Abbott

EU Declaration of Conformity

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

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9120	Creatinine2	53251	W01010207

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

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

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

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

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

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

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

Digitally signed by Ceaicovschi Tudor
Date: 2025.12.13 09:34:16 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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
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

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

Abbott

EU Declaration of Conformity

Basic UDI-DI: 03807401DAT0002EQ
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
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-JUL-2023
Supersedes: 23-May-2022

Place Issued: Irving, Texas
Effective (Date or Lot Number): 20-JUL-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: M S Waheed
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

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă şi cod dimensiune	Denumirea produsului şi denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fabrikationssted) (Navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locație producție) (nume și adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Conformity Assessment Procedure	Annex II and III	Full Name
BG	Процедура за оценка на съответствието	Приложение II и III	Пълно наименование
CS	Postup posuzování shody	Příloha II a III	Celý název
DA	Overensstemmelsesvurderingsprocedure	Bilag II og III	Fulde navn
DE	Konformitätsbewertungsverfahren	Anhang II und III	Vollständiger Name
EL	Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα II και III	Πλήρης ονομασία
ES	Procedimiento de evaluación de la conformidad	Anexos II y III	Nombre completo
ET	Vastavushindamismenetlus	II ja III lisa	Täisnimi
FR	Procédure d'évaluation de la conformité	Annexes II et III	Nom complet
HR	Postupak ocjenjivanja sukladnosti	Prilog II. i III.	Puni naziv
HU	Megfelelőségértékelési eljárás	II. és III. melléklet	Teljes név
IT	Procedura di valutazione della conformità	Allegati II e III	Nome completo
LV	Atbilstības novērtēšanas procedūra	II un III pielikums	Pilns nosaukums
LT	Atitikties vertinimo procedūra	II ir III priedai	Vardas ir pavardė
NO	Framgangsmåte for samsvarsvurdering	Vedlegg II og III	Fullt navn
PL	Procedura oceny zgodności	Załącznik II oraz III	Imię i nazwisko
PT	Procedimento de avaliação da conformidade	Anexo II e III	Nome completo
RO	Procedură de evaluare a conformității	Anexa II și III	Numele complet
SK	Postup posudzovania zhody	Príloha II a III	Celý názov
SV	Förfarande för bedömning av överensstämmelse	Bilaga II och III	Fullständigt namn
TR	Uygunluk Değerlendirme Prosedürü	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnat pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	**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.**
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика; освен това отговаря(т) на приложимите разпоредби на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението на употребата на определени опасни вещества в електрическото и електронното оборудване и на приложимите разпоредби на Директива 2006/42/ЕО на Европейския парламент и на Съвета от 17 май 2006 г. относно машините, и за изменение на Директива 95/16/ЕО, както е транспонирана в националното законодателство на държавите членки. Тази декларация се прави в съответствие с Приложение IV на Регламента за IVD, Приложение VI на Директивата за ограничаване на опасните вещества (ROHS) и Приложение II на Директивата относно машините и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro; a že je (jsou) dále ve shodě s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních a s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2006/42/ES ze dne 17. května 2006 o strojních zařízeních a o změně směrnice 95/16/ES, jak byla provedena ve vnitrostátním právu členských států. Toto prohlášení je v souladu s Přílohou IV nařízení IVD, Přílohou VI směrnice ROHS a Přílohou II směrnice o strojních zařízeních a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr, ligesom det overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr samt overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2006/42/EF af 17. maj 2006 om maskiner og ændring af direktiv 95/16/EF, som det er transponeret i medlemsstaternes lovgivning. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV, ROHS-direktivets bilag VI samt maskindirektivets bilag II og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen und zusätzlich die entsprechenden Bestimmungen der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten sowie der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG gemäß Umsetzung in den Gesetzen der Mitgliedsstaaten. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung, Anhang VI der RoHS-Richtlinie und Anhang II der Maschinen-Richtlinie und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα και επίσης συμμορφώνονται με τις ισχύουσες διατάξεις της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 σχετικά με τους περιορισμούς στη χρήση συγκεκριμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό, καθώς και με τις ισχύουσες διατάξεις της Οδηγίας 2006/42/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 17ης Μαΐου 2006 σχετικά με τον μηχανικό εξοπλισμό και την τροποποιητική Οδηγία 95/16/ΕΚ όπως αυτή μεταφέρθηκε στη νομοθεσία των κρατών μελών. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD, το Παράρτημα VI της Οδηγίας ROHS και το Παράρτημα II της Οδηγίας για τον μηχανικό εξοπλισμό και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico *in vitro* descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico *in vitro*; y además cumple(n) las disposiciones aplicables de la Directiva 2011/65/EU del Parlamento Europeo y del Consejo del 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, y las disposiciones aplicables de la Directiva 2006/42/EC del Parlamento Europeo y del Consejo del 17 de mayo de 2006 sobre maquinaria, y la Directiva de enmienda 95/16/EC tal y como se ha incorporado en las leyes de los Estados Miembros. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD, Anexo VI de la Directiva ROHS y Anexo II de la Directiva de máquinas y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele ning lisaks vastab see kohaldatavatele sätetele Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivis 2011/65/EL (teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes) ja Euroopa Parlamendi ja nõukogu direktiivis 2006/42/EÜ, 17. mai 2006, mis käsitleb masinaid ja millega muudetakse direktiivi 95/16/EÜ, nagu see on üle võetud liikmesriikide seadustesse. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale, ROHS direktiivi VI lisale ja masinadirektiivi II lisale ning see on välja antud tootja vastutusel.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic *in vitro*, aux dispositions applicables de la Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, aux dispositions applicables de la Directive 2006/42/CE du Parlement européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la Directive 95/16/CE, telles que transposées dans le droit national des États membres. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV, à l'Annexe VI de la Directive ROHS ainsi qu'à l'Annexe II de la Directive Machines sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima; i dodatno primjenjivim odredbama Direktive 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi, te primjenjivim odredbama Direktive 2006/42/EZ Europskog parlamenta i Vijeća od 17. svibnja 2006. o strojevima zamjenjujući Direktivu 95/16/EZ kako je pretočeno u zakone država članica. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD, Prilogom VI. Direktive ROHS i Prilogom II. Direktive o strojevima i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete vonatkozó rendelkezéseit; továbbá az Európai Parlament és a Tanács egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU (2011. június 8.) irányelve (RoHS irányelv) vonatkozó rendelkezéseit; valamint az Európai Parlament és a Tanács a gépekről és a 95/16/EK irányelv módosításáról szóló 2006/42/EK (2006. május 17.) irányelve vonatkozó rendelkezéseit a tagállamok jogrendjébe átültető rendelkezéseknek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében, a RoHS irányelv VI. mellékletében és a gépekről szóló irányelv II. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.

