ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 001922 0008 Rev. 04

Manufacturer: **Abbott Ireland Diagnostics Division**
Finisklin Business Park
Sligo
IRELAND

Product Category(ies): **Products for determination of infection markers and tumour markers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 001922 0008 Rev. 04

Report no.: 713252089 / 713251178-02

Valid from: 2022-05-02
Valid until: 2025-05-26

Date, 2022-05-02

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Ceaicovschi Tudor
Date: 2024.03.28 11:20:54 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 001922 0008 Rev. 04

Model(s): **Products for the determination of infection markers for Hepatitis B, cytomegalovirus, rubella and tumour marker PSA**

Facility(ies): Abbott Ireland Diagnostics Division
Finisklin Business Park, Sligo, IRELAND

The products detailed below are covered under the scope of this certificate:

Annex II List A Products

Product Name	REF N°
ARCHITECT HBsAg Qualitative II Calibrators	2G22-01
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-30
ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit	2G23-25
ARCHITECT HBsAg Calibrators	3M61-02
ARCHITECT HBsAg Controls	6C36-10
ARCHITECT HBsAg Reagent Kit	6C36-29
ARCHITECT HBsAg Reagent Kit	6C36-34
ARCHITECT HBsAg Reagent Kit	6C36-35
ARCHITECT HBsAg Reagent Kit	6C36-43
ARCHITECT HBsAg Reagent Kit	6C36-44
ARCHITECT Anti-HBs Calibrators	7C18-01
ARCHITECT Anti-HBs Calibrators	7C18-03
ARCHITECT Anti-HBs Controls	7C18-10
ARCHITECT Anti-HBs Controls	7C18-13
ARCHITECT Anti-HBs Reagent Kit	7C18-20
ARCHITECT Anti-HBs Reagent Kit	7C18-25

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Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 001922 0008 Rev. 04

Annex II List A Products

Product Name	REF N°
ARCHITECT Anti-HBs Reagent Kit	7C18-27
ARCHITECT Anti-HBs Reagent Kit	7C18-28
ARCHITECT Anti-HBs Reagent Kit	7C18-30
ARCHITECT Anti-HBs Reagent Kit	7C18-34
ARCHITECT Anti-HBs Reagent Kit	7C18-37
ARCHITECT Anti-HBs Reagent kit	7C18-38
ARCHITECT HBsAg Confirmatory V.1 Calibrators	9C94-01
ARCHITECT HBsAg Confirmatory V.1 Controls	9C94-10
ARCHITECT HBsAg Confirmatory V.1 Reagent Kit	9C94-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-35
ARCHITECT Anti-HBs Reagent Kit	7C18-29
ARCHITECT Anti-HBs Reagent Kit	7C18-41
ARCHITECT Anti-HBs Reagent Kit	7C18-39
ARCHITECT Anti-HBs Reagent Kit	7C18-42
ARCHITECT Anti-HBs Reagent Kit	7C18-33
Alinity i HBsAg Calibrators	08P0801
Alinity i HBsAg Controls	08P0810
Alinity i HBsAg Reagent Kit	08P0852
Alinity i HBsAg Confirmatory V.1 Calibrators	08P0901
Alinity i HBsAg Confirmatory V.1 Controls	08P0910
Alinity i HBsAg Confirmatory V.1 Reagent Kit	08P0922
Alinity i HBsAg Qualitative II Calibrators	08P1001
Alinity i HBsAg Qualitative II Controls	08P1010

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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 001922 0008 Rev. 04

