

# Certificate of Approval

This is to certify that the Management System of:

## Abbott GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

MDSAP Facility Identifier: F003705

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

### ISO 13485:2016

#### Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1  
(Excluding Part 1.6) – Full Quality Assurance Procedure

#### Brazil:

RDC ANVISA n. 16/2013  
RDC ANVISA n. 23/2012  
RDC ANVISA n. 67/2009

#### Canada:

Medical Devices Regulations – Part 1- SOR 98/282

#### Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68  
PMD Act

#### United States:

21 CFR 803  
21 CFR 806  
21 CFR 807 – Subparts A to D  
21 CFR 820

Approval number: MDSAP – 0079011

#### The scope of this approval is applicable to:

Design, development, manufacture, control of contract manufacturers, registration, stockholding and distribution of in-vitro diagnostic devices.



David Derrick

Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited



Lloyd's Register Quality Assurance  
Limited is an MDSAP authorised  
auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

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# Certificate of Approval

This is to certify that the Management System of:

## Abbott GmbH & Abbott Diagnostics GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

has been approved by Lloyd's Register to the following standards:

### ISO 9001:2015

Approval number: ISO 9001 – 00004791

**The scope of this approval is applicable to:**

Design, development, manufacture, control of contract manufacturers, registration, stockholding and distribution of in-vitro diagnostic devices.



**David Derrick**

Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited



# Certificate of Approval

This is to certify that the Management System of:

## Abbott GmbH & Abbott Diagnostics GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

has been approved by Lloyd's Register to the following standards:

**EN ISO 13485:2016 | ISO 13485:2016**

Approval number: ISO 13485 – 00004790

**The scope of this approval is applicable to:**

Design, development, manufacture, control of contract manufacturers, registration, stockholding and distribution of in-vitro diagnostic devices.



**David Derrick**

Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited





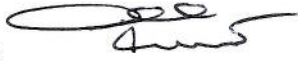
## Declaration of Conformity


**Certificate Identification:** AIDD 3P36  
**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 3P36-25 3P36-30 3P36-35	17259	ARCHITECT AFP Reagent	Self-declared
3P36-01	38167	ARCHITECT AFP Calibrators	Self-declared
3P36-10	38166	ARCHITECT AFP Controls	Self-declared
<b>Authorized European Representative (Name and Address)</b>	N/A		
<b>Storage site of technical documentation (Name and Address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.		
<b>Harmonized Standards</b>	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: Niall Plunkett  
 Position: Quality Manager  
 Date of Approval: 07 Jun 14  
 Date Issued: 07 Jul 14  
 Supersedes: 13 Jan 2013

Signature:   
 Full Name: Lorraine Whitney  
 Position: Senior Manager Regulatory Affairs  
 Date of Approval: 04 July 2014  
 Place Issued: AIDD Sligo  
 Effective (Date or Lot Number): 07 Jul 14



## Declaration of Conformity

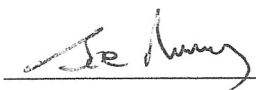
**Certificate Identification:** DoC-7C18 (re-standardised Mag-Sep) -AIDD Sligo  
**Legal Manufacturer's Name:** Abbott Ireland Diagnostics Division  
**Legal Manufacturer's Address:** Finisklin Business Park, Sligo, Ireland

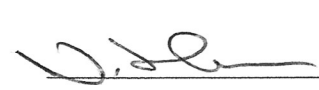
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7C18-29	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-39	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-33	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-41	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-42	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-03	41997	ARCHITECT Anti-HBs Calibrators	Annex II List A
7C18-13	41998	ARCHITECT Anti-HBs Controls	Annex II List A

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
<b>Notified Body number</b>	0123
<b>Approval Certificate No.</b>	V7 001922 0012
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
<b>Harmonized Standards</b>	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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature:   
 Full Name: Joe Murray  
 Position: Director Quality Assurance/Site Quality Head

Signature:   
 Full Name: Noel Haren  
 Position: Manager Regulatory Affairs

Date of Approval: 12 Oct 2021

Date of Approval: 18 OCT 2021

Date Issued: 18 OCT 2021

Place Issued: AIDD, Sligo

Supersedes: 25 Nov 2019

Effective (Date or Lot Number): 18 OCT 2021



## 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

<b>Authorized European Representative (Name and Address)</b>	Abbott GmbH Max-Planck-Ring-2 65205 Wiesbaden, Germany
<b>Storage Site of Technical Documentation (Name and Address)</b>	Fisher Diagnostics a division of Fisher Scientific Company LLC a part of Thermo Fisher Scientific Inc. 8365 Valley Pike, Middletown, VA 22645-1905
<b>Harmonized Standards</b>	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: 29 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

## Declaration of Conformity


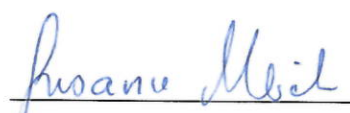
**Certificate Identification:** DoC-2K45-SD DELK TPM  
**Legal Manufacturer's Name:** Abbott GmbH  
**Legal Manufacturer's Address:** Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K45-24	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-29	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-39	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-02	38231	ARCHITECT CA 125 II Calibrators	Self-declared
2K45-11	38230	ARCHITECT CA 125 II Controls	Self-declared

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania 19355, USA.
<b>Harmonized Standards</b>	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: <u></u>	Signature: <u></u>
Full Name: <b>Dr. Jörg Amborn</b>	Full Name: <b>Susanne Ulrich</b>
Position: <b>Director Quality Assurance</b>	Position: <b>Senior Manager Regulatory Affairs</b>
Date of Approval: <u>2020-05-14</u>	Date of Approval: <u>12/ May / 2020</u>
	Date Issued: <u>14- May- 2020</u>
	Place Issued: 65205 Wiesbaden, Germany
	Supersedes: 12-May-2017
	Effective (Date or Lot Number): <u>14- May- 2020</u>

# Declaration of Conformity



**Certificate Identification:** DoC-2K44-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
2K44-21	60975	ARCHITECT CA 15-3 Reagent Kit	Self-declared
2K44-27	60975	ARCHITECT CA 15-3 Reagent Kit	Self-declared
2K44-37	60975	ARCHITECT CA 15-3 Reagent Kit	Self-declared
2K44-02	38223	ARCHITECT CA 15-3 Calibrators	Self-declared
2K44-11	38222	ARCHITECT CA 15-3 Controls	Self-declared

