

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: Siobhan Wright

Full Name: **Siobhan Wright**

Position: **Director Quality Assurance/
Site Quality Head**

Date of Approval: 24-APR-19

Date Issued: 24-APR-19

Supersedes: 25-May-2017

Signature: Lorraine Whitney

Full Name: **Lorraine Whitney**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 19 APR 2019

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

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

Declaration of Conformity

Certificate Identification:	<u>S1497</u>
Legal Manufacturer's Name:	<u>Abbott Ireland Diagnostics Division</u>
Legal Manufacturer's Address:	<u>Lisnamuck, Longford, Co. Longford, Ireland.</u>

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K77-20 7K77-25	30323	ARCHITECT Progesterone Reagent Kits	Self-declared
7K77-01	30504	ARCHITECT Progesterone Calibrators	Self-declared
7K77-10	N/A	ARCHITECT Progesterone Controls	Self-declared
7K77-50	N/A	ARCHITECT Progesterone Manual Diluent	Self-declared

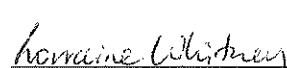
Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC 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: 
 Full Name (printed): **Stefan Molitor**
 Position: **Quality Manager**

Date: 30 May 2007

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

Date: 30 May 2007

Date Issued: 30 May 2007

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

Supersedes: N/A

Effective (Lot number or date) 30 May 2007

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: <u><i>Siobhan Wright</i></u> Full Name: Siobhan Wright Position: Director Quality Assurance/ Site Quality Head Date of Approval: <u>24-APR-19</u> Date Issued: <u>24-APR-19</u> Supersedes: <u>25-May-2017</u>	Signature: <u><i>Lorraine Whitney</i></u> Full Name: Lorraine Whitney Position: Senior Manager Regulatory Affairs/ Date of Approval: <u>19 APR 2019</u> Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland Effective (Date or Lot Number): <u>24-APR-19</u>
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Declaration of Conformity

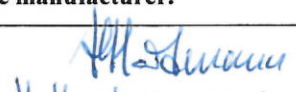
Certificate Identification:	<u>DOC-2P13-SD-DLK-OEM</u>
Legal Manufacturer's Name:	<u>Abbott GmbH & Co. KG</u>
Legal Manufacturer's Address:	<u>Max-Planck-Ring 2, 65205 Wiesbaden, Germany</u>

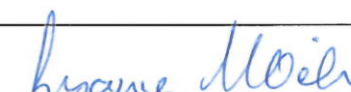
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2P13-25	61077	Architect 2nd Generation Testosterone Reagent Kit (100 tests)	Self-declared
2P13-28	61077	Architect 2nd Generation Testosterone Reagent Kit (100 tests)	Self-declared
2P13-20	61077	Architect 2nd Generation Testosterone Reagent Kit (400 tests)	Self-declared
2P13-23	61077	Architect 2nd Generation Testosterone Reagent Kit (400 tests)	Self-declared
2P13-01	58381	Architect 2nd Generation Testosterone Calibrators	Self-declared
2P13-10	58380	Architect 2nd Generation Testosterone Controls	Self-declared

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Axis-Shield Diagnostics Ltd, Luna Place, The Technology Park, Dundee DD2 1XA, Scotland
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: Christian Braemer
Position: Manager Quality
Date of Approval: 2015-11-10

Signature: 
Full Name: Susanne Ulrich
Position: Senior Manager Regulatory Affairs Site Operations Germany
Date of Approval: 10/Nov/2015
Date Issued: 16/Nov/2015
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 17 Nov 2014
Effective (Date or Lot Number): 16/Nov/2015



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Product Service

EC Certificate

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

No. V1 001922 0008 Rev. 03

Manufacturer:

Abbott Ireland Diagnostics Division
Finisklin Business Park
Sligo
IRELAND

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

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

Report no.:

713158801-03

Valid from:

2020-01-15

Valid until:

2024-05-26

Date,

2020-01-15

Christoph Dicks
Head of Certification/Notified Body



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Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 001922 0008 Rev. 03

Model(s):

**Products for the determination
of infection markers for Hepatitis B,
cytomegalovirus, rubella and tumour
marker PSA**

Facility(ies):

Abbott Ireland Diagnostics Division
Finisklin Business Park, Sligo, IRELAND

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

Annex II List A Products

Product Name	REF N°
ARCHITECT HBsAg Qualitative II Calibrators	2G22-01
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-30
ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit	2G23-25
ARCHITECT HBsAg Calibrators	3M61-01
ARCHITECT HBsAg Calibrators	3M61-02
ARCHITECT HBsAg Controls	6C36-10
ARCHITECT HBsAg Reagent Kit	6C36-22
ARCHITECT HBsAg Reagent Kit	6C36-27
ARCHITECT HBsAg Reagent Kit	6C36-32
ARCHITECT HBsAg Reagent Kit	6C36-29
ARCHITECT HBsAg Reagent Kit	6C36-34
ARCHITECT HBsAg Reagent Kit	6C36-35
ARCHITECT HBsAg Reagent Kit	6C36-43
ARCHITECT HBsAg Reagent Kit	6C36-44
ARCHITECT HBsAg Reagent Kit	6C36-41
ARCHITECT HBsAg Reagent Kit	6C36-42
ARCHITECT Anti-HBs Calibrators	7C18-01
ARCHITECT Anti-HBs Calibrators	7C18-03
ARCHITECT Anti-HBs Controls	7C18-10
ARCHITECT Anti-HBs Controls	7C18-13
ARCHITECT Anti-HBs Reagent Kit	7C18-20
ARCHITECT Anti-HBs Reagent Kit	7C18-25



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Product Service

EC Certificate

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

No. V1 001922 0008 Rev. 03

Annex II List A Products

Product Name	REF N°
ARCHITECT Anti-HBs Reagent Kit	7C18-27
ARCHITECT Anti-HBs Reagent Kit	7C18-28
ARCHITECT Anti-HBs Reagent Kit	7C18-30
ARCHITECT Anti-HBs Reagent Kit	7C18-34
ARCHITECT Anti-HBs Reagent Kit	7C18-37
ARCHITECT Anti-HBs Reagent kit	7C18-38
ARCHITECT HBsAg Confirmatory V.1 Calibrators	9C94-01
ARCHITECT HBsAg Confirmatory V.1 Controls	9C94-10
ARCHITECT HBsAg Confirmatory V.1 Reagent Kit	9C94-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-35
ARCHITECT Anti-HBs Reagent Kit	7C18-29
ARCHITECT Anti-HBs Reagent Kit	7C18-41
ARCHITECT Anti-HBs Reagent Kit	7C18-39
ARCHITECT Anti-HBs Reagent Kit	7C18-42
ARCHITECT Anti-HBs Reagent Kit	7C18-33
Alinity i HBsAg Calibrators	08P0801
Alinity i HBsAg Controls	08P0810
Alinity i HBsAg Reagent Kit	08P0852
Alinity i HBsAg Confirmatory V.1 Calibrators	08P0901
Alinity i HBsAg Confirmatory V.1 Controls	08P0910
Alinity i HBsAg Confirmatory V.1 Reagent Kit	08P0922
Alinity i HBsAg Qualitative II Calibrators	08P1001
Alinity i HBsAg Qualitative II Controls	08P1010



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Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 001922 0008 Rev. 03