Annex II List A Products

Product Name	REF N°
Alinity i HBsAg Qualitative II Reagent Kit	08P1022
Alinity i HBsAg Qualitative II Confirmatory Reagent Kit	08P1122
Alinity i Anti-HBs Reagent Kit	07P8922
Alinity i Anti-HBs Controls	07P8910
Alinity i Anti-HBs Calibrators	07P8901
Alinity i Anti-HBs Reagent Kit	07P8952
Alinity s HBsAg Reagent Kit	06P0255
Alinity s HBsAg Reagent Kit	06P0260
Alinity s HBsAg Confirmatory Reagent Kit	06P0357
Alinity s HBsAg Confirmatory Reagent Kit	06P0359
Alinity s HBsAg Calibrator Kit	06P0202
Alinity s HBSAg Calibrator Kit	06P0204
Alinity s HBsAg Assay Control Kit	06P0210
Alinity s HBsAg Assay Control Kit	06P0213
Alinity s HBsAg Release Control Kit	06P0212
Alinity s HBsAg Release Control Kit	06P0215
ARCHITECT HBsAg Qualitative II Controls	2G22-10
Alinity i HBsAg Qualitative II Reagent Kit	08P1032
Alinity i HBsAg Reagent Kit	08P0832
Alinity i HBsAg Reagent Kit	08P0822
Alinity i HBsAg Reagent Kit	08P0857
Alinity i Anti-HBs Reagent Kit	07P8932
Alinity i Anti-HBs Reagent Kit	07P8957
Alinity i HBsAg Next Qualitative Calibrators	01R6401
Alinity i HBsAg Next Qualitative Controls	01R6410
Alinity i HBsAg Next Qualitative Reagent Kit	01R6422
Alinity i HBsAg Next Qualitative Reagent Kit	01R6432
Alinity i HBsAg Next Confirmatory Reagent Kit	01R6522
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-25
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-30
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-35
ARCHITECT HBsAg Next Confirmatory Reagent Kit	4P77-25
ARCHITECT HBsAg Next Qualitative Calibrators	4P76-01
ARCHITECT HBsAg Next Qualitative Controls	4P76-10

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TÜV SÜD Product Service

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Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 001922 0008 Rev. 04

Annex II List B Products

Product Name	REF N°
ARCHITECT Rubella IgM Reagent Kit	6C18-25
ARCHITECT Rubella IgM Calibrator	6C18-01
ARCHITECT Rubella IgM Controls	6C18-10
ARCHITECT Rubella IgM Controls	6C18-13
ARCHITECT Rubella IgG Reagent Kit	6C17-26/36
ARCHITECT Rubella IgG Calibrators	6C17-03
ARCHITECT Rubella IgG Controls	6C17-13
ARCHITECT Free PSA Reagent Kit	7K71-20/25
ARCHITECT Free PSA Calibrators	7K71-01
ARCHITECT Free PSA Controls	7K71-10
ARCHITECT Total PSA Reagent Kit	7K70-20/25/30/35
ARCHITECT Total PSA Calibrators	7K70-01
ARCHITECT Total PSA Controls	7K70-10
ARCHITECT CMV IgG Avidity Reagent Kit	3L46-25
ARCHITECT CMV IgG Avidity Calibrator and Controls	3L46-11
ARCHITECT CMV IgG Reagent Kit	6C15-20/25/30
ARCHITECT CMV IgG Calibrators	6C15-01
ARCHITECT CMV IgG Controls	6C15-10
ARCHITECT CMV IgM Reagent Kit	6C16-20/25/30
ARCHITECT CMV IgM Calibrator	6C16-01
ARCHITECT CMV IgM Controls	6C16-10
Alinity i CMV IgG Reagent Kit	07P4222 / 07P4232
Alinity i CMV IgG Calibrators	07P4201

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TÜV SÜD Product Service

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Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 001922 0008 Rev. 04

