Abbott

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**

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)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 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: [signature]

Full Name: Katerina Damjanoska

Position: Site Quality Director

Date of Approval: 5/29/2019

Date Issued: 22 July 2019

Supersedes: 02 June 2015

Digitally signed by Ceaicovschi Tudor
Date: 2021.04.18 11:08:24 EEST
Reason: MoldSign Signature
Location: Moldova

Signature: [signature]

Full Name: Mary Ann Muszynski

Position: Regulatory Affairs Director

Date of Approval: 22 July 19

Place Issued: Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064 USA

Effective (Date or Lot Number): 22 July 19

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

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

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 0130 Rev. 02

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

Product: **Screening test for Hepatitis B marker**

Model(s): **ARCHITECT Anti-HBc II**

Parameters:

Product Name	REF N°
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
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

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_27

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

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

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 001922 0012 Rev. 00

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

Product: **Non-Screening test for Hepatitis B marker**

Model(s): **ARCHITECT Anti-HBs**

Parameters:

Product Name	REF N°
ARCHITECT Anti-HBs Reagent Kit	7C18-20
ARCHITECT Anti-HBs Reagent Kit	7C18-25
ARCHITECT Anti-HBs Reagent Kit	7C18-30
ARCHITECT Anti-HBs Reagent Kit	7C18-27
ARCHITECT Anti-HBs Reagent Kit	7C18-34
ARCHITECT Anti-HBs Reagent Kit	7C18-37
ARCHITECT Anti-HBs Reagent Kit	7C18-28
ARCHITECT Anti-HBs Reagent Kit	7C18-38
ARCHITECT Anti-HBs Reagent Kit	7C18-29
ARCHITECT Anti-HBs Reagent Kit	7C18-33
ARCHITECT Anti-HBs Reagent Kit	7C18-39
ARCHITECT Anti-HBs Reagent Kit	7C18-41
ARCHITECT Anti-HBs Reagent Kit	7C18-42
ARCHITECT Anti-HBs Calibrators	7C18-01
ARCHITECT Anti-HBs Calibrators	7C18-03
ARCHITECT Anti-HBs Controls	7C18-10
ARCHITECT Anti-HBs Controls	7C18-13

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.: 713155489-2_02

Valid from: 2019-03-30
Valid until: 2022-05-24

Date, 2019-03-29

Stefan Preiß

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

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

TÜV®

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

EC Design - Examination Certificate

Annex IV, section 4 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Device Description:
Chemiluminescent Microparticle Immunoassay for the quantitative determination of antibody to Hepatitis B surface antigen (anti-HBs) in human serum or plasma

Device Classifications:
Annex II List A

Model Type:
Please refer to Attachment: 1

We hereby declare that a design examination has been carried out on the device(s) listed, following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV section 4 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the design of the device(s) listed conforms with the relevant provisions of Annex IV section 4 of the aforementioned directive as transposed into national legislation. This certificate is issued with 1 attachment listing product references.

File Number	A18074	Cycle Start Date	August 12, 2018
Certificate Number	562.180812	Effective Date	August 12, 2018
Initial Issue Date	April 25, 2008	Expiry Date	August 11, 2023

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 1 of 1

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

Model/Type	Classification	G/UMDN Code
ARCHITECT Anti-HBs Reagent Kit - 7C18-20/25/30	Annex II List A	48316
ARCHITECT Anti-HBs Calibrators - 7C18-01	Annex II List A	41997
ARCHITECT Anti-HBs Controls - 7C18-10	Annex II List A	41998
ARCHITECT Anti-HBs Reagent Kit - 7C18-27/28/34/37/38	Annex II List A	48316
ARCHITECT Anti-HBs Calibrators - 7C18-03	Annex II List A	41997
ARCHITECT Anti-HBs Controls - 7C18-13	Annex II List A	41998
ARCHITECT Anti-HBs Reagent Kit - 7C18-29/33/39/41/42	Annex II List A	48316

