Abbott

Declaration of Conformity

Certificate Identification: DOC-07P5520, 07P5530-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
07P5520	53301	Alinity c Glucose Reagent Kit	**Self-declared**
07P5530	53301	Alinity c Glucose Reagent Kit	

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

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

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

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

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 13-Oct-2017
Effective (Date or Lot Number): 22-Jul-2021

Digitally signed by Ceaicovschi Tudor
Date: 2024.12.10 09:51:00 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Abbott

Declaration of Conformity

Certificate Identification: DoC-04V5121, 04V5131-SD DELK
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04V5121	53229	Alinity c Total Bilirubin Reagent Kit	**Self-declared**
04V5131	53229	Alinity c Total Bilirubin Reagent Kit	**Self-declared**

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

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

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

Signature: _____

Full Name: **Joerg Amborn**

Position: **Director, Quality Assurance**

Date of Approval: 2020-06-09

Signature: _____

Full Name: **Noah Lermer**

Position: **Director Regulatory Affairs**

Date of Approval: 12-Jun-20

Date Issued: 12-Jun-20

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 27-Feb-2019

Effective (Date or Lot Number): 12-Jun-20

Abbott

Declaration of Conformity

Certificate Identification:	DOC-07P9720-SD DELK TPM
Legal Manufacturer's Name:	Abbott GmbH
Legal Manufacturer's Address:	Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P9720	53236	Alinity c Direct Bilirubin Reagent Kit	**Self-declared**

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

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

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

Signature: C. Becker

Full Name: **Claudia Becker**

Position: **Director Quality Assurance**

Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins

Full Name: **Tiffini Jenkins**

Position: **Manager Regulatory Affairs**

Date of Approval: 11-Jul-2021

Date Issued: 22-Jul-2021

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 19-Feb-2019

Effective (Date or Lot Number): 22-Jul-2021

ABBOTT

Declaration of Conformity

Certificate Identification: 04T84
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8420	52925	Alanine Aminotransferase2	**Self-declared**
04T8430	52925	Alanine Aminotransferase2	**Self-declared**

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

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

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

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

ABBOTT

Declaration of Conformity

Certificate Identification: 04T86
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8620	52954	Aspartate Aminotransferase2	**Self-declared**
04T8630	52954	Aspartate Aminotransferase2	**Self-declared**

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

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

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

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

ABBOTT

Declaration of Conformity

Certificate Identification: 04T96
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
04T9620	53030	Gamma-Glutamyl Transferase2	**Self-declared**
04T9630	53030	Gamma-Glutamyl Transferase2	**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:	09-SEP-2021	Date of Approval:	09 - Sep - 2021
Date Issued:	09-SEP-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	09 - Sep - 2021

ABBOTT

Declaration of Conformity

Certificate Identification: 04T85
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
04T8520	52941	Amylase2	**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:	25-OCT-20	Date of Approval:	25 OCT 2020
Date Issued:	25-OCT-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	25-OCT-20

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: **04Y85-20** Description: **Lipase NG OC Reagent Kit**

EDMA: **11.01.01.23**

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: **04Y85-20** Descrizione: **Lipase NG OC Reagent Kit**

EDMA: **11.01.01.23**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
28/02/2019

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

Declaration of Conformity

Certificate Identification: 04U08
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
04U0820	53590	Urea Nitrogen2	**Self-declared**
04U0830	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:	
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-MAR-2021	Date of Approval:	24 MARCH 2021
Date Issued:	24-MAR-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	24-MAR-2021

ABBOTT

Declaration of Conformity

Certificate Identification: 04T91
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
04T9120	53251	Creatinine2	**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:		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:	21-OCT-2021	Date of Approval:	21-OCT-2021
Date Issued:	21-OCT-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	21-OCT-2021

ABBOTT

Declaration of Conformity

Certificate Identification:	04U09
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04U0920	53583	Uric Acid2	**Self-declared**
04U0930	53583	Uric Acid2	**Self-declared**

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

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

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

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	18-NOV-20	Date of Approval:	18 Nov 2020
Date Issued:	18-NOV-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	18-NOV-20

ABBOTT

Declaration of Conformity

Certificate Identification: 04T81
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
04T8120	53989	Total Protein2	**Self-declared**
04T8130	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:	**Director Regulatory Affairs**
Date of Approval:	22-OCT-20	Date of Approval:	22 OCT 2020
Date Issued:	22-OCT-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	22-OCT-20