Annex II List B Products

Product Name	REF N°
Alinity i CMV IgG Controls	07P4210
Alinity i CMV IgM Reagent Kit	07P4422 / 07P4432
Alinity i CMV IgM Calibrator	07P4401
Alinity i CMV IgM Controls	07P4410
Alinity i Rubella IgG Reagent Kit	08P4622 / 08P4632
Alinity i Rubella IgG Calibrators	08P4601
Alinity i Rubella IgG Controls	08P4610
Alinity i Rubella IgM Reagent Kit	08P4722 / 08P4732
Alinity i Rubella IgM Calibrator	08P4701
Alinity i Rubella IgM Controls	08P4710
Alinity i Rubella IgM Controls	08P4713
Alinity i CMV IgG Avidity Reagent Kit	07P4322
Alinity i CMV IgG Avidity Controls	07P4310
Alinity s CMV IgG Qualitative Reagent Kit	06P1045
Alinity s CMV IgG Qualitative Calibrator Kit	06P1002
Alinity s CMV IgG Qualitative Assay Control Kit	06P1010
Alinity s CMV IgG Qualitative Release Control Kit	06P1012
Alinity i Free PSA Reagent Kit	07P9320 / 07P9330
Alinity i Free PSA Calibrators	07P9301
Alinity i Free PSA Controls	07P9310
Alinity i Total PSA Reagent Kit	07P9220 / 07P9230
Alinity i Total PSA Calibrators	07P9201
Alinity i Total PSA Controls	07P9210

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ABBOTT

Declaration of Conformity

Certificate Identification: 7K77
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
7K77-20 7K77-25 7K77-35	54322	ARCHITECT Progesterone Reagent Kit	**Self-declared**
7K77-01	54325	ARCHITECT Progesterone Calibrators	**Self-declared**
7K77-10	54326	ARCHITECT Progesterone Controls	**Self-declared**
7K77-50	58208	ARCHITECT Progesterone Manual Diluent	**Self-declared**

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

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name:	**Siobhan Wright**	Full Name:	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	24-APR-19	Date of Approval:	19 APR 2019
Date Issued:	24-APR-19	Place Issued	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes	05-May-2016	Effective (Lot number or date)	24-APR-19

Abbott

Declaration of Conformity

Certificate Identification:	7K76
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
7K76-20 7K76-25 7K76-30 7K76-35	54335	ARCHITECT Prolactin Reagent Kit	**Self-declared**
7K76-01	54337	ARCHITECT Prolactin Calibrators	**Self-declared**
7K76-10	54338	ARCHITECT Prolactin Controls	**Self-declared**

Authorized European Representative (Name and Address)	N/A
Storage of site technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. Department: Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name:	**Siobhan Wright**	Full Name:	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Senior Manager Regulatory Affairs/**
Date of Approval:	24-APR-19	Date of Approval:	19 APR 2019
Date Issued:	24-APR-19	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	25-May-2017	Effective (Date or Lot Number):	24-APR-19

Abbott

Declaration of Conformity

Certificate Identification: DoC-3P36- AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3P36-20	58348	ARCHITECT AFP Reagent Kit	**Self-Declared**
3P36-25	58348	ARCHITECT AFP Reagent Kit	**Self-Declared**
3P36-30	58348	ARCHITECT AFP Reagent Kit	**Self-Declared**
3P36-35	58348	ARCHITECT AFP Reagent Kit	**Self-Declared**
3P36-01	54062	ARCHITECT AFP Calibrators	**Self-Declared**
3P36-10	54063	ARCHITECT AFP Controls	**Self-Declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Joe Murray
Full Name: Joe Murray
Position: Quality Manager
Date of Approval: 05 Jan 17

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 05 Jan 17
Date Issued: 05 Jan 17
Place Issued: AIDD Sligo
Supersedes: 25 Sep 14
Effective (Date or Lot Number): 05 Jan 17

Declaration of Conformity

Certificate Identification: 07K75
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
7K75-20 7K75-25 7K75-30 7K75-35	54187	ARCHITECT FSH Reagent Kit	**Self-declared**
7K75-01	38255	ARCHITECT FSH Calibrators	**Self-declared**
7K75-10	38254	ARCHITECT FSH Controls	**Self-declared**

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

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC and transposed Irish Regulation S.I. No 304 of 2001 and to the EC Directive 98/79/EC as it is transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Siobhan Wright
Full Name: **Siobhan Wright**
Position: **Director Quality Assurance/Site Quality Head**
Date of Approval: 24-APR-19
Date Issued: 24-APR-19
Supersedes: 15 Nov 2018