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania 19355, USA.
<b>Harmonized Standards</b>	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.**

<p>Signature: <u></u></p> <p>Full Name: <b>Claudia Becker</b></p> <p>Position: <b>Director Quality Assurance</b></p> <p>Date of Approval: <u>25 May 2021</u></p>	<p>Signature: <u></u></p> <p>Full Name: <b>Susanne Ulrich</b></p> <p>Position: <b>Assoc. Director Regulatory Affairs</b></p> <p>Date of Approval: <u>25 May 2021</u></p> <p>Date Issued: <u>25-May-2021</u></p> <p>Place Issued: 65205 Wiesbaden, Germany</p> <p>Supersedes: 12-May-2017</p> <p>Effective (Date or Lot Number): <u>25-May-2021</u></p>
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## 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 <sub>XR</sub> Reagent Kit	Self-declared
2K91-32	60976	ARCHITECT CA 19-9 <sub>XR</sub> Reagent Kit	Self-declared
2K91-39	60976	ARCHITECT CA 19-9 <sub>XR</sub> Reagent Kit	Self-declared
2K91-03	38225	ARCHITECT CA 19-9 <sub>XR</sub> Calibrators	Self-declared
2K91-12	38224	ARCHITECT CA 19-9 <sub>XR</sub> Controls	Self-declared

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania 19355, USA.
<b>Harmonized Standards</b>	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: <u>C. Becker</u>	Signature: <u>Susanne Ulrich</u>
Full Name: <b>Claudia Becker</b>	Full Name: <b>Susanne Ulrich</b>
Position: <b>Director Quality Assurance</b>	Position: <b>Assoc. Director Regulatory Affairs</b>
Date of Approval: <u>20 Dec 2021</u>	Date of Approval: <u>21 Dec 2021</u>
	Date Issued: <u>21- Dec - 2021</u>
	Place Issued: 65205 Wiesbaden, Germany
	Supersedes: 19-June-2019
	Effective (Date or Lot Number): <u>21- Dec - 2021</u>



## Declaration of Conformity

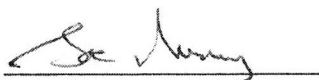
**Certificate Identification:** DoC-7K68- AIDD Sligo  
**Legal Manufacturer's Name:** Abbott Ireland Diagnostics Division  
**Legal Manufacturer's Address:** Finisklin Business Park, Sligo, Ireland

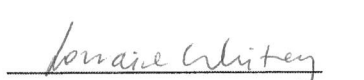
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K68-22	54615	ARCHITECT CEA Reagent Kit	Self-declared
7K68-27	54615	ARCHITECT CEA Reagent Kit	Self-declared
7K68-32	54615	ARCHITECT CEA Reagent Kit	Self-declared
7K68-35	54615	ARCHITECT CEA Reagent Kit	Self-declared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

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
<b>Harmonized Standards</b>	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:** Joe Murray  
**Position:** Quality Manager  
**Date of Approval:** 05 Jan 17

**Signature:**   
**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

## 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	30321	ARCHITECT Estradiol Reagent Kits	<b>Self-declared</b>
7K72-01	38249	ARCHITECT Estradiol Calibrators	<b>Self-declared</b>
7K72-10	38248	ARCHITECT Estradiol Controls	<b>Self-declared</b>
7K72-50	N/A	ARCHITECT Estradiol Manual Diluent	<b>Self-declared</b>

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
<b>Harmonized Standards</b>	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: *Siobhán Wright*  
 Full Name (printed): **Siobhán Wright**  
 Position: **Quality Manager**

Signature: *Lorraine Whitney*  
 Full Name (printed): **Lorraine Whitney**  
 Position: **Manager Regulatory Affairs**

Date: 05 NOV 2013

Date: 01 NOV 2013

Date Issued: 05 NOV 2013

Place Issued: Abbott Ireland Diagnostics Division,  
Lisnamuck, Longford, Co. Longford, Ireland.

Supersedes: 30 MAR 2012

Effective (Lot number or date) 05 NOV 2013

## Declaration of Conformity

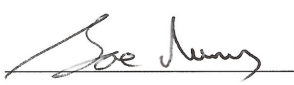
**Certificate Identification:** DoC-7K71- AIDD Sligo  
**Legal Manufacturer's Name:** Abbott Ireland Diagnostics Division  
**Legal Manufacturer's Address:** Finisklin Business Park, Sligo, Ireland


List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K71-20	54669	ARCHITECT Free PSA Reagent Kit	Annex II List B
7K71-25	54669	ARCHITECT Free PSA Reagent Kit	Annex II List B
7K71-01	38183	ARCHITECT Free PSA Calibrators	Annex II List B
7K71-10	38182	ARCHITECT Free PSA Controls	Annex II List B

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
<b>Notified Body number</b>	0123
<b>Approval Certificate No.</b>	V1 0019220008
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
<b>Harmonized Standards</b>	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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature:   
 Full Name: Joe Murray  
 Position: Director Quality Assurance/Site Quality Head

Signature:   
 Full Name: Noel Haren  
 Position: Manager Regulatory Affairs

Date of Approval: 20 Nov 19  
 Date Issued: 20 NOV 2019

Date of Approval: 19 Nov 2019

Supersedes: 14 October 2019

Place Issued: AIDD, Sligo

Effective (Date or Lot Number): 20 NOV 2019

## Declaration of Conformity

**Certificate Identification:** 7K63  
**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
7K63-27 7K63-32 7K63-37	54417	ARCHITECT Free T <sub>3</sub> Reagent Kit	Self-declared
7K63-02	38261	ARCHITECT Free T <sub>3</sub> Calibrators	Self-declared
7K63-12	54418	ARCHITECT Free T <sub>3</sub> Controls	Self-declared
<b>Authorized European Representative (Name and Address)</b>		N/A	
<b>Storage of technical documentation (Name and Address)</b>		Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland	
<b>Harmonized Standards</b>		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.**