ABBOTT

Declaration of Conformity

Certificate Identification:	04U30
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
04U3020	53599	Albumin BCG2	**Self-declared**
04U3030	53599	Albumin BCG2	**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 (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	25-OCT-20	Date of Approval:	25 OCT 2020
Date Issued:	25-OCT-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	N/A	Effective (Date or Lot Number):	25-OCT-20

ABBOTT

Declaration of Conformity

Certificate Identification: 04T88
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
04T8820	53362	Cholesterol2	**Self-declared**
04T8830	53362	Cholesterol2	**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:	25-NOV-20	Date of Approval:	25 NOV 2020
Date Issued:	25-NOV-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	25-NOV-20

ABBOTT

Declaration of Conformity

Certificate Identification: 04U06
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04U0620	53462	Triglyceride2	**Self-declared**

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

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

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

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

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0498KJ
Basic UDI-DI Name: Iron2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9820	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: R. McEntire
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

Declaration of Conformity

Certificate Identification:	DOC-07P5720, 07P5730-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
07P5720	45789	Alinity c Calcium Reagent Kit	**Self-declared**
07P5730	45789	Alinity c Calcium 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	Signature:	Tiffini Jenkins
Full Name:	**Claudia Becker**	Full Name:	**Tiffini Jenkins**
Position:	**Director Quality Assurance**	Position:	**Manager Regulatory Affairs**
Date of Approval:	22 Jul 2021	Date of Approval:	11-Jul-2021
		Date Issued:	22-Jul-2021
		Place Issued:	65205 Wiesbaden, Germany
		Supersedes:	31-Dec-2016
		Effective (Date or Lot Number):	22-Jul-2021

ABBOTT

Declaration of Conformity

Certificate Identification: 08P19
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
08P1925 08P1934	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 (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	13-Jul-20	Date of Approval:	13 July 2020
Date Issued:	13-Jul-20	Place Issued	AIDD, Longford
Supersedes:	13 Jun 2020	Effective (Date)	13-Jul-20

Abbott

IVDD Declaration of Conformity Attribute Update Letter

Number: 1

List Number and Size Code	Name and Descriptions of Devices	GMDN Code
08P4321	Alinity c Hemoglobin A1c Reagent Kit	59090

Legal Manufacturer (Name and Address)	Abbott GmbH Max-Plank-Ring 2 65205 Wiesbaden, Germany
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.

This letter must be used in conjunction with the Declaration of Conformity issued in accordance with In Vitro Diagnostic Directive 98/79/EC.

IVD Directive 98/79/EC Declaration of Conformity Identification	DoC-08P4320, 08P4301, 08P4310-SD DLK TPM – Date of Approval 02-Feb-2022
Description of updated attributes from IVD Directive 98/79/EC Declaration of Conformity	Create new size code for Alinity c Hemoglobin A1c Reagent Kit (LN 08P4321) for logistical reasons to implement the REACH change to meet the requirements of the REACH Restriction relating to Dimethylformamide (DMF).

This letter documents that the device listed above continues to comply with the In Vitro Diagnostic Directive 98/79/EC and meets the applicable transitional provisions of Regulation (EU) 2022/112 of the European Parliament and the Council of 25 January 2022 and is considered a non-significant change per MDCG 2022-6 (Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR).

Full Name: **Claudia Becker**
Function: **Director Quality Assurance**
Signature: C. Becker
Date of Approval: 26 Jul 2023
Date Issued: 26 Jul 2023

Full Name: **Susanne Ulrich**
Function: **Associate Director Regulatory Affairs**
Signature: Susanne Ulrich
Date of Approval: 26/Jul/2023
Place Issued: Wiesbaden
Effective (Date or Lot Number): 26 Jul 2023

Abbott

Declaration of Conformity

Certificate Identification: DOC-08P4320, 08P4301, 08P4310-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
08P4320	59090	Alinity c Hemoglobin A1c Reagent Kit	**Self-declared**
08P4301	53315	Alinity c Hemoglobin A1c Calibrators	**Self-declared**
08P4310	44435	Alinity c Hemoglobin A1c Controls	**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: 12-Feb-2019
Effective (Date or Lot Number): 02 Feb 2022