Annex II List A Products

Product Name	REF N°
Alinity i HBsAg Qualitative II Reagent Kit	08P1022
Alinity i HBsAg Qualitative II Confirmatory Reagent Kit	08P1122
Alinity i Anti-HBs Reagent Kit	07P8922
Alinity i Anti-HBs Controls	07P8910
Alinity i Anti-HBs Calibrators	07P8901
Alinity i Anti-HBs Reagent Kit	07P8952
Alinity s HBsAg Reagent Kit	06P0255
Alinity s HBsAg Reagent Kit	06P0260
Alinity s HBsAg Confirmatory Reagent Kit	06P0357
Alinity s HBsAg Confirmatory Reagent Kit	06P0359
Alinity s HBsAg Calibrator Kit	06P0202
Alinity s HBSAg Calibrator Kit	06P0204
Alinity s HBsAg Assay Control Kit	06P0210
Alinity s HBsAg Assay Control Kit	06P0213
Alinity s HBsAg Release Control Kit	06P0212
Alinity s HBsAg Release Control Kit	06P0215
ARCHITECT HBsAg Qualitative II Controls	2G22-10
Alinity i HBsAg Qualitative II Reagent Kit	08P1032
Alinity i HBsAg Reagent Kit	08P0832
Alinity i HBsAg Reagent Kit	08P0822
Alinity i HBsAg Reagent Kit	08P0857
Alinity i Anti-HBs Reagent Kit	07P8932
Alinity i Anti-HBs Reagent Kit	07P8957
Alinity i HBsAg Next Qualitative Calibrators	01R6401
Alinity i HBsAg Next Qualitative Controls	01R6410
Alinity i HBsAg Next Qualitative Reagent Kit	01R6422
Alinity i HBsAg Next Qualitative Reagent Kit	01R6432
Alinity i HBsAg Next Confirmatory Reagent Kit	01R6522
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-25
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-30
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-35
ARCHITECT HBsAg Next Confirmatory Reagent Kit	4P77-25
ARCHITECT HBsAg Next Qualitative Calibrators	4P76-01
ARCHITECT HBsAg Next Qualitative Controls	4P76-10

Page 4 of 6

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

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Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 001922 0008 Rev. 03

Annex II List B Products

Product Name	REF N°
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



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Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 001922 0008 Rev. 03

Annex II List B Products

Product Name	REF N°
Alinity i CMV IgG Controls	07P4210
Alinity i CMV IgM Reagent Kit	07P4422 / 07P4432
Alinity i CMV IgM Calibrator	07P4401
Alinity i CMV IgM Controls	07P4410
Alinity i Rubella IgG Reagent Kit	08P4622 / 08P4632
Alinity i Rubella IgG Calibrators	08P4601
Alinity i Rubella IgG Controls	08P4610
Alinity i Rubella IgM Reagent Kit	08P4722 / 08P4732
Alinity i Rubella IgM Calibrator	08P4701
Alinity i Rubella IgM Controls	08P4710
Alinity i CMV IgG Avidity Reagent Kit	07P4322
Alinity i CMV IgG Avidity Controls	07P4310
Alinity s CMV IgG Qualitative Reagent Kit	06P1045
Alinity s CMV IgG Qualitative Calibrator Kit	06P1002
Alinity s CMV IgG Qualitative Assay Control Kit	06P1010
Alinity s CMV IgG Qualitative Release Control Kit	06P1012
Alinity i Free PSA Reagent Kit	07P9320 / 07P9330
Alinity i Free PSA Calibrators	07P9301
Alinity i Free PSA Controls	07P9310
Alinity i Total PSA Reagent Kit	07P9220 / 07P9230
Alinity i Total PSA Calibrators	07P9201
Alinity i Total PSA Controls	07P9210



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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



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Product Service

EC Certificate

EC Design-Examination Certificate

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

No. V7 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



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Product Service

EC Certificate

EC Design-Examination Certificate

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

No. V7 001922 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



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
Certificate Number 562.180812
Initial Issue Date April 25, 2008

Cycle Start Date August 12, 2018
Effective Date August 12, 2018
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



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
Certificate Number 562.180812
Initial Issue Date April 25, 2008

Cycle Start Date August 12, 2018
Effective Date August 12, 2018
Expiry Date August 11, 2023

Authorised by

Notified Body

0843

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

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



Check Certificate
Status: [here](#)

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



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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 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



