

Declaration of Conformity

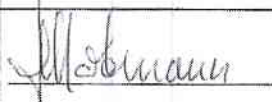
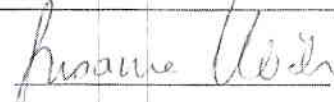
Certificate Identification: DoC-6C32/7P24-AII DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C32-20	48331	ARCHITECT HBeAg Reagent Kit (4x100 Tests)	Annex II List A
6C32-25	48331	ARCHITECT HBeAg Reagent Kit (1x100 Tests)	Annex II List A
6C32-27	48331	ARCHITECT HBeAg Reagent Kit (1x100 Tests)	Annex II List A
6C32-37	48331	ARCHITECT HBeAg Reagent Kit (1x500 Tests)	Annex II List A
6C32-01	42007	ARCHITECT HBeAg Calibrators	Annex II List A
6C32-10	42008	ARCHITECT HBeAg Controls	Annex II List A
7P24-01	42007	ARCHITECT HBeAg Quantitative Calibrators	Annex II List A
7P24-10	42008	ARCHITECT HBeAg Quantitative Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	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: 0088/0964174/00035 TÜV SÜD: V7 010051 0120
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: <u></u> Full Name: Dr. Herbert Hartmann Position: Manager Quality Systems Date of Approval: <u>20/19-03-29</u> Date Issued: <u>29/Mar/2019</u> Supersedes: 27-Feb-2018	Signature: <u></u> Full Name: Susanne Ulrich Position: Senior Manager Regulatory Affairs Date of Approval: <u>29/03/2019</u> Place Issued: 65205 Wiesbaden, Germany Effective (Date or Lot Number): <u>30/Mar/2019</u>
--	--

Declaration of Conformity

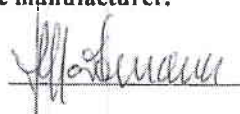
Certificate Identification: DoC-6C34-AII DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C34-20	48348	ARCHITECT Anti-HBe Reagent Kit (4x100 Tests)	Annex II List A
6C34-25	48348	ARCHITECT Anti-HBe Reagent Kit (1x100 Tests)	Annex II List A
6C34-35	48348	ARCHITECT Anti-HBe Reagent Kit (1x500 Tests)	Annex II List A
6C34-01	30871	ARCHITECT Anti-HBe Calibrator	Annex II List A
6C34-10	31014	ARCHITECT Anti-HBe 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: 0088/0964174/00036 TÜV SÜD: V7 010051 0124
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: 
Full Name: Dr. Herbert Hartmann
Position: Manager Quality Systems
Date of Approval: 2019-03-29

Signature: 
Full Name: Susanne Ulrich
Position: Senior Manager Regulatory Affairs
Date of Approval: 29/03/2019
Date Issued: 29/ Mar/ 2019
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 19-Apr-2016
Effective (Date or Lot Number): 30/ Mar/ 2019



Declaration of Conformity

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

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K68-22	30288	ARCHITECT CEA Reagent	Self-declared
7K68-27	30288	ARCHITECT CEA Reagent	Self-declared
7K68-32	30288	ARCHITECT CEA Reagent	Self-declared
7K68-35	30288	ARCHITECT CEA Reagent	Self-declared
7K68-02	38174	ARCHITECT CEA Calibrators	Self-declared
7K68-12	38173	ARCHITECT CEA Controls	Self-declared
Authorized European Representative (Name and Address)	N/A		
Storage site of technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.		
Harmonized Standards	Listed in the Technical Documentation		

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

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

Signature:

Full Name: Niall Plunkett

Position: Quality Manager

Date of Approval: 14 Jul 14

Date Issued: 14 Jul 14

Supersedes: 30 Nov 2009

Signature:

Full Name: Lorraine Whitney

Position: Senior Manager Regulatory Affairs

Date of Approval: 11 Dec 2014

Place Issued: AIDD Sligo

Effective (Date or Lot Number):

14 Jul 14



Declaration of Conformity

Certificate Identification:
Legal Manufacturer's Name:

02K45 LC
Abbott Laboratories
Diagnostics Division

IRIS V4

Legal Manufacturer's Address:

Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K45-20 2K45-23 2K45-25 2K45-28 2K45-35 2K45-38	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-01	38231	ARCHITECT CA 125 II Calibrators	Self-declared
2K45-10	38230	ARCHITECT CA 125 II 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)	Fujirebio Diagnostics, Incorporated 201 Great Valley Parkway Malvern, PA 19355, USA Fujirebio Diagnostics, Inc. Seguin, TX 78155, USA		
Harmonized Standards	Listed in the Technical Documentation		

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

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

Signature:

Full Name:

Elizabeth Leibham

Position: Quality Manager

Date of Approval:

5/11/2015

Date Issued:

5/28/2015

Supersedes: February 28, 2012

Signature:

Full Name:

Mary C. Murphy

Position: Regulatory Affairs Manager

Date of Approval:

5/14/2015

Place Issued:

Abbott Laboratories Diagnostic Division
Abbott Park, IL 60064 U.S.A.

