

Declaration of Conformity


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

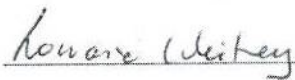
ARCHITECT Solutions
Abbott Ireland Diagnostics Division
Finisklin Business Park
Sligo
Ireland

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
Authorized European Representative (Name and Address)	N/A		
Storage site of technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County 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: 
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:
Legal Manufacturer's Name:
Legal Manufacturer's Address:

AIDD 3P36
Abbott Ireland Diagnostics Division
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
Authorized European Representative (Name and Address)		N/A	
Storage site of technical documentation (Name and Address)		Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County 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: _____

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



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



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 010051 0124 Rev. 02

Manufacturer:

Abbott GmbH

Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

Product:

Non-Screening test for Hepatitis B marker

Model(s):

ARCHITECT Anti-HBe

Parameters:

Product Name

REF N°

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
Anti-HBe Reagent Kit	6C34-74
Anti-HBe Reagent Kit	6C34-77
Anti-HBe Calibrator	6C34-09
Anti-HBe Controls	6C34-19

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. See also notes overleaf.

Report No.:

713177008-2_22

Valid from:

2020-01-28

Valid until:

2022-05-25

Date,

2020-01-28

Christoph Dicks
Head of Certification/Notified Body

Declaration of Conformity

Certificate Identification: DoC-7C18-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
7C18-27	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-37	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-34	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-28	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-38	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

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V1 0019220008
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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:  **N. WALSH**

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

Date of Approval: 25 Nov 19

Date Issued: 25 Nov 19

Supersedes: 07 Oct 2019

Signature: 

Full Name: Noel Haren
 Position: Manager Regulatory Affairs

Date of Approval: 21 Nov 2019

Place Issued: AIDD Sligo

Effective (Date or Lot Number): 25 Nov 19

x refer to attached
 delegation Walsh
 25 Nov 19

Declaration of Conformity

Certificate Identification: DoC-7C18-40-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
7C18-40	48318	ARCHITECT Anti-HBs Specimen Diluent	Self-declared
Authorized European Representative (Name and Address)		N/A	
Storage of site 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.

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Signature: 

Full Name: Joe Murray

Position: Quality Manager

Date of Approval: 10 Jan 17

Date Issued: 11 JAN 2017

Supersedes: 27 May 2015

Signature: 

Full Name: Lorraine Whitney

Position: Senior Manager Regulatory Affairs

Date of Approval: 11 JAN 2017

Place Issued: AIDD, Sligo

Effective (Date or Lot Number): 11 JAN 2017

Declaration of Conformity


Certificate Identification:	<u>DOC-6C37-22/-27/-32/-37-AII DLK</u>
Legal Manufacturer's Name:	<u>Abbott GmbH</u>
Legal Manufacturer's Address:	<u>Max-Planck-Ring 2, 65205 Wiesbaden, Germany</u>

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C37-22	48366	ARCHITECT Anti-HCV Reagent Kit (4x100Tests)	Annex II List A
6C37-27	48366	ARCHITECT Anti-HCV Reagent Kit (1x100Tests)	Annex II List A
6C37-32	48366	ARCHITECT Anti-HCV Reagent Kit (4x500 Tests)	Annex II List A
6C37-37	48366	ARCHITECT Anti-HCV Reagent Kit (1x500 Tests)	Annex II List A
6C37-01	41972	ARCHITECT Anti-HCV Calibrator	Annex II List A
6C37-10	41973	ARCHITECT Anti-HCV Controls	Annex II List A

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

Signature: 

Full Name: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-03-09

Signature: 

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 04/RS/2020

Date Issued: 09-Mar-2020

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 17-Dec-2019

Effective (Date or Lot Number): 09-Mar-2020



Declaration of Conformity

Certificate Identification: 02K46 LC IRIS V2
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 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 & Co. KG 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.

