Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016

Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018
Expiry date: 12 October 2021
Certificate identity number: 10155326

Original approval(s):
ISO 13485 – 7 December 2017

Approval number(s): ISO 13485 – 0015680

The scope of this approval is applicable to:
Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Certificate identity number: 10155326

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 13485:2016 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 13485:2016 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS

001

Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 9001:2015

Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018
Expiry date: 12 October 2021
Certificate identity number: 10155324

Original approval(s):
ISO 9001 – 3 December 2017

Approval number(s): ISO 9001 – 0015681

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register

Certificate Schedule

Certificate identity number: 10155324

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 9001:2015 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 9001:2015 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 9001:2015 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS

001

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 001922 0017 Rev. 00

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

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

Model(s): **ARCHITECT HBsAg**

Parameters:

Product Name	REF N°
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	6C36-41
ARCHITECT HBsAg Reagent Kit	6C36-42
ARCHITECT HBsAg Reagent Kit	6C36-43
ARCHITECT HBsAg Reagent Kit	6C36-44
ARCHITECT HBsAg Calibrators	3M61-01
ARCHITECT HBsAg Calibrators	3M61-02
ARCHITECT HBsAg Controls	6C36-10

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_07

Valid from: 2019-03-30
Valid until: 2022-03-31

Date, 2019-03-29

Stefan Preiß

Page 1 of 1
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

A4 / 07.17

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 Immunoassays for the detection of Hepatitis B Surface Antigen on the Abbott ARCHITECT analyser

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	October 11, 2018
Certificate Number	471.181011	Effective Date	October 11, 2018
Initial Issue Date	June 23, 2006	Expiry Date	March 31, 2022

Authorised by

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

Notified Body
0843

Check Certificate Status:

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 HBsAg Calibrators 3M61-01	Annex II List A	-
ARCHITECT HBsAg Calibrators 3M61-02	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-22	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-27	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-29	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-32	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-34	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-35	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-41	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-42	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-43	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-44	Annex II List A	-
ARCHITECT HBsAg Controls 6C36-10	Annex II List A	-

File Number A18074
Certificate Number 471.181011
Initial Issue Date June 23, 2006

Cycle Start Date October 11, 2018
Effective Date October 11, 2018
Expiry Date March 31, 2022

Authorised by

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

Notified Body
0843

Check Certificate Status:

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

Abbott

Declaration of Conformity

Certificate Identification:	DoC-6C36-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
6C36-22	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
6C36-27	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
6C36-29	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
6C36-32	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
6C36-34	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
6C36-35	48321	ARCHITECT HBsAg Reagent Kit	Annex II List A
3M61-01	41999	ARCHITECT HBsAg Calibrators	Annex II List A
3M61-02	41999	ARCHITECT HBsAg Calibrators	Annex II List A
6C36-10	42000	ARCHITECT HBsAg 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 UL International (UK) Ltd Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey, GU3 1LR
Notified Body number	0123 (TÜV SÜD Product Service GmbH) & 0843 (UL International (UK) Ltd)
Approval Certificate No.	V1 0019220008 (TÜV SÜD Product Service GmbH) & 361 (UL International (UK) Ltd)
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

Abbott

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:	p.p. NOEL HAGEN
Full Name:	Joe Murray	Full Name:	Lorraine Whitney
Position:	Director Quality Assurance/Site Quality Head	Position:	Senior Manager Regulatory Affairs
Date of Approval:	29 Mar 19	Date of Approval:	29 March 2019
Date Issued:	29 March 2019	Place Issued:	AIDD Sligo
Supersedes:	05 Jan 2017	Effective (Date or Lot Number):	30 March 2019

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 001922 0017 Rev. 00

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

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

Model(s): **ARCHITECT HBsAg**

Parameters:

Product Name	REF N°
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	6C36-41
ARCHITECT HBsAg Reagent Kit	6C36-42
ARCHITECT HBsAg Reagent Kit	6C36-43
ARCHITECT HBsAg Reagent Kit	6C36-44
ARCHITECT HBsAg Calibrators	3M61-01
ARCHITECT HBsAg Calibrators	3M61-02
ARCHITECT HBsAg Controls	6C36-10

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_07

Valid from: 2019-03-30
Valid until: 2022-03-31

Date, 2019-03-29

Stefan Preiß

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

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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 Immunoassays for the detection of Hepatitis B Surface Antigen on the Abbott ARCHITECT analyser

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	October 11, 2018
Certificate Number	471.181011	Effective Date	October 11, 2018
Initial Issue Date	June 23, 2006	Expiry Date	March 31, 2022

Authorised by

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

Notified Body
0843

Check Certificate Status:

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 HBsAg Calibrators 3M61-01	Annex II List A	-
ARCHITECT HBsAg Calibrators 3M61-02	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-22	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-27	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-29	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-32	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-34	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-35	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-41	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-42	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-43	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-44	Annex II List A	-
ARCHITECT HBsAg Controls 6C36-10	Annex II List A	-

File Number A18074
Certificate Number 471.181011
Initial Issue Date June 23, 2006

Cycle Start Date October 11, 2018
Effective Date October 11, 2018
Expiry Date March 31, 2022

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:

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

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TÜV SÜD Product Service

EC Certificate

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

No. V1 010051 0103 Rev. 00

Manufacturer: **Abbott GmbH & Co. KG**
Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

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

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: 713155472-1_01

Valid from: 2019-03-30
Valid until: 2021-09-30

Date, 2019-03-29

I. Preiß

Stefan Preiß

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TÜV SÜD Product Service

EC Certificate

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

No. V1 010051 0103 Rev. 00

Model(s): **Products for the determination of infection markers for HIV, Hepatitis B, Hepatitis C, HTLV, rubella, toxoplamosis**