Effective (Date or

Lot Number):

5/28/2015

Declaration of Conformity

Certificate Identification: DoC-2K91-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K91-24	60976	ARCHITECT CA 19-9 _{XR} Reagent Kit	Self-declared
2K91-32	60976	ARCHITECT CA 19-9 _{XR} Reagent Kit	Self-declared
2K91-39	60976	ARCHITECT CA 19-9 _{XR} Reagent Kit	Self-declared
2K91-03	38225	ARCHITECT CA 19-9 _{XR} Calibrators	Self-declared
2K91-12	38224	ARCHITECT CA 19-9 _{XR} Controls	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania 19355, USA.
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:



Full Name:

Claudia Becker

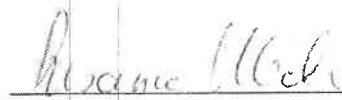
Position:

Manager Quality

Date of Approval:

16 Dec 2016

Signature:



Full Name:

Susanne Ulrich

Position:

Senior Manager Regulatory Affairs

Date of Approval:

16 Dec 2016

Date Issued:

16 Dec 2016

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

Not applicable

Effective (Date or Lot Number):

16 Dec 2016

Declaration of Conformity

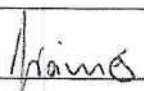
Certificate Identification:	<u>DOC-1P65-SD DLK OEM</u>
Legal Manufacturer's Name:	<u>Abbott GmbH & Co. KG</u>
Legal Manufacturer's Address:	<u>Max-Planck-Ring 2, 65205 Wiesbaden, Germany</u>

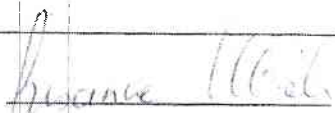
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1P65-35	61080	ARCHITECT Anti-CCP Reagent Kit (1x500 Tests)	Self-declared
1P65-25	61080	ARCHITECT Anti-CCP Reagent Kit (1x100 Tests)	Self-declared
1P65-10	54899	ARCHITECT Anti-CCP Controls	Self-declared
1P65-01	54898	ARCHITECT Anti-CCP Calibrators	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 Brämer**
 Position: **Manager Quality**

Signature: 
 Full Name: **Susanne Ulrich**
 Position: **Senior Manager Regulatory Affairs, Site Operations, Germany**

Date of Approval: 03-Mar-2016

Date of Approval: 03/March/2016
 Date Issued: 03/March/2016
 Place Issued: **65205 Wiesbaden, Germany**
 Supersedes: **17 Nov 2014**
 Effective (Date or Lot Number): 03/March/2016



Declaration of Conformity

Certificate Identification:

03L53 LC

IRIS V4

Legal Manufacturer's Name:

Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address:

Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L53-25	54130	ARCHITECT C-Peptide Reagent Kit	Self-declared
3L53-01	41836	ARCHITECT C-Peptide Calibrators	Self-declared
3L53-10	41837	ARCHITECT C-Peptide 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)		Biokit S. A., 08186 Llica d'Amunt, Barcelona, Spain	
Harmonized Standards		Listed in the Technical Documentation	

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

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

Signature:

Elizabeth Leibham
Elizabeth Leibham

Full Name:

Position: Quality Manager

Date of Approval:

6/4/2015

6/9/2015

Date Issued:

Supersedes: August 8, 2012

Signature:

Mary Caren Murawski

Full Name:

Mary Caren Murawski

Position:

Regulatory Affairs Manager

Date of Approval:

6/9/2015

Abbott Laboratories

Place Issued:

Diagnostics Division

Abbott Park, IL 60064 USA

Effective (Date or Lot Number):

6/9/2015



Declaration of Conformity

Certificate Identification:

02K46 LC

IRIS V2

Legal Manufacturer's Name:

Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address:

Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K46-20 2K46-25	58728	ARCHITECT Anti-Tg Reagent Kit	Self-declared
2K46-01	55199	ARCHITECT Anti-Tg Calibrators	Self-declared
2K46-10	55200	ARCHITECT Anti-Tg Controls	Self-declared
Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany		
Storage site of technical documentation (name and address)	Fisher Diagnostics a division of Fisher Scientific Company LLC a part of Thermo Fisher Scientific Inc. 8365 Valley Pike, Middletown, VA 22645-1905		
Harmonized Standards	Listed in the Technical Documentation		