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Signature: Elizabeth Leibham
Full Name: Elizabeth Leibham
Position: Quality Manager
Date of Approval: 5/11/2015
Date Issued: 5/28/2015
Supersedes: May 23, 2005

Signature: Mary Caren Murawski
Full Name: Mary Caren Murawski
Position: Regulatory Affairs Manager
Date of Approval: 5/14/2015
Place Issued: Abbott Laboratories Diagnostic Division
Abbott Park, IL 60064 USA.
Effective (Date or Lot Number): 5/28/2015

Declaration of Conformity

Certificate Identification:

02K47 LC

IRIS V2

Legal Manufacturer's Name:

Abbott Laboratories

Diagnostics Division

Legal Manufacturer's Address:

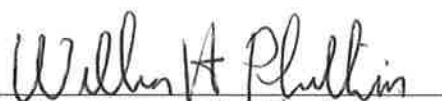
Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K47-20 2K47-22 2K47-25 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 & Co. KG 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, Middleton, VA 22645-1905 USA	
Harmonized Standards		Listed in the Technical Documentation	

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Signature:



Full Name:

William H Phillips

Position: Quality Manager

Date of Approval:

12/09/2014

Date Issued:

12/15/2014

Supersedes:

28 July 2006

Signature:



Full Name:

Mary Caven Musewski

Position: Regulatory Affairs Manager

Date of Approval:

12/11/2014

Place Issued:

Abbott Laboratories Diagnostics Div.
Abbott Park, IL 60064 USA

Effective (Date or

Lot Number):

12/15/2014

Declaration of Conformity

Certificate Identification: DoC-2K91-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH & Co. KG
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.

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Signature:



Full Name:

Dr. Jörg Amborn

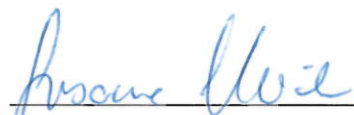
Position:

Director Quality Assurance

Date of Approval:

2019-06-19

Signature:



Full Name:

Susanne Ulrich

Position:

Senior Manager Regulatory Affairs

Date of Approval:

19/ Jun / 2019

Date Issued:

19/ Jun / 2019

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

16. December 2016

Effective (Date or Lot Number):

19/ Jun / 2019

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.

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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: 08D15 LC IRIS V5.1
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
8D15-25 8D15-35	54125	ARCHITECT Cortisol Reagent Kit	Self-declared
8D15-02	54126	ARCHITECT Cortisol Calibrators	Self-declared
Authorized European Representative (name and address)		Abbott GmbH & Co. KG 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	

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Signature: William H Phillips
Full Name: William H Phillips
Position: Quality Manager
Date of Approval: 5/19/2015
6/4/2015
Date Issued:

see attached
delegation
memo

Signature: Mary Caren Murawski
Full Name: Mary Caren Murawski
Position: Regulatory Affairs Manager
Date of Approval: 6/3/15
Abbott Laboratories
Place Issued: Diagnostic Division
Abbott Park, IL 60064 USA
Effective (Date or Lot Number): 6/4/2015

Supersedes: August 8, 2012

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

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

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Signature: 

Full Name: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-03-09

Signature: 

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 02/175/2020

Date Issued: 09/03/2020

Place Issued: **65205 Wiesbaden, Germany**

Supersedes: **21-Oct-2019**

Effective (Date or Lot Number): 09-Mar-2020

Declaration of Conformity

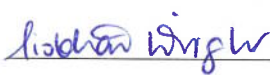
Certificate Identification: 07K72
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.


