



Certificate of Approval

This is to certify that the Management System of:

Abbott GmbH & Co. KG & Abbott Diagnostics GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016

A handwritten signature in cursive script that reads 'David Derrick'.

David Derrick - Area Operations Manager UK & Ireland

Issued By: Lloyd's Register Quality Assurance Limited

Current Issue Date: 1 October 2018

Expiry Date: 30 September 2021

Certificate Issue Number: 10137049

Certificate approval number: LRQ 0925480/A

Original Approvals:

ISO 13485 – 23 September 1994

Approval Certificate Number: 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

Logotipas (Lloyd's Register)

PATVIRTINAMASIS SERTIFIKATAS

Šiuo patvirtiname, kad
**Abbott GmbH & Co. KG
& Abbott Diagnostics GmbH**

Max-Planck-Ring 2, 65205 Vysbaden, Vokietija

Vadybos sistemą LRQA patvirtino pagal šį standartą:

ISO 13485:2016

(parašas)

David Derrick – regiono operacijų vadovas JK ir Airija

Išdavė: Lloyd's Register Quality Assurance Limited

Dabartinė išdavimo data: 2018 m. spalio 1 d.

Galioja iki 2021 m. rugsėjo 30 d.

Išduoto sertifikato numeris 10137049

Sertifikato patvirtinimo numeris LRQ 0925480/A

Originalus patvirtinimas

ISO 13485 – 1994 m. rugsėjo 23 d.

Patvirtinamojo sertifikato numeris ISO 13485 – 00004790

Šio patvirtinimo taikymo sritis:

In vitro diagnostinių prietaisų kūrimas, tobulinimas, gamyba, gamintojų sutarčių kontrolė,
registracija, sandėliavimas ir platinimas

Tikslus ir oficialus dokumento vertimas iš anglų kalbos

Vertė: Regina Žlabytė

Data: 2019-06-25

UAB "Diagnostinės sistemos"

Kalvarijų sodų 1-oj g.2, LT-08315 Vilnius

Tel. 8 5 274 04 94



Sertifikatas

Nr. Q5 001922 0022 Rev. 01

Sertifikato gavėjas:	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo AIRIJA
Gamykla (-os):	Abbott Ireland Diagnostics Division Finisklin Business Park, Sligo AIRIJA
Sertifikavimo ženklas:	(sertifikavimo ženklas)
Sertifikavimo sritis:	<i>In vitro</i> diagnostinių tyrimų rinkinių, reagentų ir įprastinių skystų priedų skirtų donorų atrankiniams tyrimams, hepatitų, vėžių, širdies žymenų, įgimtų ar užkrečiamų ligų nustatymui ir /ar stebėjimui, užkrečiamų ligų , įgimtų vaisiaus sutrikimų nustatymui, endokrininių sutrikimų ir hematologiniai sutrikimų, terapinių vaistų stebėjimui ir infekcinių virusinių ligų nustatymui ir/ar stebėjimui kūrimas, tobulinimas ir gamyba.
Taikomas standartas (-ai):	EN ISO 13485:2016 Medicinos prietaisai – kokybės vadybos sistemos – Reglamentuojantys reikalavimai (ISO 13485:2016) DIN EN ISO 13485:2016

„TÜV SÜD Product Service GmbH“ sertifikavimo įstaiga patvirtina, kad aukščiau minėta įmonė sukūrė ir palaiko kokybės vadybos sistemą, atitinkančią išvardytų standartų reikalavimus. Taip pat žr. Pastabas kitoje pusėje.

Ataskaitos Nr.: 713178712-05

Galioja nuo: 2020-04-24
Galioja iki: 2023-03-24

(parašas)

Data: 2020-04-24 Christoph Dicks
Sertifikavimo/paskelbtosios įstaigos vadovas

Lapas 1 iš 1

Tikslus ir oficialus dokumento vertimas iš anglų kalbos

Vertė: Regina Žlabytė

Data: 2020-10-05

UAB "Diagnostinės sistemos"

Kalvarijų sodų 1-oj g.2, LT-08315 Vilnius

Tel. 8 5 274 04 94





Certificate of Approval

This is to certify that the Management System of:

Abbott GmbH & Co. KG & Abbott Diagnostics GmbH

Max-Planck-Ring 2, 65205 Wiesbaden, Germany

has been approved by LRQA to the following standards:

ISO 9001:2015

A handwritten signature in black ink that reads 'David Derrick'.