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

ABBOTT

Declaration of Conformity

Certificate Identification: 02P40
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
2P40-25 2P40-35	54254	ARCHITECT LH Reagent Kit	**Self-declared**
2P40-01	38270	ARCHITECT LH Calibrators	**Self-declared**

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

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC and transposed Irish Regulation S.I. No 304 of 2001 and to the EC Directive 98/79/EC as it is transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Siobhan Wright
Full Name: **Siobhan Wright**
Position: **Director Quality Assurance/Site Quality Head**
Date of Approval: 24-APR-19
Date Issued: 24-APR-19
Supersedes: 12 OCT 2018

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

Abbott

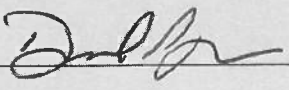
Declaration of Conformity

Certificate Identification:	02K46 LC	IRIS V3
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division	
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA	

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K46-20	58728	ARCHITECT Anti-Tg Reagent Kit	**Self-declared**
2K46-25	58728	ARCHITECT Anti-Tg Reagent Kit	**Self-declared**
2K46-01	55199	ARCHITECT Anti-Tg Calibrators	**Self-declared**
2K46-10	55200	ARCHITECT Anti-Tg Controls	**Self-declared**

Authorized European Representative (Name and Address)	Abbott GmbH Max-Planck-Ring-2 65205 Wiesbaden, Germany
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 22645-1905
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: Daniel Glynn

Position: Manager, Global PQA

Date of Approval: 7-1-2021

Date Issued: 1 July 2021

Supersedes: 5/28/2015

Signature: 

Full Name: Jacek Gorzowski

Position: Associate Director Regulatory Affairs

Date of Approval: 1 July 2021

Place Issued: Abbott Laboratories Diagnostics Division
Abbott Park, IL 60064 U.S.A.

Effective (Date or Lot Number): 1 July 2021

Abbott

Declaration of Conformity

Certificate Identification: 02K47 LC IRIS V4
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

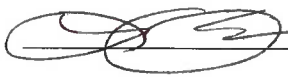
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K47-20	58729	ARCHITECT Anti-TPO Reagent Kit	**Self-declared**
2K47-25	58729	ARCHITECT Anti-TPO Reagent Kit	**Self-declared**
2K47-27	58729	ARCHITECT Anti-TPO Reagent Kit	**Self-declared**
2K47-01	55210	ARCHITECT Anti-TPO Calibrators	**Self-declared**
2K47-10	55211	ARCHITECT Anti-TPO Controls	**Self-declared**

Authorized European Representative (Name and Address)	Abbott GmbH Max-Planck-Ring-2 65205 Wiesbaden, Germany
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 22645-1905
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: Elizabeth Wernquist
Position: Director QA, LC Site
Date of Approval: 27 OCT 2021
Date Issued: 8 November 2021
Supersedes: 11 July 2017

Signature: 

Full Name: Jacek Gorzowski
Position: Associate Director Regulatory Affairs
Date of Approval: 8 November 2021
Place Issued: Abbott Laboratories Diagnostics Division
Abbott Park, IL 60064 U.S.A.
Effective (Date or Lot Number): 8 November 2021

ABBOTT

Declaration of Conformity

Certificate Identification: 07K61
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K61-25 7K61-35	60779	ARCHITECT B12 Reagent Kit	**Self-declared**
7K61-01	41337	ARCHITECT B12 Calibrators	**Self-declared**
7K61-10	41338	ARCHITECT B12 Controls	**Self-declared**

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

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC and transposed Irish Regulation S.I. No 304 of 2001 and to the EC Directive 98/79/EC as it is transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Siobhan Wright
Full Name: **Siobhan Wright**
Position: **Director Quality Assurance/Site Quality Head**
Date of Approval: 24-APR-19
Date Issued: 24-APR-19
Supersedes: 12 OCT 2018