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACP0775J9
Basic UDI-DI Name: Alinity c Ultra HDL
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P7520	Alinity c Ultra HDLReagent Kit	53391	W01010215
07P7530	Alinity c Ultra HDLReagent Kit	53391	W01010215

Manufacturer (Name and Address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
Manufacturer SRN	DE-MF-000009455	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of manufacture) (Name and Address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65, 80339 München, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, including an assessment of the technical documentation for devices concerned on the basis of representative samples.	**EU Certificate No.** **No. V12 010051 0137**
Common Specifications (CS)	N/A	

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

Full Name: Claudia Becker
Function: Director Quality Assurance
Signature: C. Becker
Date of Approval: 12 Oct 2023

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

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

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

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

SEKISUI DIAGNOSTICS
Because every result matters™

DECLARATION OF CONFORMITY

Manufacturer:	Sekisui Diagnostics P.E.I. Inc 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada
European Representative:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany

Product:

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

Classification: General IVD

Conformity Assessment Route: Annex III, self-certified

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

Place of Issue: Prince Edward Island, Canada

Signature: _____ 29-Jun-2021

Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

Date

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

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: **04Y85-01** Description: **Lipase NG OC Cal**

EDMA: **11.50.03.01**

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: **04Y85-01** Descrizione: **Lipase NG OC Cal**

EDMA: **11.50.03.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
28/02/2019

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: **04Y85-10** Description: **Lipase NG OC CTRL 1**

EDMA: **11.50.01.01**

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: **04Y85-10** Descrizione: **Lipase NG OC CTRL 1**

EDMA: **11.50.01.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
28/02/2019

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

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: **04Y85-11** Description: **Lipase NG OC CTRL 2**

EDMA: **11.50.01.01**

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: **04Y85-11** Descrizione: **Lipase NG OC CTRL 2**

EDMA: **11.50.01.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
28/02/2019

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

IVDD Declaration of Conformity Attribute Update Letter

Number: 1

List Number and Size Code	Name and Descriptions of Devices	GMDN Code
08P4321	Alinity c Hemoglobin A1c Reagent Kit	59090

Legal Manufacturer (Name and Address)	Abbott GmbH Max-Plank-Ring 2 65205 Wiesbaden, Germany
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.

This letter must be used in conjunction with the Declaration of Conformity issued in accordance with In Vitro Diagnostic Directive 98/79/EC.

IVD Directive 98/79/EC Declaration of Conformity Identification	DoC-08P4320, 08P4301, 08P4310-SD DLK TPM – Date of Approval 02-Feb-2022
Description of updated attributes from IVD Directive 98/79/EC Declaration of Conformity	Create new size code for Alinity c Hemoglobin A1c Reagent Kit (LN 08P4321) for logistical reasons to implement the REACH change to meet the requirements of the REACH Restriction relating to Dimethylformamide (DMF).

This letter documents that the device listed above continues to comply with the In Vitro Diagnostic Directive 98/79/EC and meets the applicable transitional provisions of Regulation (EU) 2022/112 of the European Parliament and the Council of 25 January 2022 and is considered a non-significant change per MDCG 2022-6 (Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR).

Full Name: **Claudia Becker**
Function: **Director Quality Assurance**
Signature: C. Becker
Date of Approval: 26 Jul 2023
Date Issued: 26 Jul 2023

Full Name: **Susanne Ulrich**
Function: **Associate Director Regulatory Affairs**
Signature: Susanne Ulrich
Date of Approval: 26/Jul/2023
Place Issued: Wiesbaden
Effective (Date or Lot Number): 26 Jul 2023

Abbott

Declaration of Conformity

Certificate Identification: DOC-08P4320, 08P4301, 08P4310-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
08P4320	59090	Alinity c Hemoglobin A1c Reagent Kit	**Self-declared**
08P4301	53315	Alinity c Hemoglobin A1c Calibrators	**Self-declared**
08P4310	44435	Alinity c Hemoglobin A1c Controls	**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: 12-Feb-2019
Effective (Date or Lot Number): 02 Feb 2022

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 A1c	Assayed/bi-level	04V0610

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)**

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

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 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

Abbott

Declaration of Conformity

Certificate Identification: DOC-04U7501-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
04U7501	54760	Alinity c Iron 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: 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: 12-Oct-2018
Effective (Date or Lot Number): 10-Jun-2021

