Abbott

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:	HHartmann	Signature:	Susanne Ulrich
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:	27-Feb-2018	Effective (Date or Lot Number):	30/Mar/2019

Abbott

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: [signature]

Full Name: **Dr. Herbert Hartmann**

Position: **Manager Quality Systems**

Date of Approval: 2019-03-29

Signature: [signature]

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: 19-Apr-2016

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

Abbott

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:		Signature:	Lorraine Whitney
Full Name:	Niall Plunkett	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	14 Jul 14	Date of Approval:	11 July 2014
Date Issued:	14 JUL 14	Place Issued:	AIDD Sligo
Supersedes:	30 Nov 2009	Effective (Date or Lot Number):	14 JUL 14

Abbott

Declaration of Conformity

Certificate Identification:	02K45 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
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: Elizabeth Leibham
Full Name: Elizabeth Leibham
Position: Quality Manager
Date of Approval: 5/11/2015
Date Issued: 5/28/2015
Supersedes: February 28, 2012

Signature: Mary Carol Murphy
Full Name: Mary Carol 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

Abbott

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: C. Becker
Full Name: **Claudia Becker**
Position: **Manager Quality**
Date of Approval: 16 Dec 2016

Signature: Susanne Ulrich
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

Abbott

Declaration of Conformity

Certificate Identification: DOC-1P65-SD DLK OEM
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
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: Brämer
Full Name: **Christian Brämer**
Position: **Manager Quality**
Date of Approval: 03-Mar-2016

Signature: Susanne Ulrich
Full Name: **Susanne Ulrich**
Position: **Senior Manager Regulatory Affairs, Site Operations, Germany**
Date of Approval: 8/Mar/2016
Date Issued: 03/March/2016.
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 17 Nov 2014
Effective (Date or Lot Number): 03/March/2016

Abbott

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

Full Name: Elizabeth Leibham

Position: Quality Manager

Date of Approval: 6/4/2015

Date Issued: 6/9/2015

Supersedes: August 8, 2012

Signature: Mary Caren Murawski

Full Name: Mary Caren Murawski

Position: Regulatory Affairs Manager

Date of Approval: 6/9/2015

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

Effective (Date or Lot Number): 6/9/2015

Abbott

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 Caren Murawski
Full Name: Mary Caren Murawski
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

ABBOTT

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:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name:	**Siobhan Wright**	Full Name:	**Lorraine Whitney**
Position:	**Quality Manager**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	09-JAN-15	Date of Approval:	06 JAN 2015
Date Issued:	09 JAN 15	Place Issued	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes	26 JAN 11	Effective (Lot number or date)	09 JAN 15

Abbott

Declaration of Conformity

Certificate Identification:	7K59
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
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:		Signature:	
Full Name:	Kevin Callaghan	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Regulatory Affairs Manager
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

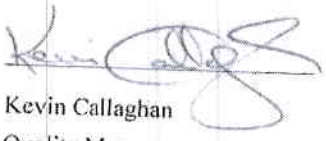
Certificate Identification:	7K59
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford
	Co. Longford
	Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
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:		Signature:	
Full Name:	Kevin Callaghan	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Regulatory Affairs Manager
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-8K27-SD-DLK-OEM
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
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: 2017-11-21
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 23 Sep 2015
Effective (Date or Lot Number): 2017-11-21

Abbott

Declaration of Conformity

Certificate Identification: DOC-4P72-SD DLK OEM
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
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

Abbott

Declaration of Conformity

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

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

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany 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:	
Full Name:	Joe Murray	Full Name:	Lorraine Whitney NOEL HIARCN
Position:	Director Quality Assurance/Site Quality Head	Position:	Senior Manager Regulatory Affairs
Date of Approval:	28 Mar 19	Date of Approval:	29 March 2019
Date Issued:	29 March 2019		
Supersedes:	11 Jan 2017	Place Issued:	AIDD Sligo
		Effective (Date or Lot Number):	30 March 2019

Abbott

Declaration of Conformity

Certificate Identification: ARCHITECT Solutions
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
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:		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:	15 Jun 2012	Effective (Date or Lot Number):	07 JUL 14

Abbott

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		Signature	
Full Name:	_Lauren Sieber_	Full Name:	_Deborah Hinkley_
Position:	Product Quality Assurance Manager	Position:	Regulatory Affairs Director
Date of Approval:	5/28/2015	Date of Approval:	5/29/2015
Date Issued:	06/02/2015	Place Issued:	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Supersedes:	June 13, 2013	Effective (Date or Lot Number):	06/05/2015

Abbott

A Promise for Life

This document certifies that:

Sergiu Sorocovici

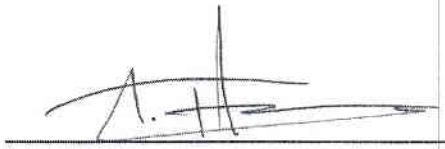
has completed

Architect i2000SR

Level1 / Level 2

Application, Operation, Troubleshooting

from 9 February 2015 to 13 February 2015



Trainer : **Athanasios Plakas**

Date: **13 Feb 2015**

Abbott

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This document certifies that:

Alexei Legun

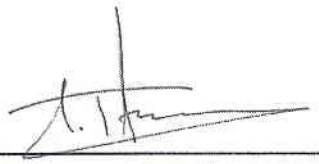
has completed

Architect i2000SR

Level1 / Level 2

Application, Operation, Troubleshooting

from 9 February 2015 to 13 February 2015



Trainer : **Athanasios Plakas**

Date: **13 Feb 2015**