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

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ARK0245MK
Basic UDI-DI Name: ARCHITECT CA 125 II
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
2K45-24	ARCHITECT CA 125 II Reagent Kit	54588	W0102030106
2K45-29	ARCHITECT CA 125 II Reagent Kit	54588	W0102030106
2K45-39	ARCHITECT CA 125 II Reagent Kit	54588	W0102030106
2K45-02	ARCHITECT CA 125 II Calibrators	38231	W0102152205
2K45-11	ARCHITECT CA 125 II Controls	38230	W0102152005

Manufacturer (Name and Address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
Manufacturer SRN	DE-MF-000009455	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of manufacture) (Name and Address)	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, PA 19355 USA	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, including an assessment of the technical documentation for devices concerned on the basis of representative samples.	**EU Certificate No. No. V12 0100510137**
Common Specifications (CS)	N/A	

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

Full Name: Claudia Becker
Function: Director Quality Assurance
Signature: C. Becker
Date of Approval: 15 Mar 2024

Full Name: Susanne Ulrich
Function: Assoc. Director Regulatory Affairs
Signature: Susanne Ulrich
Date of Approval: 12/12/2024

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

Date Issued: 15 Mar 2024
Place Issued: 65205 Wiesbaden, Germany

Supersedes: 26-Jan-2023
Effective (Date or Lot Number): 15 Mar 2024

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 dvoučíslí 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- 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 iepakojuma kods	Produkta un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimas
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 și cod dimensiune	Denumirea produsului și 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 Ürün 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 şi 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 (fremstillingssted) (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 şi adresă)	SRN reprezentant autorizat	Produs de către (locaţie producţie) (nume şi 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	Notified Body (Name and Identification Number)	Conformity Assessment Procedure
BG	Нотифициран орган (име и идентификационен номер)	Процедура за оценка на съответствието
CS	Oznámený subjekt (název a identifikační číslo)	Postup posuzování shody
DA	Bemyndiget organ (navn og identifikationsnummer)	Overensstemmelsesvurderingsprocedure
DE	Benannte Stelle (Name und Identifikationsnummer)	Konformitätsbewertungsverfahren
EL	Κοινοποιημένος Οργανισμός (Όνομα και Αριθμός ταυτοποίησης)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Organismo Notificado (nombre y número de identificación	Procedimiento de evaluación de la conformidad
ET	Teavitatud asutus (nimi ja identifitseerimisnumber)	Vastavushindamismenetlus
FR	Organisme notifié (nom et numéro d'identification)	Procédure d'évaluation de la conformité
HR	Prijavljeno tijelo (naziv i identifikacijski broj)	Postupak ocjenjivanja sukladnosti
HU	Bejelentett szervezet (név és azonosító szám)	Megfelelőségértékelési eljárás
IT	Organismo notificato (nome e numero di identificazione)	Procedura di valutazione della conformità
LV	Pilnvarotā iestāde (nosaukums un identifikācijas numurs)	Atbilstības novērtēšanas procedūra
LT	Notifikuotoji įstaiga (pavadinimas ir identifikacinis numeris)	Atitikties vertinimo procedūra
NO	Meldt organ (navn og identifikasjonsnummer)	Framgangsmåte for samsvarsvurdering
PL	Jednostka notyfikowana (nazwa i numer identyfikacyjny)	Procedura oceny zgodności
PT	Organismo Notificado (Nome e Número de Identificação)	Procedimento de avaliação da conformidade
RO	Organism notificat (nume şi număr de identificare)	Procedură de evaluare a conformității
SK	Notifikovaný orgán (Názov a identifikačné číslo)	Postup posudzovania zhody
SV	Anmält organ (namn och identifikationsnummer)	Förfarande för bedömning av överensstämmelse
TR	Onaylanmış Kuruluş (İsim ve Tanım Numarası)	Uygunluk Değerlendirme Prosedürü