Abbott

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

Abbott

Declaration of Conformity

Certificate Identification: DOC-08P6001-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
08P6001	47868	Alinity c Multiconstituent 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: 19-Aug-2019
Effective (Date or Lot Number): 02 Feb 2022

ABBOTT

Declaration of Conformity

Certificate Identification: 04V62
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
04V6201	47868	Consolidated Chemistry Calibrator	**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 and Randox Laboratories Ltd, 30 Randalstown Road, Antrim, Co. Antrim, BT41 4FL, UK
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:	14-DEC-2021	Date of Approval:	15-DEC-2021
Date Issued:	15-DEC-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	21 October 2021	Effective (Date or Lot Number):	15-DEC-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-09P1401, 09P1403-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
09P1401	53356	Alinity c Lipid Multiconstituent Calibrator Kit	**Self-declared**
09P1403	53356	Alinity c Lipid Multiconstituent 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: 22 Dec 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 21-Dec-21
Date Issued: 22 Dec 2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 19-Feb-2018-
Effective (Date or Lot Number): 22 Dec 2021

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: **08P6501** Description: **Alinity c Clinical Chemistry Calibrator Kit**

EDMA: **11.50.03.01**

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: **08P6501** Descrizione: **Alinity c Clinical Chemistry Calibrator Kit**

EDMA: **11.50.03.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
06/04/2017

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

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: **08P6510** Description: **Alinity c Clinical Chemistry Control 1 Kit**

EDMA: **11.50.01.01**

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: **08P6510** Descrizione: **Alinity c Clinical Chemistry Control 1 Kit**

EDMA: **11.50.01.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
06/04/2017

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

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: **08P6511** Description: **Alinity c Clinical Chemistry Control 2 Kit**

EDMA: **11.50.01.01**

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: **08P6511** Descrizione: **Alinity c Clinical Chemistry Control 2 Kit**

EDMA: **11.50.01.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
06/04/2017

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

Mod. 98 - Rev.4 - Data:03/09/2013

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: **08P6503** Description: **Alinity c Clinical Chemistry Calibrator Kit**

EDMA: **11.50.03.01**

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: **08P6503** Descrizione: **Alinity c Clinical Chemistry Calibrator Kit**

EDMA: **11.50.03.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
07/02/2018

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

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: **08P6515** Description: **Alinity c Clinical Chemistry Control 1 Kit**

EDMA: **11.50.01.01**

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: **08P6515** Descrizione: **Alinity c Clinical Chemistry Control 1 Kit**

EDMA: **11.50.01.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
07/02/2018

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: **08P6516** Description: **Alinity c Clinical Chemistry Control 2 Kit**

EDMA: **11.50.01.01**

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: **08P6516** Descrizione: **Alinity c Clinical Chemistry Control 2 Kit**

EDMA: **11.50.01.01**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
07/02/2018

Abbott

EU Declaration of Conformity

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

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P9870	Alinity c-series Maintenance Solutions:		
	• Water Bath Additive	56676	W0201010185
	• Cleaning Solution	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; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

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

Full Name: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 23-May-2022

Full Name: Michele Smith-Waheed
Function: Associate Director, Regulatory Affairs
Signature: MSWaheed
Date of Approval: 23-May-2022

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

Date Issued: 23-May-2022
Supersedes: N/A

Place Issued: Irving, Texas
Effective (Date or Lot Number): 23-May-2022

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0002FQ
Basic UDI-DI Name: Alinity c-series Acid Probe Wash
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
01R6070	Alinity c-series Acid Probe 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; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.
This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 23-May-2022
Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038

Full Name: Michele Smith-Waheed
Function: Associate Director, Regulatory Affairs
Signature: MSWaheed
Date of Approval: 23-MAY-2022

Date Issued: 23-MAY-2022
Supersedes: N/A

Place Issued: Irving, Texas
Effective (Date or Lot Number): 23-MAY-2022

Abbott

EU Declaration of Conformity

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

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P7740	Alinity c-series 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; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

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

Full Name: Kevin Richardson
Function: Director, Instrument Quality
Signature: Kevin Richardson
Date of Approval: 20-JULY-2023

Full Name: Melissa Vaughan
Function: Director, Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: July 20, 2023

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

Date Issued: 20-JULY-2023
Supersedes: 23-May-2022

Place Issued: Irving, Texas
Effective (Date or Lot Number): 20-JULY-2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0002EQ
Basic UDI-DI Name: Alinity c-series Alkaline Wash
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08P7840	Alinity c-series 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; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