EN	**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.**
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici *in vitro*; è(sono) inoltre conforme(i) alle disposizioni applicabili della direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, e alle disposizioni applicabili della direttiva 2006/42/CE del Parlamento europeo e del Consiglio del 17 maggio 2006 relativa alle macchine e che modifica la direttiva 95/16/CE come recepite nelle legislazioni degli Stati membri. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD, all'allegato VI della direttiva ROHS e all'allegato II della direttiva macchine ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm un papildus prasībām, kas noteiktas Eiropas Parlamenta un Padomes Direktīvā 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās un Eiropas Parlamenta un Padomes Direktīvā 2006/42/EK (2006. gada 17. maijs) par mašīnām, un ar kuru groza Direktīvu 95/16/EK, kā tā ieviesta dalībvalstu tiesību aktos. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu, ROHS direktīvas VI pielikumu un Direktīvas par mašīnām II pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas; taip pat ji (jos) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvos 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo taikomas nuostatas ir 2006 m. gegužės 17 d. Europos Parlamento ir Tarybos direktyvos 2006/42/EB dėl mašinų, iš dalies keičiančios Direktyvą 95/16/EB, taikomas nuostatas, perkeltas į valstybių narių teisės aktus. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu, ROHS direktyvos VI priedu ir Mašinų direktyvos II priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til *in vitro*-diagnostikk, og ytterligere overholder gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2011/65/EU av 8. juni 2011 om bruksbegrensninger av visse farlige stoffer i elektrisk og elektronisk utstyr, og til gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2006/42/EF av 17. mai 2006 om maskiner, og endring av direktiv 95/16/EF som innarbeidet i medlemsstatenes lovgivning. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen, vedlegg VI i ROHS-direktivet og vedlegg II i maskindirektivet og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro, a ponadto wymagania Dyrektywy 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, Dyrektywy 2006/42/WE Parlamentu Europejskiego i Rady z dnia 17 maja 2006 r. w sprawie maszyn, zmieniającej Dyrektywę 95/16/WE, w sposób, w jaki zostały one wdrożone do ustawodawstwa państw członkowskich. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR, Załącznikiem VI Dyrektywy ROHS oraz Załącznikiem II Dyrektywy Maszynowej i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico *in vitro*; e adicionalmente, em conformidade com as disposições aplicáveis da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos, e com as disposições aplicáveis da Diretiva 2006/42/CE do Parlamento Europeu e do Conselho, de 17 de maio de 2006, sobre máquinas e que altera a Diretiva 95/16/CE, conforme transposta nas leis dos Estados membros. Esta declaração é feita de acordo com o Anexo IV do Regulamento IVD, o Anexo VI da Diretiva ROHS e o Anexo II da Diretiva relativa às Máquinas e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro; și, în plus, respectă dispozițiile aplicabile din Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricția utilizării anumitor substanțe periculoase în echipamentele electrice și electronice și cu dispozițiile aplicabile din Directiva 2006/42/CE a Parlamentului European și a Consiliului din 17 mai 2006 privind utilajele și modificarea Directivei 95/16/CE, transpusă în legile statelor membre. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD, anexa VI la Directiva ROHS și anexa II la Directiva utilajelor și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) in vitro uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro; a že je (sú) ďalej v zhode s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach a s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2006/42/ES zo 17. mája 2006 o strojových zariadeniach a o zmene a doplnení Smernice 95/16/ES tak, ako boli transponované do zákonov členských štátov. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD, Prílohou VI k Smernici ROHS a Prílohou II k Smernici o strojových zariadeniach a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för *in vitro*-diagnostik samt även överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning samt med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2006/42/EG av den 17 maj 2006 om maskiner och om ändring av direktiv 95/16/EG (omarbetning) som införlivats i medlemsstaternas lagstiftning. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen, bilaga VI till ROHS-direktivet samt bilaga II till maskindirektivet och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu ve ayrıca elektrikli ve elektronik cihazlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin 8 Haziran 2011 tarihli Konseyin ve 2011/65/EU sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine, makinelere ilişkin 17 Mayıs 2006 tarihli Konseyin ve 2006/42/EC sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine ve üye devlet yasalarına aktarılan 95/16/EC sayılı ek Direktife uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV, ROHS Direktifi Ek VI ve Makineler Direktifi Ek II uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altında yayınlanmıştır.