EN	**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**
BG	Система за управление на качеството Приложение IX, глави I и III, включително оценка на техническата документация на съответните изделия въз основа на представителни проби
CS	Systém řízení kvality Příloha IX Kapitoly I a III, včetně posouzení technické dokumentace dotčených prostředků na základě reprezentativních vzorků
DA	Kvalitetsstyringssystem Bilag IX kapitel I og III, Herunder en vurdering af den tekniske dokumentation for relevant udstyr på baggrund af repræsentative prøver
DE	Qualitätsmanagementsystem Anhang IX Kapitel I und III, einschließlich einer Bewertung der Technischen Dokumentation für betroffene Produkte auf der Grundlage repräsentativer Stichproben
EL	Σύστημα Διαχείρισης Ποιότητας Παράρτημα IX Κεφάλαια I και III, συμπεριλαμβάνεται αξιολόγηση του τεχνικού φακέλου για προϊόντα που εξετάζονται με βάση αντιπροσωπευτικά δείγματα
ES	Sistema de Gestión de Calidad Anexo IX, capítulos I y III, se incluye una evaluación de la documentación técnica para los productos afectados sobre la base de muestras representativas
ET	Kvaliteedijuhtimissüsteem IX lisa I ja III peatükk Sealhulgas asjaomaste seadmete tehnilise dokumentatsiooni hindamist esindavate valimite põhjal
FR	Système de gestion de la qualité Annexe IX Chapitres I et III, Inclut une évaluation de la documentation technique pour les dispositifs concernés, sur la base d'échantillons représentatifs
HR	Sustav upravljanja kvalitetom Prilog IX., Poglavlja I. i III., uključujući ocjenjivanje tehničke dokumentacije za predmetne proizvode na temelju reprezentativnih uzoraka
HU	Minőségirányítási rendszer IX. melléklet, I. és III. fejezet, ideértve az érintett eszközök műszaki dokumentációjának reprezentatív minták alapján való értékelését
IT	Sistema di gestione della qualità Allegato IX Capitoli I e III, compresa una valutazione della documentazione tecnica per i dispositivi interessati sulla base di campioni rappresentativi
LV	Kvalitātes vadības sistēma IX pielikuma I un III nodaļa, tostarp attiecīgo ierīču tehniskās dokumentācijas novērtējums, pamatojoties uz reprezentatīviem paraugiem
LT	Kokybės valdymo sistema IX priedo I ir III skyriai, įskaitant atitinkamų priemonių techninės dokumentacijos vertinimą remiantis tipiniais pavyzdžiais
NO	Kvalitetsstyringssystem Vedlegg IX kapittel I og III, inkludert en vurdering av den tekniske dokumentasjonen for aktuelt utstyr på grunnlag av representative prøver
PL	System Zarządzania Jakością Załącznik IX, Rozdziały I oraz III, w tym ocena dokumentacji technicznej danych wyrobów na podstawie reprezentatywnych próbek
PT	Sistema de gestão da qualidade Anexo IX Capítulos I e III, Incluindo uma avaliação da documentação técnica para os dispositivos em questão com base em amostras representativas
RO	Sistemul de management al calității Anexa IX, Capitolele I și III inclusiv o evaluare a documentației tehnice pentru dispozitivele în cauză pe baza unor probe reprezentative.
SK	Systém riadenia kvality Príloha IX Kapitoly I a III, vrátane posúdenia technickej dokumentácie príslušných pomôcok na základe reprezentatívnych vzoriek
SV	Kvalitetsledningssystem Bilaga IX Kapitel I och III, Inklusive en bedömning av den tekniska dokumentationen för berörda produkter som grundar sig på representativa urval
TR	Kalite Yönetim Sistemi Ek IX Bölüm I ve III Temsili numuneler bazında ilgili cihazlar için teknik dokümantasyonun değerlendirilmesi dahil