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

Full Name: Kevin Richardson
Function: Director, Instrument Quality
Signature: Kevin Richardson
Date of Approval: 20-JULY-2023
Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038 USA

Full Name: Melissa Vaughan
Function: Director, Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: July 20, 2023

Date Issued: 20-JULY-2023
Supersedes: 23-May-2022

Place Issued: Irving, Texas
Effective (Date or Lot Number): 20-JULY-2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 03807401A10002EQ
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-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; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

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

Full Name: Kevin Richardson
Function: Director, Instrument Quality
Signature: Kevin Richardson
Date of Approval: 20-July-2023

Full Name: Melissa Vaughan
Function: Director, Regulatory Affairs
Signature: Melissa Vaughan
Date of Approval: July 20, 2023

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

Date Issued: 20-Jul4-2023
Supersedes: 23-May-2022

Place Issued: Irving, Texas
Effective (Date or Lot Number): 20-Jul4-2023

Abbott

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; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.
This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 23-May-2022
Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038

Full Name: Michele Smith-Waheed
Function: Associate Director, Regulatory Affairs
Signature: MSWaheed
Date of Approval: 23-MAY-2022

Date Issued: 23-MAY-2022
Supersedes: N/A

Place Issued: Irving, Texas
Effective (Date or Lot Number): 23-MAY-2022

Abbott

EU Declaration of Conformity

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

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

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

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

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

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

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

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

Date Issued: 2022-November-15
Supersedes: 01 September 2022

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

Abbott

EU Declaration of Conformity

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

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

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

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

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

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

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

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

Date Issued: 15 Nov 2022
Supersedes: 02 September 2022

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

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0483K5
Basic UDI-DI Name: Alkaline Phosphatase2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8320	Alkaline Phosphatase2	52929	W01010105
04T8330	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 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: 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
Supersedes: N/A

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

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0499KL
Basic UDI-DI Name: Lactate Dehydrogenase2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9920	Lactate Dehydrogenase2	53072	W01010119
04T9930	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 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 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: Siobhan Wright
Function: Director Quality Assurance/Site Quality Head
Signature: Siobhan Wright
Date of Approval: 14-DEC-2021

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S Gallagher
Date of Approval: 13-DEC-2021

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

Date Issued: 14-DEC-2021
Supersedes: N/A

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 14-DEC-2021

Abbott

EU Declaration of Conformity

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

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

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

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

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

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

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

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

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

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

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

ITALCERT

CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2023-10-24	2026-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

ITALCERT

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.
Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CE DECLARATION OF CONFORMITY

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**BIOKIT, S.A.** **Av. Can Montcau, 7** **08186 Lliçà d'Amunt** **Barcelona** **Spain**

Biokit hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Biokit erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Biokit declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Biokit déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Biokit dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Biokit declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Biokit erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Biokit bekräftar härmed att nedan uppräknade produkt(er) är förenlig(a) med de EU-direktiv och standarder som identifieras i denna deklaration

Η Biokit με το παρόν δηλώνει ότι το προϊόν(–τα) που αναφέρονται κατωτέρω συμμορφώνονται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που παρατίθενται στην παρούσα δήλωση.

EU Directive:
EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-Direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998)

Standard(s):
Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπο(-α)

ISO 13485

Notified Body:
Benannte Stelle Organismo Notificado Organisme Notifié Organismo Notificato Organismo Notificado Teknisk Kontrollorgon Anmält Organ Κοινοποιημένος Οργανισμός

Name: *Other Devices*	Code: *N/A*

- Certificate N°: N/A Annex III

Product(s):
Produkt(e) Producto(s) Produit(s) Prodotto(i) Produto(s) Produkt(er) Produkt(er) Προϊόν(-τα)

Product(s) *Produkt(e)* *Producto(s)* *Produit(s* *Prodotto(i)*	*Produto(s)* *Produkt(er)* *Produkt(er)* *Προϊόν(-τα)*
P/N	
01R0620	**Alinity c ASO Reagent (300 test)**
01R0630	**Alinity c ASO Reagent (780 test)**
01R0601	**Alinity c ASO Standard**

Signature
Pau Planas
CEO
Biokit, S.A

August 28th, 2018
Date

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: **07P5620** Description: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

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: **07P5620** Descrizione: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