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

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Signature: 
 Full Name: **Siobhan Wright**
 Position: **Director Quality Assurance/
Site Quality Head**

Signature: 
 Full Name: **Lorraine Whitney**
 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

Declaration of Conformity

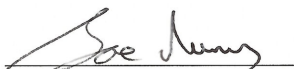
Certificate Identification: DoC-7K71- AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

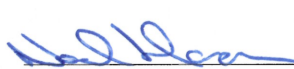
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K71-20	54669	ARCHITECT Free PSA Reagent Kit	Annex II List B
7K71-25	54669	ARCHITECT Free PSA Reagent Kit	Annex II List B
7K71-01	38183	ARCHITECT Free PSA Calibrators	Annex II List B
7K71-10	38182	ARCHITECT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

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V1 0019220008
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

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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 ₃ Reagent Kit	Self-declared
7K63-02	38261	ARCHITECT Free T ₃ Calibrators	Self-declared
7K63-12	54418	ARCHITECT Free T ₃ 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	

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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: 01-MAY-2020

Date Issued: 01-MAY-2020

Supersedes: 24-April-2019

Signature: Lorraine Whitney

Full Name: **Lorraine Whitney**

Position: **Senior Manager
Regulatory Affairs**

Date of Approval: 01 MAY 2020

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

Effective (Date or Lot Number): 01-MAY-2020

Declaration of Conformity

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

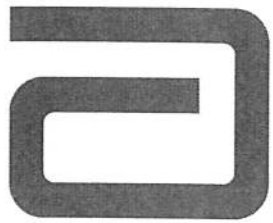
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K65-22 7K65-24 7K65-27 7K65-29 7K65-32 7K65-34 7K65-35 7K65-39	54413	ARCHITECT Free T4 Reagent Kit	Self-declared
7K65-02	38259	ARCHITECT Free T4 Calibrators	Self-declared
7K65-10	38258	ARCHITECT Free T4 Controls	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.	
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*
 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 26th April 19.

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

Lorraine Whitney 19 APR 2019

Lorraine Whitney

Senior Manager Regulatory Affairs

Site Operations Ireland

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

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

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

Signature: 

Full Name: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-03-12

Date Issued: 12-Mar-2020

Supersedes: 19-Dec-2019

Signature: 

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 12/12/2020

Place Issued: 65205 Wiesbaden, Germany

Effective (Date or Lot Number): 12-Mar-2020

Declaration of Conformity

Certificate Identification: DoC-6C36-41/42/43/44-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
6C36-41	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
6C36-42	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
6C36-43	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
6C36-44	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V1 0019220008
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County 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 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: 20 Nov 19

Date Issued: 20 NOV 2019

Supersedes: 14 October 2019

Signature: 

Full Name: Noel Haren
 Position: Manager Regulatory Affairs

Date of Approval: 19 Nov 2019

Place Issued: AIDD Sligo

Effective (Date or Lot Number): 20 NOV 2019

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.

<p>Signature: <u><i>Siobhan Wright</i></u></p> <p>Full Name: Siobhan Wright</p> <p>Position: Director Quality Assurance/Site Quality Head</p> <p>Date of Approval: <u>24-APR-19</u></p> <p>Date Issued: <u>24-APR-19</u></p> <p>Supersedes: <u>12 OCT 2018</u></p>	<p>Signature: <u><i>Lorraine Whitney</i></u></p> <p>Full Name: Lorraine Whitney</p> <p>Position: Senior Manager Regulatory Affairs/</p> <p>Date of Approval: <u>19 APR 2019</u></p> <p>Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland</p> <p>Effective (Date or Lot Number): <u>24-APR-19</u></p>
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Declaration of Conformity


Certificate Identification: DoC-6C55-63, 6E23-68-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
6C55-63	58793	ARCHITECT Trigger Solution	Self-declared
6E23-68	61163	ARCHITECT Pre-Trigger Solution	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: 
 Full Name: Joe Murray
 Position: Director Quality Assurance/Site Quality Head
 Date of Approval: 28 Sep 2020
 Date Issued: 29 Sep 2020
 Supersedes: N/A

Signature: 
 Full Name: Noel Haren
 Position: Manager Regulatory Affairs
 Date of Approval: 29 Sep 2020
 Place Issued: AIDD Sligo
 Effective (Date or Lot Number): 29 Sep 2020