EN	EU Certificate No.	Common Specifications (CS)	Full Name
BG	ЕС Сертификат №	Общи спецификации (ОС)	Пълно наименование
CS	Číslo certifikátu EU	Společné specifikace	Celý název
DA	EU-certifikatnummer	Fælles specifikationer	Fulde navn
DE	Nr. des EU-Zertifikats	Gemeinsame Spezifikationen (GS)	Vollständiger Name
EL	Αριθμός πιστοποιητικού ΕΕ	Κοινές προδιαγραφές (ΚΠ)	Πλήρης ονομασία
ES	Número certificado UE	Especificaciones comunes	Nombre completo
ET	EL-i sertifikaadi nr	Ühtsed kirjeldused	Täisnimi
FR	N° certificat UE	Spécifications communes	Nom complet
HR	EU potvrda br.	Zajedničke specifikacije („CS“)	Puni naziv
HU	EU-tanúsítvány száma	Egységes előírások	Teljes név
IT	N° del certificato UE	Specifiche comuni (SC)	Nome completo
LV	ES sertifikāta Nr.	Kopīgās specifikācijas	Pilns nosaukums
LT	ES sertifikatas Nr.	Bendrosios specifikacijos	Vardas ir pavardė
NO	EU-sertifikatnr.	Felles spesifikasjoner	Fullt navn
PL	Nr Certyfikatu UE	Wspólne specyfikacje	Imię i nazwisko
PT	Certificado UE Nº	Especificações comuns	Nome completo
RO	Nr. certificat UE:	Specificaţii comune (CS)	Numele complet
SK	Certifikát EÚ č.	Spoločné špecifikácie	Celý názov
SV	Nummer på EU-intyg	Gemensamma specifikationer	Fullständigt namn
TR	AB Sertifika Numarası	Genel Spesifikasyonlar (GS)	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	Funcţia	Semnat pentru şi 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	**I, 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.**
BG	Аз, долуподписаният, с настоящото декларирам, 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. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD и за нейното издаване отговорност носи единствено производителят.
CS	Já, níže podepsaný(-á) tímto prohlašuji, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) 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. Toto prohlášení je v souladu s Přílohou IV Nařízení IVD a je vydáno na výhradní odpovědnost výrobce.
DA	Jeg, 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. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV og udstedes under fabrikantens eneansvar.
DE	Ich, der Unterzeichner, erkläre 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. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εγώ, ο υπογράφων δηλώνω 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. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή
ES	Yo, el abajo firmante, por la presente declaro 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*. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD y es emitida bajo la responsabilidad única del fabricante.
ET	Mina, allakirjutanu, kinnitan, 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. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
FR	Je soussigné(e), déclare 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*. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV sous la seule responsabilité du fabricant.
HR	Ja, niže potpisan/a, ovim putem izjavljujem 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. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírott ezennel kijelentem, 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 (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.
IT	Io, sottoscritto, con la presente dichiaro che il dispositivo(i) medico-diagnostico *in vitro* sopra descritto è conforme 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*. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Es, apakšā parakstījies, ar šo paziņoju, 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. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu un ir izdota vienīgi uz ražotāja atbildību.
LT	Aš, toliau pasirašęs (-iusi), pareiškiu, 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 taikomas nuostatas. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu ir išduota tik gamintojo atsakomybe.
NO	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. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen og er utstedt under produsentens eneansvar.
PL	Ja, niżej podpisany(-a), niniejszym oświadczam, 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. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR i wydana na wyłączną odpowiedzialność producenta.
PT	Eu, abaixo assinado, declaro 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*. Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD e é emitida sob a exclusiva responsabilidade do fabricante.

RO	Subsemnatul, declar că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispoziţiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European şi al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro. Prezenta declaraţie este emisă în conformitate cu anexa IV la Regulamentul IVD şi este emisă sub responsabilitatea exclusivă a producătorului.
SK	Ja, dolupodpísaný(-á), týmto vyhlasujem. že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) 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. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Jag, undertecknad, 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. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen och utfärdas under tillverkarens enskilda ansvar.
TR	Ben, aşağıda imzası bulunan, yukarıda belirtilen in vitro diagnostik medikal cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Direktifi ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Medikal Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu beyan ederim. Bu beyan IVD Direktifi Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.