<p>Signature: <u><i>Siobhan Wright</i></u></p> <p>Full Name: <b>Siobhan Wright</b></p> <p>Position: <b>Director Quality Assurance/ Site Quality Head</b></p> <p>Date of Approval: <u>01-MAY-2020</u></p> <p>Date Issued: <u>01-MAY-2020</u></p> <p>Supersedes: <u>24-April-2019</u></p>	<p>Signature: <u><i>Lorraine Whitney</i></u></p> <p>Full Name: <b>Lorraine Whitney</b></p> <p>Position: <b>Senior Manager Regulatory Affairs</b></p> <p>Date of Approval: <u>01 MAY 2020</u></p> <p>Place Issued: <b>Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.</b></p> <p>Effective (Date or Lot Number): <u>01-MAY-2020</u></p>
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### Declaration of Conformity

<b>Certificate Identification:</b>	7K65-22/-24/-27/-29/-32/-34/-35/-39, 7K65-02, 7K65-10
<b>Legal Manufacturer's Name:</b>	Abbott Ireland Diagnostics Division
<b>Legal Manufacturer's Address:</b>	Lisnamuck, Longford
	Co. Longford
	Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K65-22 7K65-24 7K65-27 7K65-29 7K65-32 7K65-34 7K65-35 7K65-39	54413	ARCHITECT Free T4 Reagent Kit	<b>Self-declared</b>
7K65-02	38259	ARCHITECT Free T4 Calibrators	<b>Self-declared</b>
7K65-10	38258	ARCHITECT Free T4 Controls	<b>Self-declared</b>

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

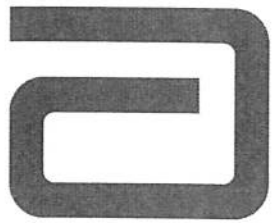
We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they 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*  
 Full Name: **Siobhan Wright**  
 Position: **Director Quality Assurance/  
Site Quality Head**  
 Date of Approval: 29-APR-19  
 Date Issued: 29-APR-19  
 Supersedes: 26-July-2017

Signature: *p.p. SANDRA GALLAGHER S Gallagher*  
 Full Name: **Lorraine Whitney**  
 Position: **Senior Manager Regulatory Affairs**  
 Date of Approval: 25-APR-2019  
 Place Issued: **Abbott Ireland Diagnostics Division,  
Lisnamuck, Longford, Co. Longford,  
Ireland**  
 Effective (Date or Lot Number): 29-APR-19



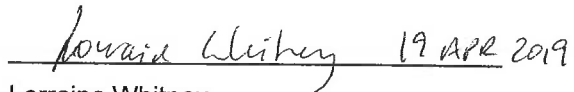


# Memo

To Whom it may concern

I will be out of office Tues 23rd to Fri 26<sup>th</sup> April 19.

My signature during this time is delegated to Noel Haren and Sandra Gallagher.

 19 APR 2019

Lorraine Whitney

Senior Manager Regulatory Affairs

Site Operations Ireland

## Declaration of Conformity

**Certificate Identification:** DoC 8L44 AII DELK  
**Legal Manufacturer's Name:** Abbott GmbH  
**Legal Manufacturer's Address:** Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8L44-25	48304	ARCHITECT Anti-HBc II Reagent Kit (1x100 Tests)	Annex II List A
8L44-30	48304	ARCHITECT Anti-HBc II Reagent Kit (4x500 Tests)	Annex II List A
8L44-35	48304	ARCHITECT Anti-HBc II Reagent Kit (1x500 Tests)	Annex II List A
8L44-01	41983	ARCHITECT Anti-HBc II Calibrator	Annex II List A
8L44-10	41984	ARCHITECT Anti-HBc II Controls	Annex II List A

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
<b>Notified Body number</b>	TÜV SÜD: 0123
<b>Approval Certificate No.</b>	TÜV SÜD: V7 010051 0130
<b>Storage site of technical documentation (name and address)</b>	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
<b>Harmonized Standards</b>	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 IV 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: 06 May 2021

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 04 May 2021

Date Issued: 06-May-2021

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 09-Mar-2020

Effective (Date or Lot Number): 06-May-2021

# Declaration of Conformity

**Certificate Identification:** DoC-6C32/7P24-AII DELK  
**Legal Manufacturer's Name:** Abbott GmbH  
**Legal Manufacturer's Address:** Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C32-20	48331	ARCHITECT HBeAg Reagent Kit (4x100 Tests)	Annex II List A
6C32-25	48331	ARCHITECT HBeAg Reagent Kit (1x100 Tests)	Annex II List A
6C32-27	48331	ARCHITECT HBeAg Reagent Kit (1x100 Tests)	Annex II List A
6C32-37	48331	ARCHITECT HBeAg Reagent Kit (1x500 Tests)	Annex II List A
6C32-01	42007	ARCHITECT HBeAg Calibrators	Annex II List A
6C32-10	42008	ARCHITECT HBeAg Controls	Annex II List A
7P24-01	42007	ARCHITECT HBeAg Quantitative Calibrators	Annex II List A
7P24-10	42008	ARCHITECT HBeAg Quantitative Controls	Annex II List A

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
<b>Notified Body number</b>	TÜV SÜD: 0123
<b>Approval Certificate No.</b>	TÜV SÜD: V7 010051 0120
<b>Storage site of technical documentation (name and address)</b>	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
<b>Harmonized Standards</b>	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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature:		Signature:	
Full Name:	<b>Dr. Jörg Amborn</b>	Full Name:	<b>Susanne Ulrich</b>
Position:	<b>Director Quality Assurance</b>	Position:	<b>Senior Manager Regulatory Affairs</b>
Date of Approval:	<u>2020-03-12</u>	Date of Approval:	<u>12/15/2020</u>
Date Issued:	<u>12-Mar-2020</u>	Place Issued:	65205 Wiesbaden, Germany
Supersedes:	19-Dec-2019	Effective (Date or Lot Number):	<u>12-Mar-2020</u>



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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. 03**

**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. See also notes overleaf.

**Report no.:** 713158801-03

**Valid from:** 2020-01-15  
**Valid until:** 2024-05-26

**Date,** 2020-01-15

Christoph Dicks  
Head of Certification/Notified Body

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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. 03**

**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	3M61-01
ARCHITECT HBsAg Calibrators	3M61-02
ARCHITECT HBsAg Controls	6C36-10
ARCHITECT HBsAg Reagent Kit	6C36-22
ARCHITECT HBsAg Reagent Kit	6C36-27
ARCHITECT HBsAg Reagent Kit	6C36-32
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 HBsAg Reagent Kit	6C36-41
ARCHITECT HBsAg Reagent Kit	6C36-42
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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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. 03**