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

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

Annex II List A Products

Product Name	REF N°
PRISM HIV O Plus Assay Kit	3D34-48
PRISM HBsAg Assay Kit	3A47-48
PRISM HCV Assay Kit	6A52-48
PRISM HTLV-I/HTLV-II Assay Kit	6A53-48
PRISM Positive Run Control Kit	5E22-11
PRISM Run Control Kit	5E22-10
PRISM HBcore Assay Kit	1A77-48
PRISM HBsAg Confirmatory Kit	6D16-48
PRISM HIV Ag/Ab Combo Assay Kit	7G46-48
PRISM Run Control Kit	2K24-10
PRISM Positive Run Control Kit	2K24-11
ARCHITECT Anti-HCV Reagent Kit	6C37-22
ARCHITECT Anti-HCV Reagent Kit	6C37-27
ARCHITECT Anti-HCV Reagent Kit	6C37-32
ARCHITECT Anti-HCV Reagent Kit	6C37-37
ARCHITECT Anti-HCV Reagent Kit	6C37-74
ARCHITECT Anti-HCV Reagent Kit	6C37-77
ARCHITECT Anti-HCV Reagent Kit	6C37-78
ARCHITECT Anti-HCV Calibrator	6C37-01
ARCHITECT Anti-HCV Calibrator	6C37-09
ARCHITECT Anti-HCV Controls	6C37-10
ARCHITECT Anti-HCV Controls	6C37-19
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-20

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TÜV SÜD Product Service

EC Certificate

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

No. V1 010051 0103 Rev. 00

Annex II List A Products

Product Name	REF N°
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-25
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-22
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-27
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-74
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-75
ARCHITECT Anti-HBc IgM Calibrators	6C33-01
ARCHITECT Anti-HBc IgM Calibrators	6C33-02
ARCHITECT Anti-HBc IgM Calibrators	6C33-09
ARCHITECT Anti-HBc IgM Controls	6C33-10
ARCHITECT Anti-HBc IgM Controls	6C33-11
ARCHITECT Anti-HBc IgM Controls	6C33-19
ARCHITECT Anti-HBe Reagent Kit	6C34-20
ARCHITECT Anti-HBe Reagent Kit	6C34-25
ARCHITECT Anti-HBe Reagent Kit	6C34-35
ARCHITECT Anti-HBe Reagent Kit	6C34-74
ARCHITECT Anti-HBe Reagent Kit	6C34-77
ARCHITECT Anti-HBe Calibrator	6C34-01
ARCHITECT Anti-HBe Calibrator	6C34-09
ARCHITECT Anti-HBe Controls	6C34-10
ARCHITECT Anti-HBe Controls	6C34-19
ARCHITECT HBeAg Reagent Kit	6C32-20
ARCHITECT HBeAg Reagent Kit	6C32-25
ARCHITECT HBeAg Reagent Kit	6C32-27

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TÜV SÜD Product Service

EC Certificate

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

No. V1 010051 0103 Rev. 00

Annex II List A Products

Product Name	REF N°
ARCHITECT HBeAg Reagent Kit	6C32-37
ARCHITECT HBeAg Reagent Kit	6C32-74
ARCHITECT HBeAg Reagent Kit	6C32-77
ARCHITECT HBeAg Calibrators	6C32-01
ARCHITECT HBeAg Calibrators	6C32-09
ARCHITECT HBeAg Quantitative Calibrators	7P24-01
ARCHITECT HBeAg Quantitative Calibrators	7P24-09
ARCHITECT HBeAg Controls	6C32-10
ARCHITECT HBeAg Controls	6C32-19
ARCHITECT HBeAg Quantitative Controls	7P24-10
ARCHITECT HBeAg Quantitative Controls	7P24-19
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-22
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-27
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-32
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-37
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-74
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-77
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-78
ARCHITECT HIV Ag/Ab Combo Calibrator	4J27-03
ARCHITECT HIV Ag/Ab Combo Calibrator	4J27-09
ARCHITECT HIV Ag/Ab Combo Controls	4J27-12
ARCHITECT HIV Ag/Ab Combo Controls	4J27-19
ARCHITECT rHTLV I/II Reagent Kit	6L61-25

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TÜV SÜD Product Service

EC Certificate

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

No. V1 010051 0103 Rev. 00

Annex II List A Products

Product Name	REF N°
ARCHITECT rHTLV I/II Reagent Kit	6L61-30
ARCHITECT rHTLV I/II Reagent Kit	6L61-35
ARCHITECT rHTLV I/II Calibrator	6L61-01
ARCHITECT rHTLV I/II Controls	6L61-10
ARCHITECT Anti-HBc II Reagent Kit	8L44-25
ARCHITECT Anti-HBc II Reagent Kit	8L44-30
ARCHITECT Anti-HBc II Reagent Kit	8L44-35
ARCHITECT Anti-HBc II Reagent Kit	8L44-74
ARCHITECT Anti-HBc II Reagent Kit	8L44-77
ARCHITECT Anti-HBc II Reagent Kit	8L44-78
ARCHITECT Anti-HBc II Calibrator	8L44-01
ARCHITECT Anti-HBc II Calibrator	8L44-09
ARCHITECT Anti-HBc II Controls	8L44-10
ARCHITECT Anti-HBc II Controls	8L44-19
ARCHITECT HCV Ag Reagent Kit	6L47-27
ARCHITECT HCV Ag Reagent Kit	6L47-29
ARCHITECT HCV Ag Calibrators	6L47-02
ARCHITECT HCV Ag Controls	6L47-11
Alinity i Anti-HBe Reagent Kit	07P6322
Alinity i Anti-HBe Reagent Kit	07P6374
Alinity i Anti-HBe Calibrator	07P6301
Alinity i Anti-HBe Calibrator	07P6309
Alinity i Anti-HBe Controls	07P6310