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Product Service

EC Certificate

EC Design-Examination Certificate

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

No. V7 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



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Product Service

EC Certificate

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

No. V1 001922 0008 Rev. 03

Manufacturer:

Abbott Ireland Diagnostics Division
Finisklin Business Park
Sligo
IRELAND

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

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

Report no.:

713158801-03

Valid from:

2020-01-15

Valid until:

2024-05-26

Date,

2020-01-15

Christoph Dicks
Head of Certification/Notified Body



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Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 001922 0008 Rev. 03

Model(s):

**Products for the determination
of infection markers for Hepatitis B,
cytomegalovirus, rubella and tumour
marker PSA**

Facility(ies):

Abbott Ireland Diagnostics Division
Finisklin Business Park, Sligo, IRELAND

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

Annex II List A Products

Product Name	REF N°
ARCHITECT HBsAg Qualitative II Calibrators	2G22-01
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-30
ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit	2G23-25
ARCHITECT HBsAg Calibrators	3M61-01
ARCHITECT HBsAg Calibrators	3M61-02
ARCHITECT HBsAg Controls	6C36-10
ARCHITECT HBsAg Reagent Kit	6C36-22
ARCHITECT HBsAg Reagent Kit	6C36-27
ARCHITECT HBsAg Reagent Kit	6C36-32
ARCHITECT HBsAg Reagent Kit	6C36-29
ARCHITECT HBsAg Reagent Kit	6C36-34
ARCHITECT HBsAg Reagent Kit	6C36-35
ARCHITECT HBsAg Reagent Kit	6C36-43
ARCHITECT HBsAg Reagent Kit	6C36-44
ARCHITECT HBsAg Reagent Kit	6C36-41
ARCHITECT HBsAg Reagent Kit	6C36-42
ARCHITECT Anti-HBs Calibrators	7C18-01
ARCHITECT Anti-HBs Calibrators	7C18-03
ARCHITECT Anti-HBs Controls	7C18-10
ARCHITECT Anti-HBs Controls	7C18-13
ARCHITECT Anti-HBs Reagent Kit	7C18-20
ARCHITECT Anti-HBs Reagent Kit	7C18-25



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Product Service

EC Certificate

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

No. V1 001922 0008 Rev. 03

Annex II List A Products

Product Name	REF N°
ARCHITECT Anti-HBs Reagent Kit	7C18-27
ARCHITECT Anti-HBs Reagent Kit	7C18-28
ARCHITECT Anti-HBs Reagent Kit	7C18-30
ARCHITECT Anti-HBs Reagent Kit	7C18-34
ARCHITECT Anti-HBs Reagent Kit	7C18-37
ARCHITECT Anti-HBs Reagent kit	7C18-38
ARCHITECT HBsAg Confirmatory V.1 Calibrators	9C94-01
ARCHITECT HBsAg Confirmatory V.1 Controls	9C94-10
ARCHITECT HBsAg Confirmatory V.1 Reagent Kit	9C94-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-35
ARCHITECT Anti-HBs Reagent Kit	7C18-29
ARCHITECT Anti-HBs Reagent Kit	7C18-41
ARCHITECT Anti-HBs Reagent Kit	7C18-39
ARCHITECT Anti-HBs Reagent Kit	7C18-42
ARCHITECT Anti-HBs Reagent Kit	7C18-33
Alinity i HBsAg Calibrators	08P0801
Alinity i HBsAg Controls	08P0810
Alinity i HBsAg Reagent Kit	08P0852
Alinity i HBsAg Confirmatory V.1 Calibrators	08P0901
Alinity i HBsAg Confirmatory V.1 Controls	08P0910
Alinity i HBsAg Confirmatory V.1 Reagent Kit	08P0922
Alinity i HBsAg Qualitative II Calibrators	08P1001
Alinity i HBsAg Qualitative II Controls	08P1010



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Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 001922 0008 Rev. 03