## 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. 03**

## 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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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. 03**

## 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 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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## Declaration of Conformity

**Certificate Identification:** DoC-2G22-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
2G22-25	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-30	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-35	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-01	41999	ARCHITECT HBsAg Qualitative II Calibrators	Annex II List A
2G22-10	42000	ARCHITECT HBsAg Qualitative II Controls	Annex II List A

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
<b>Notified Body number</b>	0123
<b>Approval Certificate No.</b>	V7 0019220009
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
<b>Harmonized Standards</b>	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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature: 

Full Name: Joe Murray  
Position: Director Quality Assurance/Site Quality Head

Date of Approval: 27 Oct 2020

Date Issued: 27 Oct 2020

Supersedes: 25 November 2019

Signature: 

Full Name: Noel Haren  
Position: Manager Regulatory Affairs

Date of Approval: 27 Oct 2020

Place Issued: AIDD, Sligo

Effective (Date or Lot Number): 27 Oct 2020





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Product Service

# EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

**No. V7 001922 0009 Rev. 01**

**Manufacturer: Abbott Ireland Diagnostics Division**

Finisklin Business Park

Sligo

IRELAND

**Product: Screening and Confirmatory Test  
for Hepatitis B marker**

**Model(s): ARCHITECT HBsAg Qualitative II  
ARCHITECT HBsAg Qualitative II Confirmatory**

Parameters:	Product Name	REF N°
	ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-25
	ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-30
	ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-35
	ARCHITECT HBsAg Qualitative II Calibrators	2G22-01
	ARCHITECT HBsAg Qualitative II Controls	2G22-10
	ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit	2G23-25

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. 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:V7\\_001922\\_0009\\_Rev.01](http://www.tuvsud.com/ps-cert?q=cert:V7_001922_0009_Rev.01)

**Report No.:** 713190856-2

**Valid from:** 2021-05-26

**Valid until:** 2024-05-26

**Date,** 2021-05-25

Christoph Dicks

Head of Certification/Notified Body

## Declaration of Conformity

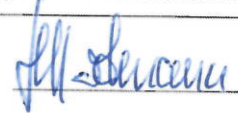
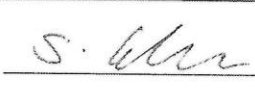
**Certificate Identification:** DOC-6C37-28/-33/-38-AII DLK  
**Legal Manufacturer's Name:** Abbott GmbH  
**Legal Manufacturer's Address:** Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C37-28	48366	ARCHITECT Anti-HCV Reagent Kit (1 x 100 Tests)	Annex II List A
6C37-33	48366	ARCHITECT Anti-HCV Reagent Kit (4 x 500 Tests)	Annex II List A
6C37-38	48366	ARCHITECT Anti-HCV Reagent Kit (1 x 500 Tests)	Annex II List A
6C37-02	41972	ARCHITECT Anti-HCV Calibrator	Annex II List A
6C37-15	41973	ARCHITECT Anti-HCV Controls	Annex II List A

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
<b>Notified Body number</b>	0123
<b>Approval Certificate No.</b>	V7 010051 0132
<b>Storage site of technical documentation (name and address)</b>	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
<b>Harmonized Standards</b>	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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

<p>Signature: <u></u></p> <p>Full Name: <b>Herbert Hartmann</b></p> <p>Position: <b>Manager Quality Systems</b></p> <p>Date of Approval: <u>2021-08-03</u></p>	<p>Signature: <u></u></p> <p>Full Name: <b>Stefan Veber</b></p> <p>Position: <b>Manager Regulatory Affairs</b></p> <p>Date of Approval: <u>2021-08-03</u></p> <p>Date Issued: <u>2021-08-03</u></p> <p>Place Issued: 65205 Wiesbaden, Germany</p> <p>Supersedes: 06-May-2021</p> <p>Effective (Date or Lot Number): <u>2021-08-03</u></p>
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# 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)

**V1 010051 0103 Rev. 10**

**Manufacturer:** **Abbott GmbH**  
Max-Planck-Ring 2  
65205 Wiesbaden  
GERMANY

**Product Category(ies): Products for determination of infection 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\\_010051\\_0103\\_Rev.10.10](http://www.tuvsud.com/ps-cert?q=cert:V1_010051_0103_Rev.10.10)

**Report no.:** 713215031

**Valid from:** 2021-08-20

**Valid until:** 2024-05-26

**Date,** 2021-08-20

Christoph Dicks  
Head of Certification/Notified Body



# 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)

**V1 010051 0103 Rev. 10**

**Model(s):**

**Products for the determination of  
infection markers for HIV, Hepatitis B,  
Hepatitis C, HTLV, toxoplasmosis**

**Facility(ies):**

**Abbott GmbH  
Max-Planck-Ring 2, 65205 Wiesbaden, GERMANY**





# 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)

## V1 010051 0103 Rev. 10

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

### Annex II List A Products

Product Name	REF N°
ABBOTT PRISM HIV O Plus Assay Kit	3D34-48
ABBOTT PRISM HBsAg Assay Kit	3A47-48
ABBOTT PRISM HCV Assay Kit	6A52-48
ABBOTT PRISM HTLV-I/HTLV-II Assay Kit	6A53-48
ABBOTT PRISM Positive Run Control Kit	5E22-11
ABBOTT PRISM Run Control Kit	5E22-10
ABBOTT PRISM HBcore Assay Kit	1A77-48
ABBOTT PRISM HBsAg Confirmatory Assay Kit	6D16-48
ABBOTT PRISM HIV Ag/Ab Combo Assay Kit	7G46-48
ABBOTT PRISM Run Control Kit	2K24-10
ABBOTT PRISM Positive Run Control Kit	2K24-11
ARCHITECT Anti-HCV Reagent Kit	6C37-22
ARCHITECT Anti-HCV Reagent Kit	6C37-27
ARCHITECT Anti-HCV Reagent Kit	6C37-32
ARCHITECT Anti-HCV Reagent Kit	6C37-37
ARCHITECT Anti-HCV Calibrator	6C37-01
ARCHITECT Anti-HCV Controls	6C37-10
ARCHITECT Anti-HCV Reagent Kit	6C37-28
ARCHITECT Anti-HCV Reagent Kit	6C37-33
ARCHITECT Anti-HCV Reagent Kit	6C37-38
ARCHITECT Anti-HCV Calibrator	6C37-02
ARCHITECT Anti-HCV Controls	6C37-15
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-22
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-27
ARCHITECT Anti-HBc IgM Calibrators	6C33-02
ARCHITECT Anti-HBc IgM Controls	6C33-11
ARCHITECT Anti-HBe Reagent Kit	6C34-20
ARCHITECT Anti-HBe Reagent Kit	6C34-25
ARCHITECT Anti-HBe Reagent Kit	6C34-35
ARCHITECT Anti-HBe Calibrator	6C34-01
ARCHITECT Anti-HBe Controls	6C34-10