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TÜV SÜD Product Service

EC Certificate

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

No. V1 010051 0103 Rev. 00

Annex II List A Products

Product Name	REF N°
Alinity i Anti-HBe Controls	07P6319
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0722
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0732
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0774
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0777
Alinity i HIV Ag/Ab Combo Calibrator	08P0701
Alinity i HIV Ag/Ab Combo Calibrator	08P0709
Alinity i HIV Ag/Ab Combo Controls	08P0710
Alinity i HIV Ag/Ab Combo Controls	08P0719
Alinity i Anti-HCV Reagent Kit	08P0622
Alinity i Anti-HCV Reagent Kit	08P0632
Alinity i Anti-HCV Reagent Kit	08P0674
Alinity i Anti-HCV Reagent Kit	08P0677
Alinity i Anti-HCV Calibrator	08P0601
Alinity i Anti-HCV Calibrator	08P0609
Alinity i Anti-HCV Controls	08P0610
Alinity i Anti-HCV Controls	08P0619
Alinity i Anti-HBc IgM Reagent Kit	07P8622
Alinity i Anti-HBc IgM Reagent Kit	07P8674
Alinity i Anti-HBc IgM Calibrators	07P8601
Alinity i Anti-HBc IgM Calibrators	07P8609
Alinity i Anti-HBc IgM Controls	07P8610
Alinity i Anti-HBc IgM Controls	07P8619

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EC Certificate

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

No. V1 010051 0103 Rev. 00

Annex II List A Products

Product Name	REF N°
Alinity i Anti-HBc II Reagent Kit	07P8722
Alinity i Anti-HBc II Reagent Kit	07P8732
Alinity i Anti-HBc II Reagent Kit	07P8774
Alinity i Anti-HBc II Reagent Kit	07P8777
Alinity i Anti-HBc II Calibrator	07P8701
Alinity i Anti-HBc II Calibrator	07P8709
Alinity i Anti-HBc II Controls	07P8710
Alinity i Anti-HBc II Controls	07P8719
Alinity i rHTLV-I/II Reagent Kit	07P6122
Alinity i rHTLV-I/II Reagent Kit	07P6132
Alinity i rHTLV-I/II Calibrator	07P6101
Alinity i rHTLV-I/II Controls	07P6110
Alinity i HBeAg Reagent Kit	07P6422
Alinity i HBeAg Reagent Kit	07P6474
Alinity i HBeAg Calibrators	07P6401
Alinity i HBeAg Calibrators	07P6409
Alinity i HBeAg Controls	07P6410
Alinity i HBeAg Controls	07P6419
Alinity i HBeAg Quantitative Calibrators	09P1001
Alinity i HBeAg Quantitative Calibrators	09P1009
Alinity i HBeAg Quantitative Controls	09P1010
Alinity i HBeAg Quantitative Controls	09P1019
Alinity s Anti-HBc Reagent Kit	06P0655

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

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

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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 010051 0103 Rev. 00

Annex II List A Products

Product Name	REF N°
Alinity s Anti-HBc Calibrator Kit	06P0602
Alinity s Anti-HBc Assay Control Kit	06P0610
Alinity s Anti-HBc Release Control Kit	06P0612
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0155
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0102
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0110
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0112
Alinity s Anti-HCV Reagent Kit	06P0455
Alinity s Anti-HCV Reagent Kit	06P0477
Alinity s Anti-HCV Calibrator Kit	06P0402
Alinity s Anti-HCV Calibrator Kit	06P0409
Alinity s Anti-HCV Assay Control Kit	06P0410
Alinity s Anti-HCV Assay Control Kit	06P0419
Alinity s Anti-HCV Release Control Kit	06P0412
Alinity s Anti-HCV Release Control Kit	06P0418
Alinity s HTLV I/II Reagent Kit	06P0755
Alinity s HTLV I/II Calibrator Kit	06P0702
Alinity s HTLV I/II Assay Control Kit	06P0710
Alinity s HTLV I/II Release Control Kit	06P0712

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EC Certificate

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

No. V1 010051 0103 Rev. 00

Annex II List B Products

Product Name	REF N°
ARCHITECT Toxo IgG Reagent Kit	6C19-25
ARCHITECT Toxo IgG Reagent Kit	6C19-35
ARCHITECT Toxo IgG Calibrators	6C19-01
ARCHITECT Toxo IgG Controls	6C19-10
ARCHITECT Toxo IgG Avidity Reagent Kit	6L37-25
ARCHITECT Toxo IgG Avidity Calibrator & Controls	6L37-11
ARCHITECT Toxo IgM Reagent Kit	6C20-25
ARCHITECT Toxo IgM Reagent Kit	6C20-35
ARCHITECT Toxo IgM Calibrator	6C20-01
ARCHITECT Toxo IgM Controls	6C20-10
ARCHITECT Rubella IgG Reagent Kit	6C17-28
ARCHITECT Rubella IgG Reagent Kit	6C17-38
ARCHITECT Rubella IgG Calibrators	6C17-02
ARCHITECT Rubella IgG Controls	6C17-12
Alinity i Toxo IgG Reagent Kit	07P4522
Alinity i Toxo IgG Reagent Kit	07P4532
Alinity i Toxo IgG Calibrators	07P4501
Alinity i Toxo IgG Controls	07P4510
Alinity i Toxo IgM Reagent Kit	07P4722
Alinity i Toxo IgM Reagent Kit	07P4732
Alinity i Toxo IgM Calibrator	07P4701
Alinity i Toxo IgM Controls	07P4710
Alinity i Toxo IgG Avidity Reagent Kit	07P4622
Alinity i Toxo IgG Avidity Controls	07P4610

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EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition, for List A products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule and continued satisfactory compliance with the requirements for verification of manufactured product.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No:	LRQ 0964174
Original Approval:	11 May 2001
Current Certificate:	1 October 2018
Certificate Expiry:	30 September 2021

LRQA Notified Body Number 0088

David Dennis

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.

Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 0964174 SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

Annex II List A Products

PRISM HIV O PLUS Assay Kit (List number 3D34-48)
PRISM HBsAg Assay Kit (List number 3A47-48)
PRISM HCV Assay Kit (List number 6A52-48)
PRISM HTLV-I/HTLV-II Assay Kit (List number 6A53-48)
PRISM Positive Run Control Kit (List number 5E22-11)
PRISM Run Control Kit (List number 5E22-10)
PRISM HBcore Assay Kit (List number 1A77–48)
PRISM HBsAg Confirmatory Kit (List number 6D16-48)
ARCHITECT Anti-HCV Reagent Kit (List numbers 6C37-22, 6C37-27, 6C37-32, 6C37-37)
ARCHITECT Anti-HCV Calibrator (List number 6C37-01)
ARCHITECT Anti-HCV Controls (List number 6C37-10)
ARCHITECT Anti-HBc IgM Reagent Kit (List numbers 6C33-20, 6C33-25, 6C33-22, 6C33-27)
ARCHITECT Anti-HBc IgM Calibrators (List numbers 6C33-01, 6C33-02)
ARCHITECT Anti-HBc IgM Controls (List numbers 6C33-10, 6C33-11)
ARCHITECT Anti-HBe Reagent Kit (List numbers 6C34-20, 6C34-25, 6C34-35)
ARCHITECT Anti-HBe Calibrator (List number 6C34-01)
ARCHITECT Anti-HBe Controls (List number 6C34-10)
ARCHITECT HBeAg Reagent Kit (List numbers 6C32-20, 6C32-25, 6C32-27, 6C32-37)
ARCHITECT HBeAg Calibrators (List number 6C32-01)
ARCHITECT HBeAg Quantitative Calibrators (List number 7P24-01)
ARCHITECT HBeAg Controls (List number 6C32-10)
ARCHITECT HBeAg Quantitative Controls (List number 7P24-10)
PRISM HIV Ag/Ab Combo Assay Kit (List number 7G46-48)
PRISM Run Control Kit (List number 2K24-10)
PRISM Positive Run Control Kit (List number 2K24-11)
ARCHITECT HIV Ag/Ab Combo Reagent Kit (List numbers 4J27-22, 4J27-27, 4J27-32, 4J27-37)
ARCHITECT HIV Ag/Ab Combo Calibrator (List number 4J27-03)
ARCHITECT HIV Ag/Ab Combo Controls (List number 4J27-12)
ARCHITECT rHTLV I/II Reagent Kit, (List numbers 6L61-25, 6L61-30, 6L61-35)
ARCHITECT rHTLV I/II Calibrator (List number 6L61-01)
ARCHITECT rHTLV I/II Controls (List number 6L61-10)
ARCHITECT Anti-HBc II Reagent Kit, (List numbers 8L44-25, 8L44-30, 8L44-35)
ARCHITECT Anti-HBc II Calibrator (List number 8L44-01)

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

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EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 0964174 SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

Annex II List A Products Continued

ARCHITECT Anti-HBc II Controls (List number 8L44-10)
ARCHITECT HCV Ag Reagent Kit (List numbers 6L47-27, 6L47-29)
ARCHITECT HCV Ag Calibrators (List number 6L47-02)
ARCHITECT HCV Ag Controls (List number 6L47-11)
Alinity i Anti-HBe Reagent Kit (List number 07P6322)
Alinity i Anti-HBe Calibrator (List number 07P6301)
Alinity i Anti-HBe Controls (List number 07P6310)
Alinity i HIV Ag/Ab Combo Reagent Kit (List numbers 08P0722, 08P0732)
Alinity i HIV Ag/Ab Combo Calibrator (List number 08P0701)
Alinity i HIV Ag/Ab Combo Controls (List number 08P0710)
Alinity i Anti-HCV Reagent Kit, (List numbers 08P0622, 08P0632)
Alinity i Anti-HCV Calibrator (List number 08P0601)
Alinity i Anti-HCV Controls (List number 08P0610)
Alinity i Anti-HBc IgM Reagent Kit (List number 07P8622)
Alinity i Anti-HBc IgM Calibrators (List number 07P8601)
Alinity i Anti-HBc IgM Controls (List number 07P8610)
Alinity i Anti-HBc II Reagent Kit (List numbers 07P8722, 07P8732)
Alinity i Anti-HBc II Calibrator (List number 07P8701)
Alinity i Anti-HBc II Controls (List number 07P8710)
Alinity i rHTLV-I/II Reagent Kit (List numbers 07P6122, 07P6132)
Alinity i rHTLV-I/II Calibrator (List number 07P6101)
Alinity i rHTLV-I/II Controls (List number 07P6110)
Alinity i HBeAg Reagent Kit (List number 07P6422)
Alinity i HBeAg Calibrators (List number 07P6401)
Alinity i HBeAg Controls (List number 07P6410)
Alinity i HBeAg Quantitative Calibrators (List number 09P1001)
Alinity i HBeAg Quantitative Controls (List number 09P1010)
Alinity s Anti-HBc Reagent Kit (List number 06P0655)
Alinity s Anti-HBc Calibrator Kit (List number 06P0602)
Alinity s Anti-HBc Assay Control Kit (List number 06P0610)
Alinity s Anti-HBc Release Control Kit (List number 06P0612)
Alinity s HIV Ag/Ab Combo Reagent Kit (List number 06P0155)

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EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 0964174 SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

Annex II List A Products Continued

Alinity s HIV Ag/Ab Combo Calibrator Kit (List number 06P0102)
Alinity s HIV Ag/Ab Assay Control Kit (List number 06P0110)
Alinity s HIV Ag/Ab Release Control Kit (List number 06P0112)
Alinity s Anti-HCV Reagent Kit (List number 06P0455)
Alinity s Anti-HCV Calibrator Kit (List number 06P0402)
Alinity s Anti-HCV Assay Control Kit (List number 06P0410)
Alinity s Anti-HCV Release Control Kit (List number 06P0412)
Alinity s HTLV I/II Reagent Kit (List number 06P0755)
Alinity s HTLV I/II Calibrator Kit (List number 06P0702)
Alinity s HTLV I/II Assay Control Kit (List number 06P0710)
Alinity s HTLV I/II Release Control Kit (List number 06P0712)