End of form

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: 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

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

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0002FQ
Basic UDI-DI Name: ICT Module
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
09D28-04	ICT Module	56676	W0201010108

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)	Canon Medical Systems Corporation 1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan
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

Declaration of Conformity

Certificate Identification: DOC-08P76, 01R60, 08P77, 08P78-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
08P7640	59238	Alinity c-series ICT Reference Solution	**Self-declared**
01R6070	56676	Alinity c-series Acid Probe Wash	**Self-declared**
08P7740	56676	Alinity c-series Acid Wash	**Self-declared**
08P7840	58236	Alinity c-series Alkaline Wash	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 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: 24-Aug-2018
Effective (Date or Lot Number): 22 Dec 2021

Abbott

IVDD Declaration of Conformity Attribute Update Letter

Number: 01

List Number and Size Code	Name and Descriptions of Devices	GMDN Code
07P5320	Alinity c ICT Sample Diluent	58237

Legal Manufacturer (Name and Address)	Abbott GmbH Max-Planck-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-07P5320-SD DELK TPM- Date of Approval: 22-JUL-2021
Description of updated attributes from IVD Directive 98/79/EC Declaration of Conformity	Change of applied GMDN code (from 58208 to 58237)

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: 04 Oct 2023
Date Issued: 05/Oct/2023

Full Name: **Bridget Norton**
Function: **Senior Manager Regulatory Affairs**
Signature: Bridget Norton
Date of Approval: 05/Oct/2023
Place Issued: Wiesbaden
Effective (Date or Lot Number): 05/Oct/2023

Abbott

Declaration of Conformity

Certificate Identification: DOC-07P5320-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
07P5320	58208	Alinity c ICT Sample Diluent	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: 05-Feb-2019
Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-08P6901-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
08P6901	47868	Alinity c ICT Serum 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-Feb-2019
Effective (Date or Lot Number): 02 Feb 2022

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	Full Name:	Rosemary McEntire
Function:	Director Quality Assurance/Site Quality Head	Function:	Manager Regulatory Affairs
Signature:		Signature:	
Date of Approval:	21 Nov 2023	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	Place Issued:	Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	09 December 2021	Effective (Date or Lot Number):	21 Nov 2023

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

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:

Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

29-Jun-2021
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: **04Y85-20** 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 07116040158
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: 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

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

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: M Smith-Waheed
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

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

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