# 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)

## V1 010051 0103 Rev. 10

### Annex II List A Products

Product Name	REF N°
ARCHITECT HBeAg Reagent Kit	6C32-20
ARCHITECT HBeAg Reagent Kit	6C32-25
ARCHITECT HBeAg Reagent Kit	6C32-27
ARCHITECT HBeAg Reagent Kit	6C32-37
ARCHITECT HBeAg Calibrators	6C32-01
ARCHITECT HBeAg Quantitative Calibrators	7P24-01
ARCHITECT HBeAg Controls	6C32-10
ARCHITECT HBeAg Quantitative Controls	7P24-10
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-22
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-27
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-32
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-37
ARCHITECT HIV Ag/Ab Combo Calibrator	4J27-03
ARCHITECT HIV Ag/Ab Combo Controls	4J27-12
ARCHITECT rHTLV I/II Reagent Kit	6L61-25
ARCHITECT rHTLV I/II Reagent Kit	6L61-30
ARCHITECT rHTLV I/II Reagent Kit	6L61-35
ARCHITECT rHTLV I/II Calibrator	6L61-01
ARCHITECT rHTLV I/II Controls	6L61-10
ARCHITECT Anti-HBc II Reagent Kit	8L44-25
ARCHITECT Anti-HBc II Reagent Kit	8L44-30
ARCHITECT Anti-HBc II Reagent Kit	8L44-35
ARCHITECT Anti-HBc II Calibrator	8L44-01
ARCHITECT Anti-HBc II Controls	8L44-10
ARCHITECT HCV Ag Controls	6L47-11
ARCHITECT HCV Ag Controls	6L47-19
ARCHITECT HCV Ag Calibrators	6L47-02
ARCHITECT HCV Ag Calibrators	6L47-09
ARCHITECT HCV Ag Reagent Kit	6L47-29
ARCHITECT HCV Ag Reagent Kit	6L47-74



# 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)

## V1 010051 0103 Rev. 10

### Annex II List A Products

Product Name	REF N°
Alinity i Anti-HBe Reagent Kit	07P6322
Alinity i Anti-HBe Reagent Kit	07P6332
Alinity i Anti-HBe Calibrator	07P6301
Alinity i Anti-HBe Controls	07P6310
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0722
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0732
Alinity i HIV Ag/Ab Combo Calibrator	08P0701
Alinity i HIV Ag/Ab Combo Controls	08P0710
Alinity i Anti-HCV Reagent Kit	08P0622
Alinity i Anti-HCV Reagent Kit	08P0632
Alinity i Anti-HCV Calibrator	08P0601
Alinity i Anti-HCV Controls	08P0610
Alinity i Anti-HCV Reagent Kit	08P0623
Alinity i Anti-HCV Reagent Kit	08P0633
Alinity i Anti-HCV Calibrator	08P0602
Alinity i Anti-HCV Controls	08P0611
Alinity i Anti-HBc IgM Reagent Kit	07P8622
Alinity i Anti-HBc IgM Calibrators	07P8601
Alinity i Anti-HBc IgM Controls	07P8610
Alinity i Anti-HBc II Reagent Kit	07P8722
Alinity i Anti-HBc II Reagent Kit	07P8732
Alinity i Anti-HBc II Calibrator	07P8701
Alinity i Anti-HBc II Controls	07P8710
Alinity i HCV Ag Reagent Kit	09P2322
Alinity i HCV Ag Controls	09P2310
Alinity i HCV Ag Calibrators	09P2301



# 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)

## V1 010051 0103 Rev. 10

### Annex II List A Products

Product Name	REF N°
Alinity i rHTLV-I/II Reagent Kit	07P6122
Alinity i rHTLV-I/II Reagent Kit	07P6132
Alinity i rHTLV-I/II Calibrator	07P6101
Alinity i rHTLV-I/II Controls	07P6110
Alinity i HBeAg Reagent Kit	07P6422
Alinity i HBeAg Reagent Kit	07P6432
Alinity i HBeAg Calibrators	07P6401
Alinity i HBeAg Controls	07P6410
Alinity i HBeAg Quantitative Calibrators	09P1001
Alinity i HBeAg Quantitative Controls	09P1010
Alinity s Anti-HBc Reagent Kit	06P0655
Alinity s Anti-HBc Calibrator Kit	06P0602
Alinity s Anti-HBc Assay Control Kit	06P0610
Alinity s Anti-HBc Release Control Kit	06P0612
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0155
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0102
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0110
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0112
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0160
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0103
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0120
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0124





# 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)

## V1 010051 0103 Rev. 10

### Annex II List A Products

Product Name	REF N°
Alinity s Anti-HCV Reagent Kit	06P0455
Alinity s Anti-HCV Calibrator Kit	06P0402
Alinity s Anti-HCV Assay Control Kit	06P0410
Alinity s Anti-HCV Release Control Kit	06P0412
Alinity s Anti-HCV Reagent Kit	06P0477
Alinity s Anti-HCV Calibrator Kit	06P0409
Alinity s Anti-HCV Assay Control Kit	06P0419
Alinity s Anti-HCV Release Control Kit	06P0418
Alinity s Anti-HCV Reagent Kit	06P0460
Alinity s Anti-HCV Calibrator Kit	06P0403
Alinity s Anti-HCV Assay Control Kit	06P0420
Alinity s Anti-HCV Release Control Kit	06P0424
Alinity s Anti-HCV II Reagent Kit	04W5655
Alinity s Anti-HCV II Calibrator Kit	04W5602
Alinity s Anti-HCV II Assay Control Kit	04W5610
Alinity s Anti-HCV II Release Control Kit	04W5612
Alinity s HTLV I/II Reagent Kit	06P0755
Alinity s HTLV I/II Calibrator Kit	06P0702
Alinity s HTLV I/II Assay Control Kit	06P0710
Alinity s HTLV I/II Release Control Kit	06P0712
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0177
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0109
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0119
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0118