David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current issue date: 1 October 2018

Expiry date: 30 September 2021

Certificate identity number: 10137050

Approval certificate 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

Logotipas (Lloyd's Register)

PATVIRTINAMASIS SERTIFIKATAS

Šiuo patvirtiname, kad
Abbott GmbH & Co. KG
& Abbott Diagnostics GmbH

Max-Planck-Ring 2, 65205 Vysbaden, Vokietija

Vadybos sistemą LRQA patvirtino pagal šį standartą:

ISO 9001:2015

(parašas)

David Derrick – regiono operacijų vadovas JK ir Airija

Išdavė: Lloyd's Register Quality Assurance Limited

Dabartinė išdavimo data: 2018 m. spalio 1 d.

Galioja iki 2021 m. rugsėjo 30 d.

Išduoto sertifikato numeris 10137050

Sertifikato patvirtinimo numeris LRQ 0925480/A

Originalus patvirtinimas

ISO 9001 – 1994 m. rugsėjo 23 d.

Patvirtinamojo sertifikato numeris ISO 9001 – 00004791

Šio patvirtinimo taikymo sritis:

In vitro diagnostinių prietaisų kūrimas, tobulinimas, gamyba, gamintojų sutarčių kontrolė,
registracija, sandėliavimas ir platinimas

Tikslus ir oficialus dokumento vertimas iš anglų kalbos

Vertė: Regina Žlabytė

Data: 2019-06-25

UAB "Diagnostinės sistemos"

Kalvarijų sodų 1-oj g.2, LT-08315 Vilnius

Tel. 8 5 274 04 94





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



ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆
認 證 證 書

M/S/01-07/2019

SERTIFIKATAS

Sertifikuojanti TÜV SÜD Management Service GmbH įstaiga

patvirtina, kad

**Abbott Ireland Diagnostics Division
Finisklin Business Park
Sligo
Airija**

įsteigė ir taiko
kokybės vadybos sistemą

***in vitro* diagnostinių tyrimų rinkinių, reagentų ir įprastų skystų reikmenų
kūrimui, vystymui ir gamybai.**

Auditas atliktas, paraiškos nr. **707114974**

Buvo pateiktas įrodymas, kad reikalavimai pagal

ISO 9001:2015

yra vykdomi

Šis sertifikatas galioja nuo **2020-04-01** iki **2023-03-31**

Sertifikato registracijos Nr. **12 100 59742**

(parašas)

(logotipai)

Produktų atitikties valdymas
Miunchenas 2020-03-25

Tikslus ir oficialus dokumento vertimas iš anglų kalbos

Vertė: Regina Žlabytė

Data:2020-10-05

UAB "Diagnostinės sistemos"

Kalvarijų sodų 1-oj g.2, LT-08315 Vilnius

Tel. 8 5 274 04 94



Declaration of Conformity

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

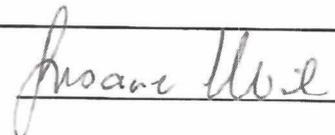
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C37-22	48366	ARCHITECT Anti-HCV Reagent Kit (4x100Tests)	Annex II List A
6C37-27	48366	ARCHITECT Anti-HCV Reagent Kit (1x100Tests)	Annex II List A
6C37-32	48366	ARCHITECT Anti-HCV Reagent Kit (4x500 Tests)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

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
Notified Body number	TÜV SÜD: 0123
Approval Certificate No.	TÜV SÜD: V7 010051 0132
Storage site of technical documentation (name and address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: 
Full Name: **Dr. Jörg Amborn**
Position: **Director Quality Assurance**
Date of Approval: 2020-03-09

Signature: 
Full Name: **Susanne Ulrich**
Position: **Senior Manager Regulatory Affairs**
Date of Approval: 04/05/2020
Date Issued: 09-Mar-2020
Place Issued: **65205 Wiesbaden, Germany**
Supersedes: **17-Dec-2019**
Effective (Date or Lot Number): 09-Mar-2020

Declaration of Conformity

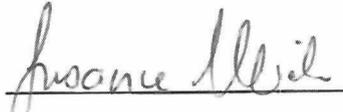
Certificate Identification: DoC 8D06-SD DELK
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8D06-32	59861	ARCHITECT Syphilis TP Reagent Kit (1x100 Tests)	Self-declared
8D06-42	59861	ARCHITECT Syphilis TP Reagent Kit (1x500 Tests)	Self-declared
8D06-04	51802	ARCHITECT Syphilis TP Calibrator	Self-declared
8D06-13	37733	ARCHITECT Syphilis TP Controls	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
Harmonized Standards	Listed in the Technical Documentation