File Number	A18074	Cycle Start Date	August 12, 2018
Certificate Number	562.180812	Effective Date	August 12, 2018
Initial Issue Date	April 25, 2008	Expiry Date	August 11, 2023

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S4 DE
00-MB-A0043 Issue: 15.0

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

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 0132 Rev. 03

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

Product: **Screening test for Hepatitis C marker**

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_28

Valid from: 2020-01-28
Valid until: 2022-03-31

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

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 0132 Rev. 03

Model(s): ARCHITECT Anti-HCV

Facility(ies): Abbott GmbH
Max-Planck-Ring 2, 65205 Wiesbaden, GERMANY

Parameters:

Product Name	REF N°
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
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

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

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

TÜV®

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 0120 Rev. 02

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

Product: **Non-Screening test for Hepatitis B marker**

Model(s): **ARCHITECT HBeAg**

Parameters:

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
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

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_18

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

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

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

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

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

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

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

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

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

TÜV®

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

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

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

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

TÜV®

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

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

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

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

TÜV®

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

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

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

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

TÜV®

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

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

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

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

TÜV®

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-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

Certificate of Approval

This is to certify that the Management System of:

Abbott GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

& Abbott Diagnostics GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

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

ISO 9001:2015

David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 17 January 2020
Expiry date: 30 September 2021
Certificate identity number: 10246646
Certificate approval number: LRQ 0925480/A

Original approval(s):
ISO 9001 – 23 September 1994

Approval number(s): 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.

UKAS MANAGEMENT SYSTEMS
001

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

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Abbott Ireland Diagnostics Division
Finisklin Business Park
Sligo
Ireland

has established and applies
a Quality Management System for

Design, development and manufacture of
in vitro diagnostic test kits,
reagents and common liquid accessories.

An audit was performed, Order No. **707114974**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-04-01** until **2023-03-31**.

Certificate Registration No.: **12 100 59742 TMS**.

Product Compliance Management
Munich, 2020-03-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstrasse 57 • 80339 München • Germany
www.tuev-sued.de/certificate-validity-check

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 001922 0022 Rev. 01

Holder of Certificate: **Abbott Ireland Diagnostics Division**
Finisklin Business Park
Sligo
IRELAND

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

Certification Mark:

Scope of Certificate: **Design, develop and manufacture of in vitro diagnostic test kits, reagents and common liquid accessories for donor screening and/or the detection and/or monitoring of hepatitis, cancers, cardiac markers, congenital transmitted diseases, determination of congenital disorders of the foetus, endocrine disorders and haematological disorders, therapeutic drug monitoring and infectious viral diseases.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713178712-05

Valid from: 2020-04-24
Valid until: 2023-03-24

Date, 2020-04-24

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

A4 / 07.17

Certificate of Approval

This is to certify that the Management System of:

Abbott GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

& Abbott Diagnostics GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

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

ISO 13485:2016

David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 17 January 2020
Expiry date: 30 September 2021
Certificate identity number: 10246647
Certificate approval number: LRQ 0925480/A

Original approval(s):

ISO 13485 – 23 September 1994

Approval number(s): 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.

UKAS MANAGEMENT SYSTEMS

001

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 054869 0011 Rev. 00

Holder of Certificate: **Abbott Ireland Diagnostics Division**
Lisnamuck
Longford
Co. Longford
IRELAND

Facility(ies): Abbott Ireland Diagnostics Division
Lisnamuck, Longford, Co. Longford, IRELAND

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design, development, and production of reagents and software for in vitro diagnostic use.**
Design, development and manufacture of in vitro diagnostic test kits and reagents for clinical chemistry.

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 054869 0011 Rev. 00

Report No.: 713189547

Valid from: 2020-09-01
Valid until: 2023-08-31

Date, 2020-08-27

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

Abbott

A Promise for Life

This document certifies that:

Sergiu Sorocovici

has completed

Architect i2000SR

Level1 / Level 2

Application, Operation, Troubleshooting

from 9 February 2015 to 13 February 2015

Trainer : **Athanasios Plakas**

Date: **13 Feb 2015**