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

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

Signature:

Elizabeth Leibham

Full Name:

Elizabeth Leibham

Position: Quality Manager

Date of Approval:

5/11/2015

Date Issued:

5/28/2015

Supersedes: May 23, 2005

Signature:

Mary Carmen Murawski

Full Name:

Mary Carmen Murawski

Position: Regulatory Affairs Manager

Date of Approval:

5/14/2015

Place Issued:

*Abbott Laboratories Diagnostic Division
Abbott Park, IL 60064 USA.*

Effective (Date or Lot Number):

5/28/2015

Declaration of Conformity

Certificate Identification: 01P74
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
1P74-25 1P74-35	60982	ARCHITECT Folate Reagent Kit	Self-declared
1P74-40	54455	ARCHITECT Folate RBC Lysis Diluent	Self-declared
1P74-50	58208	ARCHITECT Folate Manual Diluent	Self-declared
1P74-01	41931	ARCHITECT Folate Calibrators	Self-declared
1P74-10	41932	ARCHITECT Folate Controls	Self-declared
3P21-60	54455	Folate Lysis Reagent	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.

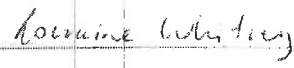
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 
Full Name: **Siobhan Wright**
Position: **Quality Manager**

Date of Approval: 09-JAN-15

Date Issued: 09 JAN 15

Supersedes 21 JAN 11

Signature: 
Full Name: **Lorraine Whitney**
Position: **Senior Manager Regulatory Affairs**

Date of Approval: 06 JAN 2015

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

Effective (Lot number or date) 09 JAN 15



Declaration of Conformity

Certificate Identification:
Legal Manufacturer's Name:
Legal Manufacturer's Address:

7K59
Abbott Ireland Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K59-20 7K59-25 7K59-30 7K59-35	61078	ARCHITECT Ferritin Reagent Kit	Self-declared
7K59-01	41927	ARCHITECT Ferritin Calibrators	Self-declared
7K59-10	41928	ARCHITECT Ferritin 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: 22 April 2014

Signature: 
Full Name: Lorraine Whitney
Position: Regulatory Affairs Manager
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



Declaration of Conformity

Certificate Identification:
Legal Manufacturer's Name:
Legal Manufacturer's Address:

7K59
Abbott Ireland Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K59-20 7K59-25 7K59-30 7K59-35	61078	ARCHITECT Ferritin Reagent Kit	Self-declared
7K59-01	41927	ARCHITECT Ferritin Calibrators	Self-declared
7K59-10	41928	ARCHITECT Ferritin 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: 22 April 2014

Signature: 
Full Name: Lorraine Whitney
Position: Regulatory Affairs Manager
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

Declaration of Conformity

Certificate Identification:	<u>DOC-8K27-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
8K27-20	54139	ARCHITECT DHEA-S Reagent Kit (4x100 Tests)	Self-declared
8K27-25	54139	ARCHITECT DHEA-S Reagent Kit (1x100 Tests)	Self-declared
8K27-10	54141	ARCHITECT DHEA-S Controls	Self-declared
8K27-01	54140	ARCHITECT DHEA-S Calibrators	Self-declared

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	BIOKIT, S.A., Can Malé, s/n, 08186 Lliçà d'Amunt, Barcelona-Spain
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature: 
 Full Name: **Dr. Holger Kost**
 Position: **Head of Quality**

Date of Approval: 2017-11-21

Signature: 
 Full Name: **Susanne Ulrich**
 Position: **Senior Manager Regulatory Affairs Site Operations Germany**

Date of Approval: 17/Nov/2017

Date Issued: 2017-11-27

Place Issued: **65205 Wiesbaden, Germany**

Supersedes: **23 Sep 2015**

Effective (Date or Lot Number): 2017-11-27

Declaration of Conformity

Certificate Identification:	<u>DOC-4P72-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
4P72-25	61010	Architect HbA1c Reagent Kit (100 tests)	Self-declared
4P72-35	61010	Architect HbA1c Reagent Kit (500 tests)	Self-declared
4P72-01	53315	Architect HbA1c Calibrators	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: S. Leschonsky
 Full Name: **Stefanie Leschonsky**
 Position: **Manager Quality**
 Date of Approval: 13. Nov. 2014

