 2B9 Canada
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:

Date of Approval:

19-NOV-2025

Signed for, and
on behalf of:

Abbott Laboratories
1915 Hurd Drive
Irving, TX 75038 USA

Date Issued:

20-NOV-2025

Supersedes:

20-July-2023

Full Name: Melissa Vaughan

Function: Director Regulatory Affairs

Signature:

Date of Approval:

20-NOV-2025

Place Issued: Irving, Texas

Effective (Date
or Lot Number):

20-NOV-2025



EU Declaration of Conformity

Basic UDI-DI: 038074DAL0002FQ
Basic UDI-DI Name: Alinity c-series Detergent B
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P9781	Alinity c-series 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 C1E 2B9 Canada
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

Full Name: Melissa Vaughan

Function: Director Good Manufacturing Practices

Function: Director Regulatory Affairs

Signature: Kevin Richardson

Signature: Melissa Vaughan

Date of Approval: 19-Nov-2025

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

Place Issued: Irving, Texas

Effective (Date
or Lot Number):

21-Nov-2025

Supersedes: 23-May-2022

DECLARATION OF CONFORMITY

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

European Representative: MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

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

Classification: General IVD

Conformity Assessment Route: Annex III, self-certified

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

Place of Issue: Prince Edward Island, Canada

Signature:



Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

29-Jun-2021
Date