Abbott

Declaration of Conformity

Certificate Identification: ARCHITECT Solutions
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
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: Lorraine Whitney
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

Digitally signed by Ceaicovschi Tudor
Date: 2020.12.28 14:12:39 EET
Reason: MoldSign Signature
Location: Moldova

Abbott

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**

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: [signature]

Full Name: Niall Plunkett

Position: Quality Manager

Date of Approval: 07 Jul 14

Date Issued: 07 Jul 14

Supersedes: 13 Jan 2013

Signature: Lorraine Whitney

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

TÜV SÜD 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

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

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

Abbott

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	Signature:	
Full Name:	Joe Murray*	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	25 NOV 19	Date of Approval:	21 Nov 2019
Date Issued:	25 NOV 19	Place Issued:	AIDD Sligo
Supersedes:	07 Oct 2019	Effective (Date or Lot Number):	25 NOV 19

* refer to attached delegation N Walsh 25/11/19

Abbott

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.

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

Signature:	Joe Murray	Signature:	Lorraine Whitney
Full Name:	Joe Murray	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	10 Jan 17	Date of Approval:	11 JAN 2017
Date Issued:	11 JAN 2017	Place Issued:	AIDD, Sligo
Supersedes:	27 May 2015	Effective (Date or Lot Number):	11 JAN 2017

Abbott

Declaration of Conformity

Certificate Identification: DOC-6C37-22/-27/-32/-37-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
6C37-22	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:		Signature:	
Full Name:	**Dr. Jörg Amborn**	Full Name:	**Susanne Ulrich**
Position:	**Director Quality Assurance**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	2020-03-09	Date of Approval:	04/03/2020
		Date Issued:	09-Mar-2020
		Place Issued:	65205 Wiesbaden, Germany
		Supersedes:	17-Dec-2019
		Effective (Date or Lot Number):	09-Mar-2020

Abbott

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

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 U.S.A.
Effective (Date or Lot Number): 5/28/2015

Abbott

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

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: William H Phillips

Full Name: William H Phillips

Position: Quality Manager

Date of Approval: 12/09/2014

Date Issued: 12/15/2014

Supersedes: 28 July 2006

Signature: Mary Ann Mucenski

Full Name: Mary Ann Mucenski

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

Abbott

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.

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: **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

Abbott

Declaration of Conformity

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

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

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

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

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

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

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

Abbott

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

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: William H Phillips For Elizabeth Leibham (see attached Delegation Memo)
Full Name: William H Phillips
Position: Quality Manager
Date of Approval: 5/19/2015
Date Issued: 6/4/2015

Signature: Mary Casey Murawski
Full Name: Mary Casey Murawski
Position: Regulatory Affairs Manager
Date of Approval: 6/3/15
Place Issued: Abbott Laboratories
Diagnostic Division
Abbott Park, IL 60064 USA

Supersedes: August 8, 2012

Effective (Date or Lot Number): 6/4/2015

Abbott

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

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: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-07-09

Signature: [signature]

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 02/MS/2020

Date Issued: 09/03/2020

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 21-Oct-2019

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

ABBOTT

Declaration of Conformity

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

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K72-20 7K72-25 7K72-35	60979	ARCHITECT Estradiol Reagent Kit	**Self-declared**
7K72-01	38249	ARCHITECT Estradiol Calibrators	**Self-declared**
7K72-10	38248	ARCHITECT Estradiol Controls	**Self-declared**
7K72-50	58208	ARCHITECT Estradiol Manual Diluent	**Self-declared**

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

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

.

Signature: Siobhan Wright
Full Name: **Siobhan Wright**
Position: **Director Quality Assurance/ Site Quality Head**
Date of Approval: 06-JUN-19
Date Issued: 06-JUN-19
Supersedes 29 April 2019

Signature: Lorraine Whitney
Full Name: **Lorraine Whitney**
Position: **Senior Manager Regulatory Affairs**
Date of Approval: 06 Jun 2019
Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Effective (Lot number or date) 06-JUN-19

Abbott

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

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

Abbott

Declaration of Conformity

Certificate Identification:	7K63
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer'sAddress:	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

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: 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

Abbott

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	Signature:	p.p. SANDRA GALLAGHER SGallagher
Full Name:	**Siobhan Wright**	Full Name:	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	29-APR-19	Date of Approval:	25-APR-2019.
Date Issued:	29-APR-19	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	26-July-2017	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

Abbott

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

Abbott

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: Joe Murray

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

ABBOTT

Declaration of Conformity

Certificate Identification: 02P40
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2P40-25 2P40-35	54254	ARCHITECT LH Reagent Kit	**Self-declared**
2P40-01	38270	ARCHITECT LH Calibrators	**Self-declared**

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

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

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

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

Abbott

Declaration of Conformity

Certificate Identification:	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:	Joe Murray	Signature:	Noel Haren
Full Name:	Joe Murray	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	28 Sep 2020	Date of Approval:	29 Sep 2020
Date Issued:	29 Sep 2020	Place Issued:	AIDD Sligo
Supersedes:	N/A	Effective (Date or Lot Number):	29 Sep 2020