End of document

Abbott

Declaration of Conformity

Certificate Identification: DoC-2K91-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
2K91-24	60976	ARCHITECT CA 19-9$_{XR}$ Reagent Kit	**Self-declared**
2K91-32	60976	ARCHITECT CA 19-9$_{XR}$ Reagent Kit	**Self-declared**
2K91-39	60976	ARCHITECT CA 19-9 $_{XR}$ Reagent Kit	**Self-declared**
2K91-03	38225	ARCHITECT CA 19-9 $_{XR}$ Calibrators	**Self-declared**
2K91-12	38224	ARCHITECT CA 19-9 $_{XR}$ Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania 19355, 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: 20 Dec 2021

Signature: Susanne Ulrich
Full Name: **Susanne Ulrich**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 21 Dec 2021
Date Issued: 21-Dec-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 19-June-2019
Effective (Date or Lot Number): 21-Dec-2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-7K68- AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K68-22	54615	ARCHITECT CEA Reagent Kit	**Self-declared**
7K68-27	54615	ARCHITECT CEA Reagent Kit	**Self-declared**
7K68-32	54615	ARCHITECT CEA Reagent Kit	**Self-declared**
7K68-35	54615	ARCHITECT CEA Reagent Kit	**Self-declared**
7K68-02	38174	ARCHITECT CEA Calibrators	**Self-declared**
7K68-12	38173	ARCHITECT CEA Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: Joe Murray
Full Name: Joe Murray
Position: Quality Manager
Date of Approval: 05 Jan 17

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 05 Jan 17
Date Issued: 05 Jan 17
Place Issued: AIDD Sligo
Supersedes: 25 Sep 2014
Effective (Date or Lot Number): 05 Jan 17

Abbott

IVDD Declaration of Conformity Attribute Update Letter

Number: 1

List Number and Size Code	Name and Descriptions of Devices	GMDN Code
7K72-20 7K72-25 7K72-35	ARCHITECT Estradiol Reagent Kit	60979
7K72-01	ARCHITECT Estradiol Calibrators	38249
7K72-10	ARCHITECT Estradiol Controls	38248
7K72-50	ARCHITECT Estradiol Manual Diluent	58237

Legal Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland
Authorized European Representative (Name and Address)	N/A
Storage Site of Technical Documentation (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland

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

IVD Directive 98/79/EC Declaration of Conformity Identification	ARCH Estradiol EU DOC-effective date 06 Jun 2019
Description of updated attributes from IVD Directive 98/79/EC Declaration of Conformity	Update to GMDN Code. GMDN Code 58208 was made obsolete by GMDN. This has been replaced with new GMDN Code 58237 for 7K72-50 ARCHITECT Estradiol Manual Diluent.

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

Full Name: David Spellman
Function: Director Quality Assurance/Site Quality Head
Signature:
Date of Approval: 21 Nov 2023
Date Issued: 21 Nov 2023

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. McEntire
Date of Approval: 21 NOV 2023
Place Issued: Lisnamuck, Longford, Co. Longford, Ireland.
Effective (Date or Lot Number): 21 Nov 2023

ABBOTT

Declaration of Conformity

Certificate Identification: 07K72
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
7K72-20 7K72-25 7K72-35	60979	ARCHITECT Estradiol Reagent Kit	**Self-declared**
7K72-01	38249	ARCHITECT Estradiol Calibrators	**Self-declared**
7K72-10	38248	ARCHITECT Estradiol Controls	**Self-declared**
7K72-50	58208	ARCHITECT Estradiol Manual Diluent	**Self-declared**

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

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name:	**Siobhan Wright**	Full Name:	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	06-JUN-19	Date of Approval:	06 Jun 2019
Date Issued:	06-JUN-19	Place Issued	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes	29 April 2019	Effective (Lot number or date)	06-JUN-19