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

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

<p>Signature: <u></u></p> <p>Full Name: Dr. Jörg Amborn</p> <p>Position: Director Quality Assurance</p> <p>Date of Approval: <u>2020-09-09</u></p>	<p>Signature: <u></u></p> <p>Full Name: Susanne Ulrich</p> <p>Position: Senior Manager Regulatory Affairs</p> <p>Date of Approval: <u>03/Sep/2020</u></p> <p>Date Issued: <u>10/Sep/2020</u></p> <p>Place Issued: 65205 Wiesbaden, Germany</p> <p>Supersedes: 09-Mar-2020</p> <p>Effective (Date or Lot Number): <u>10/Sep/2020</u></p>
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Declaration of Conformity

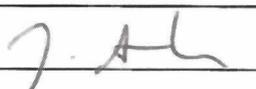
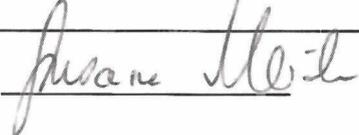
Certificate Identification: DOC-4J27-AII DLK
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Codes of Devices	GMDN Code	Names and Description of Devices	Classification
4J27-22	48446	ARCHITECT HIV Ag/Ab Combo Reagent Kit (4x100 Tests)	Annex II List A
4J27-27	48446	ARCHITECT HIV Ag/Ab Combo Reagent Kit (1x100 Tests)	Annex II List A
4J27-32	48446	ARCHITECT HIV Ag/Ab Combo Reagent Kit (4x500 Tests)	Annex II List A
4J27-37	48446	ARCHITECT HIV Ag/Ab Combo Reagent Kit (1x500 Tests)	Annex II List A
4J27-03	48448	ARCHITECT HIV Ag/Ab Combo Calibrator	Annex II List A
4J27-12	48449	ARCHITECT HIV Ag/Ab Combo Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
Notified Body number	TÜV SÜD: 0123
Approval Certificate No.	TÜV SÜD: V7 010051 0118
Storage site of technical documentation (name and address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: <u></u> Full Name: <u>Dr. Jörg Amborn</u> Position: <u>Director Quality Assurance</u> Date of Approval: <u>2020-02-10</u> Date Issued: <u>10-Nov-2020</u> Supersedes: <u>17-Dec-2019</u>	Signature: <u></u> Full Name: <u>Susanne Ulrich</u> Position: <u>Senior Manager Regulatory Affairs</u> Date of Approval: <u>09/12/2020</u> Place Issued: <u>65205 Wiesbaden, Germany</u> Effective (Date or Lot Number): <u>10-Nov-2020</u>
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Declaration of Conformity

Certificate Identification: AIDD 2G23
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
2G23-40	58208	ARCHITECT HBsAg Qualitative II Confirmatory Manual Diluent	Self-declared

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

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

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

Signature: 

Full Name: Joe Murray

Position: Quality Manager

Date of Approval: 25 May 15

Date Issued: 25 May 2015

Supersedes: 13 November 2013

Signature: 

Full Name: Lorraine Whitney

Position: Senior Manager Regulatory Affairs/Site Operations Ireland

Date of Approval: 20 MAY 2015

Place Issued: AIDD Sligo

Effective (Date or Lot Number): 25 May 2015



Declaration of Conformity

Certificate Identification: AIDD 2G23
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
2G23-25	48321	ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit	Annex II List A

Authorized European Representative (Name and Address)	N/A
Notified Body (Name and Address)	UL International (UK) Ltd. Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey, GU3 1LR United Kingdom
Approval Certificate No.	361.130510
Storage of site technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:
Full Name: Joe Murray
Position: Quality Manager
Date of Approval: 25 May 15
Date Issued: 25 May 2015
Supersedes: 13 November 2013 _____

Signature:
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs/Site Operations Ireland
Date of Approval: 20 MAY 2015
Place Issued: AIDD Sligo _____
Effective (Date or Lot Number): 25 May 2015

Declaration of Conformity

Certificate Identification: DoC-2G22-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
2G22-25	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-30	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-35	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-01	41999	ARCHITECT HBsAg Qualitative II Calibrators	Annex II List A
2G22-10	42000	ARCHITECT HBsAg Qualitative II Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V1 0019220008
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: **N. WALSH** *N Walsh*
 Full Name: *x* Joe Murray
 Position: Director Quality Assurance/Site Quality Head

Signature: *Noel Haren*
 Full Name: Noel Haren
 Position: Manager Regulatory Affairs

Date of Approval: 25 Nov 19

Date of Approval: 25 Nov 2019

Date Issued: 25 Nov 2019

Place Issued: AIDD, Sligo

Supersedes: 16 October 2019

Effective (Date or Lot Number): 25 Nov 2019

x Ref attached delegation memo N Walsh 25 Nov 19