Annex II List A Products

Product Name	REF N°
Alinity i HBsAg Qualitative II Reagent Kit	08P1022
Alinity i HBsAg Qualitative II Confirmatory Reagent Kit	08P1122
Alinity i Anti-HBs Reagent Kit	07P8922
Alinity i Anti-HBs Controls	07P8910
Alinity i Anti-HBs Calibrators	07P8901
Alinity i Anti-HBs Reagent Kit	07P8952
Alinity s HBsAg Reagent Kit	06P0255
Alinity s HBsAg Reagent Kit	06P0260
Alinity s HBsAg Confirmatory Reagent Kit	06P0357
Alinity s HBsAg Confirmatory Reagent Kit	06P0359
Alinity s HBsAg Calibrator Kit	06P0202
Alinity s HBsAg Calibrator Kit	06P0204
Alinity s HBsAg Assay Control Kit	06P0210
Alinity s HBsAg Assay Control Kit	06P0213
Alinity s HBsAg Release Control Kit	06P0212
Alinity s HBsAg Release Control Kit	06P0215
ARCHITECT HBsAg Qualitative II Controls	2G22-10
Alinity i HBsAg Qualitative II Reagent Kit	08P1032
Alinity i HBsAg Reagent Kit	08P0832
Alinity i HBsAg Reagent Kit	08P0822
Alinity i HBsAg Reagent Kit	08P0857
Alinity i Anti-HBs Reagent Kit	07P8932
Alinity i Anti-HBs Reagent Kit	07P8957
Alinity i HBsAg Next Qualitative Calibrators	01R6401
Alinity i HBsAg Next Qualitative Controls	01R6410
Alinity i HBsAg Next Qualitative Reagent Kit	01R6422
Alinity i HBsAg Next Qualitative Reagent Kit	01R6432
Alinity i HBsAg Next Confirmatory Reagent Kit	01R6522
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-25
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-30
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-35
ARCHITECT HBsAg Next Confirmatory Reagent Kit	4P77-25
ARCHITECT HBsAg Next Qualitative Calibrators	4P76-01
ARCHITECT HBsAg Next Qualitative Controls	4P76-10

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Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 001922 0008 Rev. 03

Annex II List B Products

Product Name	REF N°
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



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Product Service

EC Certificate

Full Quality Assurance System

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

No. V1 001922 0008 Rev. 03

Annex II List B Products

Product Name	REF N°
Alinity i CMV IgG Controls	07P4210
Alinity i CMV IgM Reagent Kit	07P4422 / 07P4432
Alinity i CMV IgM Calibrator	07P4401
Alinity i CMV IgM Controls	07P4410
Alinity i Rubella IgG Reagent Kit	08P4622 / 08P4632
Alinity i Rubella IgG Calibrators	08P4601
Alinity i Rubella IgG Controls	08P4610
Alinity i Rubella IgM Reagent Kit	08P4722 / 08P4732
Alinity i Rubella IgM Calibrator	08P4701
Alinity i Rubella IgM Controls	08P4710
Alinity i CMV IgG Avidity Reagent Kit	07P4322
Alinity i CMV IgG Avidity Controls	07P4310
Alinity s CMV IgG Qualitative Reagent Kit	06P1045
Alinity s CMV IgG Qualitative Calibrator Kit	06P1002
Alinity s CMV IgG Qualitative Assay Control Kit	06P1010
Alinity s CMV IgG Qualitative Release Control Kit	06P1012
Alinity i Free PSA Reagent Kit	07P9320 / 07P9330
Alinity i Free PSA Calibrators	07P9301
Alinity i Free PSA Controls	07P9310
Alinity i Total PSA Reagent Kit	07P9220 / 07P9230
Alinity i Total PSA Calibrators	07P9201
Alinity i Total PSA Controls	07P9210



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

C.D.H

Christoph Dicks
Head of Certification/Notified Body

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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:



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

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.



001



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



CERTIFICAT



CERTIFICADO



СЕРТИФИКАТ



認證證書



CERTIFICATE



ZERTIFIKAT



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

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.



001