Signature: Susanne Ulrich
 Full Name: **Susanne Ulrich**
 Position: **Senior Manager Regulatory Affairs Site Operations Germany**
 Date of Approval: 10/Nov/2014
 Date Issued: 17. Nov 2014
 Place Issued: **65205 Wiesbaden, Germany**
 Supersedes: **29 Jan 2013**
 Effective (Date or Lot Number): 17. NOV 2014



Declaration of Conformity

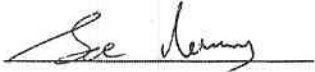
Certificate Identification: DoC-7C18-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7C18-27	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-37	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-34	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-28	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-38	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-03	41997	ARCHITECT Anti-HBs Calibrators	Annex II List A
7C18-13	41998	ARCHITECT Anti-HBs Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany UL International (UK) Ltd Womersley 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: 
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



Declaration of Conformity

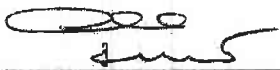
Certificate Identification:
Legal Manufacturer's Name:
Legal Manufacturer's Address:

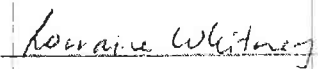
ARCHITECT Solutions
Abbott Ireland Diagnostics Division
Finisklin Business Park
Sligo
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1L56-40	Not Available	ARCHITECT Probe Conditioning Solution	Self-declared
6C54-58	Not Available	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-82	Not Available	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-88	Not Available	ARCHITECT ARM Concentrated Wash Buffer	Self-declared
6C55-60	Not Available	ARCHITECT Trigger Solution	Self-declared
6C55-82	Not Available	ARCHITECT Trigger Solution	Self-declared
6E23-65	Not Available	ARCHITECT Pre-Trigger Solution	Self-declared
6E23-82	Not Available	ARCHITECT Pre-Trigger Solution	Self-declared
7D82-50	Not Available	ARCHITECT Multi-Assay Manual Diluent	Self-declared
Authorized European Representative (Name and Address)		N/A	
Storage site of technical documentation (Name and Address)		Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.	
Harmonized Standards		Listed in the Technical Documentation	

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

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

Signature: 
Full Name: Niall Plunkett
Position: Quality Manager
Date of Approval: 07 JUL 14
Date Issued: 07 JUL 14
Supersedes: 15 Jun 2012

Signature: 
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 04 JULY 2014
Place Issued: AIDD Sligo
Effective (Date or Lot Number): 07 JUL 14



Declaration of Conformity

Certificate Identification:

ARCH Sys Acc LC

IRIS V3

Legal Manufacturer's Name:

Abbott Laboratories

Legal Manufacturer's Address:

Diagnostics Division

Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4D18-03	NA	ARCHITECT Septum	Self-declared
4D19-01	NA	ARCHITECT Replacement Caps	Self-declared
7C14-01	NA	ARCHITECT Sample Cups	Self-declared
7C15-02	NA	ARCHITECT Reaction Vessels	Self-declared
7C15-03	NA	ARCHITECT Reaction Vessels	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:

Full Name:

Lauren Sieber

Position:

Product Quality Assurance
Manager

Date of Approval:

5/28/2015

Date Issued:

06/02/2015

Supersedes:

June 13, 2013

Signature:

Full Name:

Deborah Hinkley

Position:

Regulatory Affairs
Director

Date of Approval:

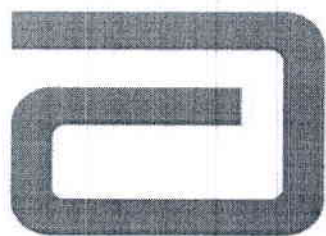
5/29/2015

Place Issued:

Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064 USA

Effective (Date or
Lot Number):

06/02/2015



Abbott

A Promise for Life

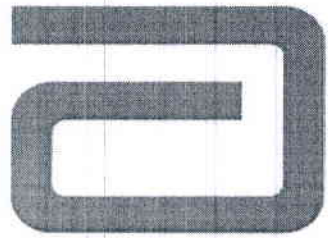
This document certifies that:
Sergiu Sorocovici
has completed

Architect i2000SR

Level1 / Level 2
Application, Operation, Troubleshooting
from 9 February 2015 to 13 February 2015

Trainer : **Athanasios Plakas**

Date: **13 Feb 2015**



Abbott

A Promise for Life

This document certifies that:

Alexei Legun

has completed

Architect i2000SR

Level1 / Level 2

Application, Operation, Troubleshooting
from 9 February 2015 to 13 February 2015

Trainer : **Athanasios Plakas**

Date: **13 Feb 2015**