Annex II List B Products

ARCHITECT Toxo IgG Reagent Kit (List numbers 6C19-25, 6C19-35)
ARCHITECT Toxo IgG Calibrators (List number 6C19-01)
ARCHITECT Toxo IgG Controls (List number 6C19-10)
ARCHITECT Toxo IgG Avidity Reagent Kit (List number 6L37-25)
ARCHITECT Toxo IgG Avidity Calibrator & Controls (List number 6L37-11)
ARCHITECT Toxo IgM Reagent Kit (List numbers 6C20-25, 6C20-35)
ARCHITECT Toxo IgM Calibrator (6C20-01)
ARCHITECT Toxo IgM Controls (6C20-10)
ARCHITECT Rubella IgG Reagent Kit (List numbers 6C17-28, 6C17-38)
ARCHITECT Rubella IgG Calibrators (List number 6C17-02)
ARCHITECT Rubella IgG Controls (List number 6C17-12)

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EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 0964174 SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

Annex II List B Products Continued

Alinity i Toxo IgG Reagent Kit (List numbers 07P4522, 07P4532)
Alinity i Toxo IgG Calibrators (List number 07P4501)
Alinity i Toxo IgG Controls (List number 07P4510)
Alinity i Toxo IgM Reagent Kit (List numbers 07P4722, 07P4732)
Alinity i Toxo IgM Calibrator (List number 07P4701)
Alinity i Toxo IgM Controls (List number 07P4710)
Alinity i Toxo IgG Avidity Reagent Kit (List number 07P4622)
Alinity i Toxo IgG Avidity Controls (List number 07P4610)

Schedule Issue: 01

Date of Schedule Issue: 1 October 2018

LRQA Notified Body Number 0088

David Dennis

Issued by: Lloyd's Register Quality Assurance Limited

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ZLG-BS-245.10.07

Product Service

EC Certificate

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

No. V1 001922 0008 Rev. 00

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.: 713155489-1_01

Valid from: 2019-03-30
Valid until: 2019-06-23

Date, 2019-03-29

Stefan Preiß

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. 00

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

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. 00

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

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. 00

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 Confirmatory Reagent Kit	06P0357
Alinity s HBsAg Calibrator Kit	06P0202
Alinity s HBsAg Assay Control Kit	06P0210
Alinity s HBsAg Release Control Kit	06P0212
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
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

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. 00

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

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. 00

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

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The design and manufacture of immunoassay based in vitro diagnostic devices for the detection and monitoring of infectious disease and other clinical markers

Device Classifications:
Annex II List A
Annex II List B

Device Descriptions and Model Type:
Please refer to Attachments: 1, 2, 3, 4, 5

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 5 attachments listing product references.

File Number	A18074	Cycle Start Date	June 24, 2016
Certificate Number	361.190129	Effective Date	January 29, 2019
Initial Issue Date	June 23, 2004	Expiry Date	June 23, 2019

Authorised by

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

Notified Body
0843

Check Certificate Status:

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

IVDD A4 S3 FD
00-MB-A0043 Issue 15.0

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 1 of 5

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

Model/Type	Classification	G/UMDN Code
ARCHITECT HBsAg Qualitative II Calibrators 2G22-01	Annex II List A	-
ARCHITECT HBsAg Qualitative II Reagent Kit 2G22-25	Annex II List A	-
ARCHITECT HBsAg Qualitative II Reagent Kit 2G22-30	Annex II List A	-
ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit 2G23-25	Annex II List A	-
ARCHITECT HBsAg Calibrators 3M61-01	Annex II List A	-
ARCHITECT HBsAg Calibrators 3M61-02	Annex II List A	-
ARCHITECT HBsAg Controls 6C36-10	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-22	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-27	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-32	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-29	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-34	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-35	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-43	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-44	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-41	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-42	Annex II List A	-
ARCHITECT Anti-HBs Calibrators 7C18-01	Annex II List A	-
ARCHITECT Anti-HBs Calibrators 7C18-03	Annex II List A	-
ARCHITECT Anti-HBs Controls 7C18-10	Annex II List A	-
ARCHITECT Anti-HBs Controls 7C18-13	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-20	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-25	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-27	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-28	Annex II List A	-

File Number	A18074	Cycle Start Date	June 24, 2016
Certificate Number	361.190129	Effective Date	January 29, 2019
Initial Issue Date	June 23, 2004	Expiry Date	June 23, 2019

Authorised by

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

Notified Body
0843

Check Certificate Status:

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

IVDD A4 S3 FD
00-MB-A0043 Issue 15.0

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 2 of 5

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

Model/Type	Classification	G/UMDN Code
ARCHITECT Anti-HBs Reagent Kit 7C18-30	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-34	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-37	Annex II List A	-
ARCHITECT Anti-HBs Reagent kit 7C18-38	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Calibrators 9C94-01	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Controls 9C94-10	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Reagent Kit 9C94-25	Annex II List A	-
ARCHITECT HBsAg Qualitative II Reagent Kit 2G22-35	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-29	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-41	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-39	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-42	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-33	Annex II List A	-
Alinity i HBsAg Calibrators 08P0801	Annex II List A	-
Alinity i HBsAg Controls 08P0810	Annex II List A	-
Alinity i HBsAg Reagent Kit 08P0852	Annex II List A	-
Alinity i HBsAg Confirmatory V.1 Calibrators 08P0901	Annex II List A	-
Alinity i HBsAg Confirmatory V.1 Controls 08P0910	Annex II List A	-
Alinity i HBsAg Confirmatory V.1 Reagent Kit 08P0922	Annex II List A	-
Alinity i HBsAg Qualitative II Calibrators 08P1001	Annex II List A	-
Alinity i HBsAg Qualitative II Controls 08P1010	Annex II List A	-
Alinity i HBsAg Qualitative II Reagent Kit 08P1022	Annex II List A	-
Alinity i HBsAg Qualitative II Confirmatory Reagent Kit 08P1122	Annex II List A	-
Alinity i Anti-HBs Reagent Kit 07P8522	Annex II List A	-
Alinity i Anti-HBs Controls 07P8910	Annex II List A	-