# 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)

## V1 010051 0103 Rev. 10

### Annex II List A Products for ARCHITECT Platform

Product Name	REF N°
Anti-HCV Reagent Kit	6C37-74
Anti-HCV Reagent Kit	6C37-77
Anti-HCV Reagent Kit	6C37-78
Anti-HCV Calibrator	6C37-09
Anti-HCV Controls	6C37-19
Anti-HBc IgM Reagent Kit	6C33-74
Anti-HBc IgM Reagent Kit	6C33-75
Anti-HBc IgM Calibrators	6C33-09
Anti-HBc IgM Controls	6C33-19
Anti-HBe Reagent Kit	6C34-74
Anti-HBe Reagent Kit	6C34-77
Anti-HBe Calibrator	6C34-09
Anti-HBe Controls	6C34-19
HBeAg Reagent Kit	6C32-74
HBeAg Reagent Kit	6C32-77
HBeAg Calibrators	6C32-09
HBeAg Quantitative Calibrators	7P24-09
HBeAg Controls	6C32-19
HBeAg Quantitative Controls	7P24-19
HIV Ag/Ab Combo Reagent Kit	4J27-74
HIV Ag/Ab Combo Reagent Kit	4J27-77
HIV Ag/Ab Combo Reagent Kit	4J27-78
HIV Ag/Ab Combo Calibrator	4J27-09
HIV Ag/Ab Combo Controls	4J27-19
Anti-HBc II Reagent Kit	8L44-74
Anti-HBc II Reagent Kit	8L44-77
Anti-HBc II Reagent Kit	8L44-78
Anti-HBc II Calibrator	8L44-09
Anti-HBc II Controls	8L44-19



# 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)

## V1 010051 0103 Rev. 10

### Annex II List A Products for Alinity i Platform

Product Name	REF N°
Anti-HBe Reagent Kit	07P6374
Anti-HBe Reagent Kit	07P6377
Anti-HBe Calibrator	07P6309
Anti-HBe Controls	07P6319
HIV Ag/Ab Combo Reagent Kit	08P0774
HIV Ag/Ab Combo Reagent Kit	08P0777
HIV Ag/Ab Combo Calibrator	08P0709
HIV Ag/Ab Combo Controls	08P0719
Anti-HCV Reagent Kit	08P0674
Anti-HCV Reagent Kit	08P0677
Anti-HCV Calibrator	08P0609
Anti-HCV Controls	08P0619
Anti-HBc II Reagent Kit	07P8774
Anti-HBc II Reagent Kit	07P8777
Anti-HBc II Calibrator	07P8709
Anti-HBc II Controls	07P8719
Anti-HBc IgM Reagent Kit	07P8674
Anti-HBc IgM Calibrators	07P8609
Anti-HBc IgM Controls	07P8619
HBeAg Reagent Kit	07P6474
HBeAg Reagent Kit	07P6477
HBeAg Calibrators	07P6409
HBeAg Controls	07P6419
HBeAg Quantitative Calibrators	09P1009
HBeAg Quantitative Controls	09P1019



# 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)

## V1 010051 0103 Rev. 10

### Annex II List B Products

Product Name	REF N°
ARCHITECT Toxo IgG Reagent Kit	6C19-25
ARCHITECT Toxo IgG Reagent Kit	6C19-35
ARCHITECT Toxo IgG Calibrators	6C19-01
ARCHITECT Toxo IgG Controls	6C19-10
ARCHITECT Toxo IgG Avidity Reagent Kit	6L37-25
ARCHITECT Toxo IgG Avidity Calibrator & Controls	6L37-11
ARCHITECT Toxo IgM Reagent Kit	6C20-25
ARCHITECT Toxo IgM Reagent Kit	6C20-35
ARCHITECT Toxo IgM Calibrator	6C20-01
ARCHITECT Toxo IgM Controls	6C20-10
Alinity i Toxo IgG Reagent Kit	07P4522
Alinity i Toxo IgG Reagent Kit	07P4532
Alinity i Toxo IgG Calibrators	07P4501
Alinity i Toxo IgG Controls	07P4510
Alinity i Toxo IgM Reagent Kit	07P4722
Alinity i Toxo IgM Reagent Kit	07P4732
Alinity i Toxo IgM Calibrator	07P4701
Alinity i Toxo IgM Controls	07P4710
Alinity i Toxo IgG Avidity Reagent Kit	07P4622
Alinity i Toxo IgG Avidity Controls	07P4610





# 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)

## V1 010051 0103 Rev. 10

### Annex II List B Products for ARCHITECT Platform

Product Name	REF N°
Toxo IgG Calibrators	6C19-09
Toxo IgG Controls	6C19-19
Toxo IgG Reagent Kit	6C19-74
Toxo IgG Reagent Kit	6C19-77
Toxo IgM Calibrators	6C20-09
Toxo IgM Controls	6C20-19
Toxo IgM Reagent Kit	6C20-74
Toxo IgM Reagent Kit	6C20-77
Toxo IgG Avidity Reagent Kit	6L37-74

### Annex II List B Products for Alinity Platform

Product Name	REF N°
Toxo IgG Calibrators	07P4509
Toxo IgG Controls	07P4519
Toxo IgG Reagent Kit	07P4574
Toxo IgG Reagent Kit	07P4577
Toxo IgM Calibrators	07P4709
Toxo IgM Controls	07P4719
Toxo IgM Reagent Kit	07P4774
Toxo IgM Reagent Kit	07P4777
Toxo IgG Avidity Reagent Kit	07P4674



**TECHNOPATH**  
CLINICAL DIAGNOSTICS

## DECLARATION OF CONFORMITY



### Manufacturer

Techno-path Manufacturing Ltd.  
Fort Henry Business Park,  
Ballina,  
Co. Tipperary,  
Ireland

Product(s):

Product Name	Category	Catalogue Number
Multichem IA Plus	Assayed/tri-level	05P76-10