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

Date / Data
30/06/2017

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: **07P5601** Description: **Alinity c CRP Vario Wide Range Calibrator Kit**

EDMA: **12.50.03.13**

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: **07P5601** Descrizione: **Alinity c CRP Vario Wide Range Calibrator Kit**

EDMA: **12.50.03.13**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

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

Date / Data
30/06/2017

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

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: **07P5602** Description: **Alinity c CRP Vario High Sensitivity Calibrator Kit**

EDMA: **12.50.03.13**

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: **07P5602** Descrizione: **Alinity c CRP Vario High Sensitivity Calibrator Kit**

EDMA: **12.50.03.13**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

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

Date / Data
30/06/2017

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

Mod. 98 - Rev.4 - Data:03/09/2013

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: **07P5621** Description: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

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: **07P5621** Descrizione: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data

12/12/2018

SENTINEL DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

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: **07P5624** Description: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

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: **07P5624** Descrizione: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

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'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
12/12/2019

CE DECLARATION OF CONFORMITY

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**BIOKIT, S.A.** **Av. Can Montcau, 7** **08186 Lliçà d'Amunt** **Barcelona** **Spain**

Biokit hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Biokit erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Biokit declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Biokit déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Biokit dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Biokit declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Biokit erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Biokit bekräftar härmed att nedan uppräknade produkt(er) är förenlig(a) med de EU-direktiv och standarder som identifieras i denna deklaration

Η Biokit με το παρόν δηλώνει ότι το προϊόν(–τα) που αναφέρονται κατωτέρω συμμορφώνονται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που παρατίθενται στην παρούσα δήλωση.

EU Directive:
EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-Direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998)

Standard(s):
Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπο(-α)

ISO 13485

Notified Body:
Benannte Stelle Organismo Notificado Organisme Notifié Organismo Notificato Organismo Notificado Teknisk Kontrollorgon Anmält Organ Κοινοποιημένος Οργανισμός

Name: ***Other Devices***	Code: ***N/A***

- Certificate Nº: N/A Annex III

Product(s):
Produkt(e) Producto(s) Produit(s) Prodotto(i) Produto(s) Produkt(er) Produkt(er) Προϊόν(-τα)

Product(s) *Produkt(e)* *Producto(s)* *Produit(s* *Prodotto(i)*	*Produto(s)* *Produkt(er)* *Produkt(er)* *Προϊόν(-τα)*
P/N	
01R1622	**Alinity c RF Reagent Kit (400 T)**
01R1632	**Alinity c RF Reagent Kit (920 T)**
01R1601	**Alinity c RF Standard**

August 28th, 2018

Signature
Pau Planas
CEO
Biokit, S.A

Date

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD** **Unit 602, International Center, No.535, Shenxu Road,** **Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Flexible Loops**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD** **(Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /** **EG Annex III (expect point 6) of IVDD 98/79/EC** **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE** **Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 2022.12.14

General Manager

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Serological Pipette**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 2022.01.01

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

CERTIFICATE OF ANALYSIS

Report No.: GM01-BN24

Product Name	Transport Swab	Specification	AMIES W/CHARCOAL
Lot. No.	20240301	Quantity	10000pcs
Mfg. Date	20240301	Exp. Date	20270228
Test Standard	Factory Standard	Report Date	2024.03.26

Item	Technical Requirement	Result	Conclusion
Appearance	The swab tip should be uniform, no black spots, no foreign impurities. The handle and tube are smooth, no edge, no crack. The label should be pasted firm.	Comply	Qualified
Size	Cotton head diameter: 4.5mm±0.5mm	4.5mm	Qualified
	Cotton head length: 15mm±0.5mm	15mm	Qualified
	Plastic stick diameter: 2.5mm±0.2mm	2.5mm	Qualified
	Total length: 178mm±2mm	178mm	Qualified
Water capacity	0.15ml±0.02ml	0.14ml	Qualified
Hydrophilicity	Add 100μL above swab, the water will no fall	Comply	Qualified
Medium Capacity	5ml±0.5ml	Comply	Qualified
Connection	Under 5.3N force, the cotton head and the handle will not fall off.	26N	Qualified
	The cap and the tube are connected firmly.	Comply	Qualified
Sterile	The transport swab should be sterile.	Comply	Qualified
Conclusion	Meet the requirement		

Inspector: Tom Li
Date: 2024.03.26

Checker: Leo Sun
Date: 2024.03.26