File Number A18074
Certificate Number 361.190129
Initial Issue Date June 23, 2004

Cycle Start Date June 24, 2016
Effective Date January 29, 2019
Expiry Date June 23, 2019

Authorised by

Notified Body
0843

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

Check Certificate Status:

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 3 of 5

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

Model/Type	Classification	G/UMDN Code
Alinity i Anti-HBs Calibrators 07P8901	Annex II List A	-
Alinity i Anti-HBs Reagent Kit 07P8952	Annex II List A	-
Alinity s HBsAg Reagent Kit 06P0255	Annex II List A	-
Alinity s HBsAg Confirmatory Reagent Kit 06P0357	Annex II List A	-
Alinity s HBsAg Calibrator Kit 06P0202	Annex II List A	-
Alinity s HBsAg Assay Control Kit 06P0210	Annex II List A	-
Alinity s HBsAg Release Control Kit 06P0212	Annex II List A	-
ARCHITECT HBsAg Qualitative II Controls 2G22-10	Annex II List A	-
Alinity i HBsAg Qualitative II Reagent Kit 08P1032	Annex II List A	-
Alinity i HBsAg Reagent Kit 08P0832	Annex II List A	-
Alinity i HBsAg Reagent Kit 08P0822	Annex II List A	-
Alinity i Anti-HBs Reagent Kit 07P8932	Annex II List A	-
Alinity i Anti-HBs Reagent Kit 07P8957	Annex II List A	-
ARCHITECT HBsAg Next Qualitative Reagent Kit - 4P76-25	Annex II List A	-
ARCHITECT HBsAg Next Qualitative Reagent Kit - 4P76-30	Annex II List A	-
ARCHITECT HBsAg Next Qualitative Reagent Kit - 4P76-35	Annex II List A	-
ARCHITECT HBsAg Next Confirmatory Reagent Kit - 4P77-25	Annex II List A	-
ARCHITECT HBsAg Next Qualitative Calibrators - 4P76-01	Annex II List A	-
ARCHITECT HBsAg Next Qualitative Controls - 4P76-10	Annex II List A	-
ARCHITECT Rubella IgM Reagent Kit 6C18-25	Annex II List B	-
ARCHITECT Rubella IgM Calibrator 6C18-01	Annex II List B	-
ARCHITECT Rubella IgM Controls 6C18-10	Annex II List B	-
ARCHITECT Rubella IgG Reagent Kit 6C17-26/36	Annex II List B	-
ARCHITECT Rubella IgG Calibrators 6C17-03	Annex II List B	-
ARCHITECT Rubella IgG Controls 6C17-13	Annex II List B	-

File Number A18074
Certificate Number 361.190129
Initial Issue Date June 23, 2004

Cycle Start Date June 24, 2016
Effective Date January 29, 2019
Expiry Date June 23, 2019

Authorised by

Notified Body
0843

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

Check Certificate Status:

IVDD A4 S3 FQ
80-MB-A0043 Issue: 15.0

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 4 of 5

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

Model/Type	Classification	G/UMDN Code
ARCHITECT Free PSA Reagent Kit 7K71-20/25	Annex II List B	-
ARCHITECT Free PSA Calibrators 7K71-01	Annex II List B	-
ARCHITECT Free PSA Controls 7K71-10	Annex II List B	-
ARCHITECT Total PSA Reagent Kit 7K70-20/25/30/35	Annex II List B	-
ARCHITECT Total PSA Calibrators 7K70-01	Annex II List B	-
ARCHITECT Total PSA Controls 7K70-10	Annex II List B	-
ARCHITECT CMV IgG Avidity Reagent Kit 3L46-25	Annex II List B	-
ARCHITECT CMV IgG Avidity Calibrator and Controls 3L46-11	Annex II List B	-
ARCHITECT CMV IgG Reagent Kit 6C15-20/25/30	Annex II List B	-
ARCHITECT CMV IgG Calibrators 6C15-01	Annex II List B	-
ARCHITECT CMV IgG Controls 6C15-10	Annex II List B	-
ARCHITECT CMV IgM Reagent Kit 6C16-20/25/30	Annex II List B	-
ARCHITECT CMV IgM Calibrator 6C16-01	Annex II List B	-
ARCHITECT CMV IgM Controls 6C16-10	Annex II List B	-
Alinity i CMV IgG Reagent Kit 07P4222 / 07P4232	Annex II List B	-
Alinity i CMV IgG Calibrators 07P4201	Annex II List B	-
Alinity i CMV IgG Controls 07P4210	Annex II List B	-
Alinity i CMV IgM Reagent Kit 07P4422 / 07P4432	Annex II List B	-
Alinity i CMV IgM Calibrator 07P4401	Annex II List B	-
Alinity i CMV IgM Controls 07P4410	Annex II List B	-
Alinity i HBsAg Reagent Kit 08P0857	Annex II List A	-
Alinity i Rubella IgG Reagent Kit 08P4622 / 08P4632	Annex II List B	-
Alinity i Rubella IgG Calibrators 08P4601	Annex II List B	-
Alinity i Rubella IgG Controls 08P4610	Annex II List B	-
Alinity i Rubella IgM Reagent Kit 08P4722 / 08P4732	Annex II List B	-

File Number A18074
Certificate Number 361.190129
Initial Issue Date June 23, 2004

Cycle Start Date June 24, 2016
Effective Date January 29, 2019
Expiry Date June 23, 2019

Authorised by

Notified Body
0843

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

Check Certificate Status:

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

IVDD A4 S3 FC
00-MS-A0043 Issue: 15.0

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 5 of 5

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

Model/Type	Classification	G/UMDN Code
Alinity i Rubella IgM Calibrator 08P4701	Annex II List B	-
Alinity i Rubella IgM Controls 08P4710	Annex II List B	-
Alinity i CMV IgG Avidity Reagent Kit 07P4322	Annex II List B	-
Alinity i CMV IgG Avidity Controls 07P4310	Annex II List B	-
Alinity s CMV IgG Qualitative Reagent Kit 06P1045	Annex II List B	-
Alinity s CMV IgG Qualitative Calibrator Kit 06P1002	Annex II List B	-
Alinity s CMV IgG Qualitative Assay Control Kit 06P1010	Annex II List B	-
Alinity s CMV IgG Qualitative Release Control Kit 06P1012	Annex II List B	-
Alinity i Free PSA Reagent Kit 07P9320 / 07P9330	Annex II List B	-
Alinity i Free PSA Calibrators 07P9301	Annex II List B	-
Alinity i Free PSA Controls 07P9310	Annex II List B	-
Alinity i Total PSA Reagent Kit 07P9220 / 07P9230	Annex II List B	-
Alinity i Total PSA Calibrators 07P9201	Annex II List B	-
Alinity i Total PSA Controls 07P9210	Annex II List B	-

File Number A18074
Certificate Number 361.190129
Initial Issue Date June 23, 2004

Cycle Start Date June 24, 2016
Effective Date January 29, 2019
Expiry Date June 23, 2019

Authorised by

Notified Body
0843

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

Check Certificate Status:

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

IVDD A4 S3 FC
00-MS-A0043 Issue: 15.0

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 Lou Murawski
Full Name: Mary Lou Murawski
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

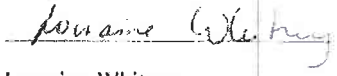
Certificate Identification: 7K63
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K63-27 7K63-32 7K63-37	54417	ARCHITECT Free T3 Reagent Kit	Self-declared
7K63-02	38261	ARCHITECT Free T3 Calibrators	Self-declared
7K63-12	54418	ARCHITECT Free T3 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:		Signature:	
Full Name:	Kevin Callaghan	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	10 May 2017	Date of Approval:	10 May 2017
Date Issued:	10 May 2017	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	24 April 2017	Effective (Date or Lot Number):	10 May 2017

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:	Kevin Callaghan	Signature:	Lorraine Whitney
Full Name:	Kevin Callaghan	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	26 June 2017	Date of Approval:	26 July 17
Date Issued:	26-JUL-2017	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	30-OCT-2015	Effective (Date or Lot Number):	26 JUL-2017

Abbott

Declaration of Conformity

Certificate Identification:	7K62
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford
	Co. Longford
	Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K62-20 7K62-25 7K62-30 7K62-35	54386	ARCHITECT TSH Reagent Kit	Self-declared
7K62-01	38272	ARCHITECT TSH Calibrators	Self-declared
7K62-10	38271	ARCHITECT TSH Controls	Self-declared

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

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

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

Signature:	Kevin Callaghan	Signature:	Lorraine Whitney
Full Name:	Kevin Callaghan	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	25 May 2017	Date of Approval:	25 May 2017
Date Issued:	25 May 2017	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	22 April 2014	Effective (Date or Lot Number):	25 May 2017

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 UL International (UK) Ltd Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey, GU3 1LR
Notified Body number	0123 (TÜV SÜD Product Service GmbH) & 0843 (UL International (UK) Ltd)
Approval Certificate No.	V1 0019220008 (TÜV SÜD Product Service GmbH) & 361 (UL International (UK) Ltd)
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: 29 Mar 19

Date Issued: 29 March 2019

Supersedes: 05 Jan 2017

Signature: P.P. NOEL HAREN

Full Name: Lorraine Whitney

Position: Senior Manager Regulatory Affairs

Date of Approval: 29 March 2019

Place Issued: AIDD Sligo

Effective (Date or Lot Number): 30 March 2019

Abbott

Declaration of Conformity

Certificate Identification: DoC 8L44 AII DELK

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
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)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
Notified Body number	LRQA:0088 TÜV SÜD: 0123
Approval Certificate No.	LRQA: 0088/0964174/00117 TÜV SÜD: V7 010051 0130
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, 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: Hartmann

Full Name: **Dr. Herbert Hartmann**

Position: **Manager Quality Systems**

Date of Approval: 2019-03-29

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 29/ Mar/ 2019

Date Issued: 29/ Mar/ 2019

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 04-May-2015

Effective (Date or Lot Number): 30/ Mar/ 2019

Abbott

Declaration of Conformity

Certificate Identification: DOC-6C37-22/-27/-32/-37-All DLK

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
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)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
Notified Body number	LRQA:0088 TÜV SÜD: 0123
Approval Certificate No.	LRQA:0088/0964174/00021 TÜV SÜD: V7 010051 0132
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden
Harmonized Standards	Listed in the Technical Documentation

Abbott

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**

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. Herbert Hartmann**	Full Name:	**Susanne Ulrich**
Position:	**Manager Quality Systems**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	2019-03-29	Date of Approval:	29/Mar/2019
		Date Issued:	29/Mar/2019
		Place Issued:	65205 Wiesbaden, Germany
		Supersedes:	04-May-2015
		Effective (Date or Lot Number):	30/Mar/2019

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:	Lorraine Whitney
Full Name:	Niall Plunkett	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	07 Jul 14	Date of Approval:	04 July 2014
Date Issued:	07 Jul 14	Place Issued:	AIDD Sligo
Supersedes:	13 Jan 2013	Effective (Date or Lot Number):	07 Jul 14

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 UL International (UK) Ltd Wonersh House The Guildway Old Portsmouth Road, Guildford, Surrey, GU3 1LR United Kingdom.
Notified Body number	0123 (TÜV SÜD Product Service GmbH) & 0843 (UL International (UK) Ltd)
Approval Certificate No.	V1 0019220008 (TÜV SÜD Product Service GmbH) & 361 (UL International (UK) Ltd)
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: 29 Mar 19
Date Issued: 29 March 2019

Supersedes: 11 Jan 2017

Signature:
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 29 March 2019
Place Issued: AIDD, Sligo
Effective (Date or Lot Number): 30 March 2019