GMDN:	47869
Classification:	Annex II List B
Conformity Route:	Annex IV
Quality Management System:	EN ISO 13485:2016
QMS/CE Certification No.:	V11038520001
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	26 May 2024
Notified Body Number:	0123

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

**Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.**

**I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 31 (Day) 01 (Month) 20 (Year)**

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

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

Ballina, Co. Tipperary 31-01-20.  
Place and Date of Issue

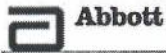


**TECHNOPATH**  
CLINICAL DIAGNOSTICS

**STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC**

<b>Standard</b>	<b>Title</b>
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
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
SOR/98-282, May 7, 1998	Canada Medical Device Regulations





## Declaration of Conformity


**Certificate Identification:**  
**Legal Manufacturer's Name:**  
**Legal Manufacturer's Address:**

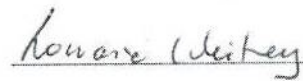
ARCHITECT Solutions  
Abbott Ireland Diagnostics Division  
Finisklin Business Park  
Sligo  
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1L56-40	59058	ARCHITECT Probe Conditioning Solution	Self-declared
6C54-58	58236	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-82	58236	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-88	58236	ARCHITECT ARM Concentrated Wash Buffer	Self-declared
6C55-60	58793	ARCHITECT Trigger Solution	Self-declared
6C55-82	58793	ARCHITECT Trigger Solution	Self-declared
6E23-65	61163	ARCHITECT Pre-Trigger Solution	Self-declared
6E23-82	61163	ARCHITECT Pre-Trigger Solution	Self-declared
7D82-50	58208	ARCHITECT Multi-Assay Manual Diluent	Self-declared
<b>Authorized European Representative (Name and Address)</b>	N/A		
<b>Storage site of technical documentation (Name and Address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.		
<b>Harmonized Standards</b>	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: Niall Plunkett  
Position: Quality Manager  
Date of Approval: 16 Oct 14  
Date Issued: 16 Oct 14  
Supersedes: 07 July 2014

Signature:   
Full Name: Lorraine Whitney  
Position: Senior Manager Regulatory Affairs  
Date of Approval: 14 Oct 2014  
Place Issued: AIDD Sligo  
Effective (Date or Lot Number): 16 Oct 14



# Declaration of Conformity

**Certificate Identification:** DoC-7K70-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
7K70-20	54665	ARCHITECT Total PSA Reagent Kit	<b>Annex II List B</b>
7K70-25	54665	ARCHITECT Total PSA Reagent Kit	<b>Annex II List B</b>
7K70-30	54665	ARCHITECT Total PSA Reagent Kit	<b>Annex II List B</b>
7K70-35	54665	ARCHITECT Total PSA Reagent Kit	<b>Annex II List B</b>
7K70-01	38208	ARCHITECT Total PSA Calibrators	<b>Annex II List B</b>
7K70-10	38207	ARCHITECT Total PSA Controls	<b>Annex II List B</b>

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
<b>Notified Body number</b>	0123
<b>Approval Certificate No.</b>	V1 0019220008
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
<b>Harmonized Standards</b>	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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: <sup>α</sup> **N. WALSH** 

Signature: 

Full Name: <sup>κ</sup> Joe Murray  
Position: Director Quality Assurance/Site Quality Head