Abbott

Declaration of Conformity

Certificate Identification:	7K75
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	30322	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 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:	Lorraine Whitney
Full Name:	Siobhan Wright	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	04-JUL-14	Date of Approval:	01 July 2014
Date Issued:	04-JUL-14 ~~02-JUL-14~~ X	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	09 APR 2008	Effective (Date or Lot Number):	04-JUL-14

X Entry Error S.Wright 04 JUL-14

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: 12-OCT-18
Date Issued: 12-OCT-18
Supersedes: 09 AUG 2012

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Sr Manager RA Site Operations Ireland
Date of Approval: 12 OCT 2018
Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford. Ireland
Effective (Date or Lot Number): 12-OCT-18

TECHNOPATH

DECLARATION OF CONFORMITY

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

Product(s):

Product Name	Catalogue Number
Multichem IA Plus	IA310X
Multichem IA Plus	IA311X
Multichem IA Plus	IA312X
Multichem IA Plus	IA313X
Multichem IA Plus	IA314X
Multichem IA Plus	05P76-10
Multichem IA Plus	IA310A
Multichem IA Plus	IA311A
Multichem IA Plus	IA312A
Multichem IA Plus	IA313A

GMDN: 47869
Classification: Annex II List B
Conformity Route: Annex IV
Quality Management System: EN ISO 13485:2012 / ISO 13485:2003
QMS/CE Certification No.: LRQ 4008261/B
Issued By: Lloyds Register LRQA, 71 Fenchurch Street, London EC3M 4BS United Kingdom
Notified Body Number: 0088

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

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

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

Bernd Hass, Head of Quality and Regulatory Affairs Date 24-Jan-2014
Techno-path Manufacturing Ltd.

TECHNOPATH

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

Standard	Title
EN ISO 15223-1:2012	Symbols for use in the labelling of medical devices
ISO 13485:2012 + AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 13640:2002	Stability Testing of In vitro diagnostic reagents

DC007 Rev 06 Issue Date:24th Jan 2014

Abbott

Declaration of Conformity

Certificate Identification:	7K76
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford
	Co. Longford
	Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K76-20 7K76-25 7K76-30 7K76-35	54335	ARCHITECT Prolactin Reagent Kit	Self-declared
7K76-01	54337	ARCHITECT Prolactin Calibrators	Self-declared
7K76-10	54338	ARCHITECT Prolactin Controls	Self-declared

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

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

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

Signature:

Full Name: Kevin Callaghan

Position: Quality Manager

Date of Approval: 25 May 2017

Date Issued: 25 May 2017

Supersedes: 02 July 2014

Signature:

Full Name: Lorraine Whitney

Position: Senior Manager Regulatory Affairs

Date of Approval: 25 May 2017

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

Effective (Date or Lot Number): 25 May 2017

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:		Signature:	
Full Name:	**Philip McGee**	Full Name:	**Lorraine Whitney**
Position:	**Quality Manager**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	29 Aug 2016	Date of Approval:	28 APR 16
Date Issued:	[illegible] 2016	Place Issued	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes	29 JAN 15	Effective (Lot number or date)	[illegible] 2016

Abbott

Declaration of Conformity

Certificate Identification: 04P56/04P58 LC IRIS V27

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
4P56-25	43472	ARCHITECT *i* System e-Assay CD-ROM WW (excluding US)	Self-declared
4P58-24	43472	ARCHITECT *i*1000SR System e-Assay CD-ROM WW (excluding US)	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: L P Schwarz

Full Name: Lawrence P. Schwarz

Position: Senior Quality Professional

Date of Approval: Feb 4, 2016

Date Issued:

Supersedes: November 16, 2015

Signature: Regina Xavier

Full Name: REGINA XAVIER (for Carey Kawanishi)

Position: Regulatory Affairs Manager

Date of Approval: 2/4/2016

Place Issued: Abbott Park.

Effective (Date or Lot Number): 2/4/2016

Murawski, Marycaren

From:	Murawski, Marycaren
Sent:	Friday, January 22, 2016 5:18 PM
To:	Chen, Jean; Hart, Megan K; Lukowski, Lisa G; Prochniak, Margaret D; Sohn, Linda J; Xavier, Regina
Cc:	Raich, Teresa J; Hinkley, Deborah N; Sanborn, Susan J; Kwiecinski, Rebecca A; Rizos, John A
Subject:	Caren Murawski Signature Authority for January 25 through February 4, 2016

Dear All,

I will be out of the office on business travel 1/25/16 through 2/4/16 with limited access to email.
Regina Xavier and Lisa Lukowski will have my signature authority 1/25/16 through 1/31/16 with the exception of personnel matters.
Margaret Prochniak and Regina Xavier will have my signature authority 2/1/16 through 2/4/16 with the exception of personnel matters.
Please contact Regina, Lisa or Marg for urgent RA issues requiring immediate attention.

Best Regards,
Caren

Mary Caren Murawski
Associate Director
Abbott Diagnostic Division
Regulatory Affairs

Abbott
100 Abbott Park Road
Dept. 93G / Bldg: AP8
Abbott Park, IL 60064-6197

Telephone: (224) 667-2817
Fax: (224) 667-4836
Mobile: (847) 393-5938
mary.murawski@abbott.com

Abbott Diagnostics

ABBOTT

Declaration of Conformity

Certificate Identification: 7K77
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K77-20 7K77-25 7K77-35	54322	ARCHITECT Progesterone Reagent Kit	**Self-declared**
7K77-01	54325	ARCHITECT Progesterone Calibrators	**Self-declared**
7K77-10	54326	ARCHITECT Progesterone Controls	**Self-declared**
7K77-50	58208	ARCHITECT Progesterone Manual Diluent	**Self-declared**

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

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

Signature:
Full Name: **Philip McGee**
Position: **Quality Manager**
Date of Approval: 29 April 2016
Date Issued: 05 May 2016
Supersedes 09 JAN 15

Signature: Lorraine Whitney
Full Name: **Lorraine Whitney**
Position: **Senior Manager Regulatory Affairs**
Date of Approval: 29 April 16
Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Effective (Lot number or date): 05 May 2016