Full Name: Noel Haren  
Position: Manager Regulatory Affairs

Date of Approval: 25 Nov 2019

Date of Approval: 25 Nov 2019

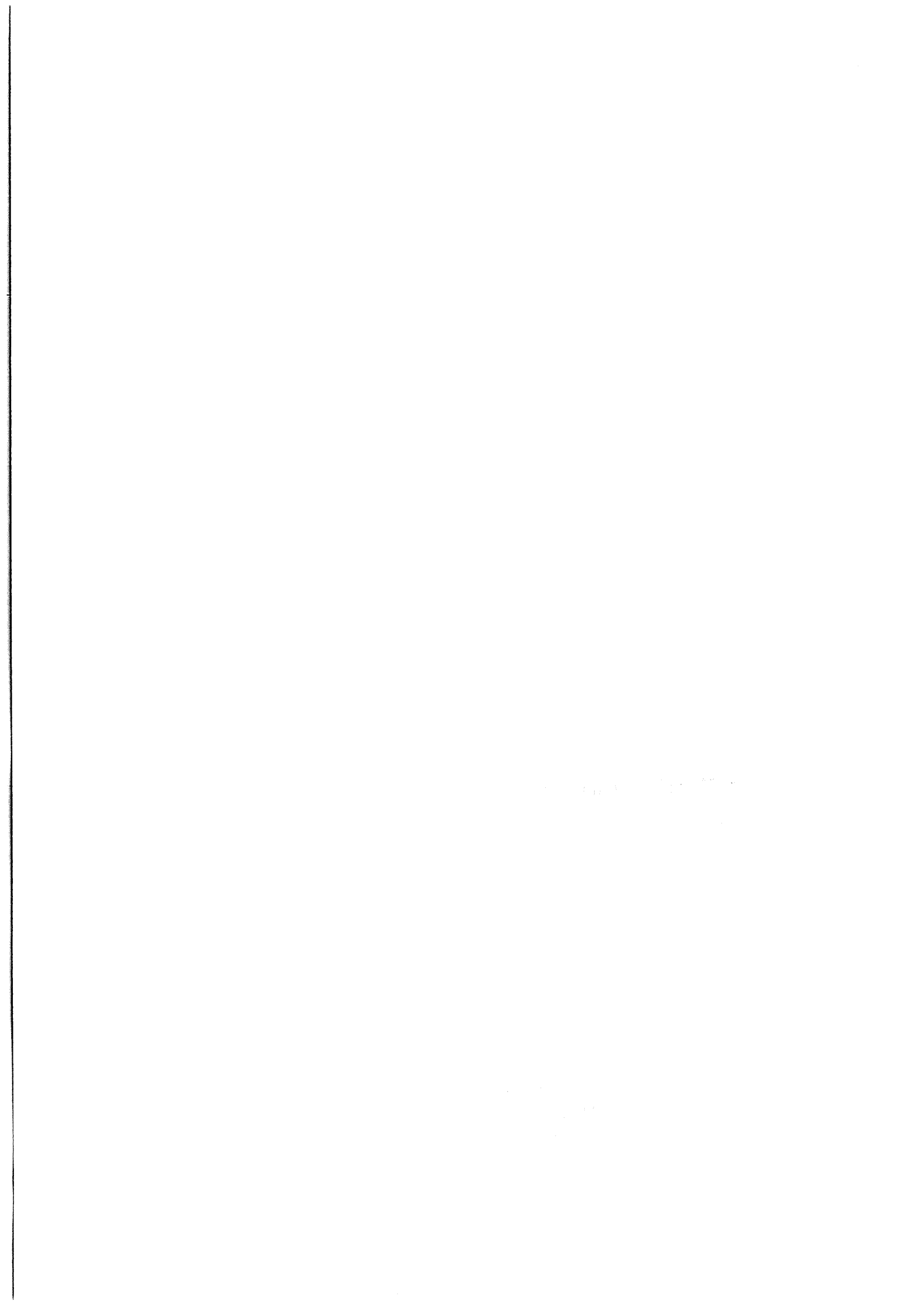
Date Issued: 25 Nov 2019

Place Issued: AIDD Sligo

Supersedes: 16 October 2019

Effective (Date or Lot Number): 25 Nov 2019

*α Ref attached delegation memo Walsh 25 Nov 2019*



## Declaration of Conformity

**Certificate Identification:** DoC-6S60-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
6S60-22	64760	SARS-CoV-2 IgG II Quant Reagent Kit	Self Declared
6S60-32	64760	SARS-CoV-2 IgG II Quant Reagent Kit	Self Declared
6S60-02	64854	SARS-CoV-2 IgG II Quant Calibrator Kit	Self Declared
6S60-12	64788	SARS-CoV-2 IgG II Quant Control Kit	Self Declared

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
<b>Harmonized Standards</b>	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: Joe Murray  
Position: Director Quality Assurance/Site Quality Head

Date of Approval: 05 Oct 2021

Date Issued: 05 OCT 2021

Supersedes: 30 April 2021

Signature: 

Full Name: Noel Haren  
Position: Manager Regulatory Affairs

Date of Approval: 05 OCT 2021

Place Issued: AIDD Sligo

Effective (Date or Lot Number): 05 OCT 2021



# Declaration of Conformity

**Certificate Identification:** ARCH Sys Acc 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
4D18-03	56701	ARCHITECT Septum	Self-declared
4D19-01	56701	ARCHITECT Replacement Caps	Self-declared
7C14-01	56676	ARCHITECT Sample Cups	Self-declared
7C15-02	56676	ARCHITECT Reaction Vessels	Self-declared
7C15-03	56676	ARCHITECT Reaction Vessels	Self-declared

<b>Authorized European Representative (Name and Address)</b>	Abbott GmbH & Co. KG Max-Planck-Ring-2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (Name and Address)</b>	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
<b>Harmonized Standards</b>	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: <u></u>	Signature: <u></u>
Full Name: <u>Katerina Damjanoska</u>	Full Name: <u>MaryCaren Musawski</u>
Position: <u>Site Quality Director</u>	Position: <u>Regulatory Affairs Director</u>
Date of Approval: <u>5/29/2019</u>	Date of Approval: <u>22 July 19</u>
Date Issued: <u>22 July 2019</u>	Place Issued: <u>Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064 USA</u>
Supersedes: <u>02 June 2015</u>	Effective (Date or Lot Number): <u>22 July 19</u>





## Declaration of Conformity

Certificate Identification: 7K64  
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
7K64-27 7K64-32 7K64-37	58330	ARCHITECT Total T <sub>3</sub> Reagent Kit	Self-declared
7K64-02	58333	ARCHITECT Total T <sub>3</sub> Calibrators	Self-declared
7K64-50	58208	ARCHITECT Total T <sub>3</sub> Manual Diluent	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: <u><i>Siobhan Wright</i></u>	Signature: <u><i>Lorraine Whitney</i></u>
Full Name: <b>Siobhan Wright</b>	Full Name: <b>Lorraine Whitney</b>
Position: <b>Director Quality Assurance/ Site Quality Head</b>	Position: <b>Senior Manager Regulatory Affairs</b>
Date of Approval: <u>22 MAY 20</u>	Date of Approval: <u>22 MAY 2020</u>
Date Issued: <u>22 MAY 20</u>	Place Issued: <b>Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland</b>
Supersedes: <u>24 April 2019</u>	Effective (Date or Lot Number): <u>22 MAY 20</u>

## Declaration of Conformity

**Certificate Identification:** 7K66  
**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
7K66-27 7K66-32 7K66-37	58322	ARCHITECT Total T4 Reagent Kit	Self Declared
7K66-02	58324	ARCHITECT Total T4 Calibrators	Self Declared
7K66-12	58325	ARCHITECT Total T4 Controls	Self Declared

<b>Authorized European Representative (Name and Address)</b>	N/A
<b>Storage of site technical documentation (Name and Address)</b>	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Ireland.
<b>Harmonized Standards</b>	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*  
 Full Name: **Siobhan Wright**  
 Position: **Director Quality Assurance/ Site Quality Head**  
 Date of Approval: 24-APR-19

Signature: *Lorraine Whitney*  
 Full Name: **Lorraine Whitney**  
 Position: **Senior Manager Regulatory Affairs**  
 Date of Approval: 19 APR 2019

Supersedes: 17-May-2016

Place Issued: **Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.**

Date Issued: 24-APR-19

Effective (Date or Lot Number): 24-APR-19

### Declaration of Conformity

**Certificate Identification:** 7K62  
**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
7K62-20 7K62-25 7K62-30 7K62-35	54386	ARCHITECT TSH Reagent Kit	Self-declared
7K62-01	38272	ARCHITECT TSH Calibrators	Self-declared
7K62-10	38271	ARCHITECT TSH Controls	Self-declared

<b>Authorized European Representative (Name and Address)</b>	N/A
<b>Storage of site technical documentation (Name and Address)</b>	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. Department: Regulatory Affairs
<b>Harmonized Standards</b>	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  
 Full Name: **Siobhan Wright**  
 Position: **Director Quality Assurance/  
Site Quality Head**  
 Date of Approval: 24-APR-19  
 Date Issued: 24-APR-19  
 Supersedes: 25-May-2017

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