

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	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.

walle Signature: Signature: Full Name: Full Name: Susanne Ulrich Dr. Herbert Hartmann Manager Quality Systems Position: Position: Senior Manager Regulatory Affairs Date of Approval: Date of Approval: Date Issued: Place Issued: 65205 Wiesbaden, Germany Effective (Date or Mary 2619 Supersedes: 27-Feb-2018 Lot Number):



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

Full Name: Susanne Ulrich

Position:

Manager Quality Systems

Senior Manager Regulatory Position:

Date of Approval:

Date of Approval:

Date Issued:

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

19-Apr-2016

Effective (Date or

Lot Number):

30/ Mar/ 20/19

Legal Manufact List Numbers and Size Code of Devices 7K68-22 7K68-32	e Identification: acturer's Name: turer's Address: GMDN Code	AIDD 7K68 Abbott Ireland Diagnostics Division Finisklin Business Park Sligo Ireland Names and Description of Device		
Rand Size Code of Devices PK 68-22 PK 68-27 PK 68-32		Names and Description of Device		
7K68-27 7K68-32 7K68-35	30288		8	Classification
7K68-32		ARCHITECT CEA Reagent		Self-declared
K68-35	30288	ARCHITECT CEA Reagent		Self-declared
	30288	ARCHITECT CEA Reagent		Self-declared
N 60 60	30288	ARCHITECT CEA Reagent		Self-declared
K68-02	38174	ARCHITECT CEA Calibrators		Self-declared
K68-12	38173	ARCHITECT CEA Controls		Self-declared
(Nar Storage	Prized European Representative me and Address) site of technical documentation me and Address)	Abbott Ireland Diagnostics Division, Pinisklin B Department; Regulatory Affairs.	usiness Par	k, Sligo, County Sligo, Ireland.
Harmo	nized Standards	Listed in the Technical Documentation		
narking, conform Council of 27 Octo tates. This déclaration is a nanufacturer. Signature:	with the applicat ober 1998 on In V	e that the in vitro diagnostic medical devices ole provisions of the EC Directive 98/79/EC of the Diagnostic Medical Devices as they are ce with Annex III of the IVD Directive and is is	f the Euro transposed sued unde	pean Parliament and of the Linto the laws of the membe
Full Name:	Niall Plunkett		- Halley- 17 (2000)	ine Whitney
Position:	Quality Manager	Position	Senior M	anager Regulatory Affairs
Date of Approval:	14 2mr 1	Date of Approval	11 30	ccy 3014
Date Issued:	A JAC	Place Issued		AIDD Sligo
Supersedes:		Effective (Date of Lot Number).	.] 14	JUL 17

Abbott

Certificate Identification: Legal Manufacturer's Name: 02K45 LC Abbott Laboratories

Diagnostics Division

Abbott Park II 60064 LISA

Legal Manuia	cturer's Address:	Abbott Park, IL 60064 USA	
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K45-20	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-23			
2K45-25			
2K45-28			
2K45-35			
2K45-38			
2K45-01	38231	ARCHITECT CA 125 II Calibrators	Self-declared
2K45-10	38230	ARCHITECT CA 125 II Controls	Self-declared
Aut	horized European Representative	Abbott GmbH & Co. KG Max-Planck-Ring-2	
(Na	ame and Address)	65205 Wiesbaden, Germany	
Storag	ge site of technical	Fujirebio Diagnostics, Incorporated	
documentation		201 Great Valley Parkway	
	ame and Address)	Malvern, PA 19355, USA	
		Fujirebio Diagnostics, Inc.	
		Seguin, TX 78155, USA	
Harm	onized 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:	Mabeth Seitham	Signature: Mark Milliams
Full Name:	Dizabeth Leibham	Full Name: Maria Care on Museum St.
Position:	Quality Manager	Position: Regulatory Affairs Manager
Date of Approval:	5/11/2015	Date of Approval: 5 14 72515
Date Issued:	5/28/2015	Place Issued: About tarrectories Diegnostic Division
Supersedes:	February 28, 2012	Effective (Date or 5/28/2015 Lot Number):



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	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania
documentation (name and address)	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. Jeles	Signature:	Moune Meh
Full Name:	Claudia Becker	Full Name:	Susanne Ulrich
Position:	Manager Quality	Position:	Senior Manager Regulatory Affairs
Date of Approval:	16 Dec 2016	Date of Approval:	16/ Dec / Just
		Date Issued:	16/Dec / 2016
		Place Issued:	65205 Wiesbaden, Germany
		Supersedes:	Not applicable
		Effective (Date or Lot Number):	16/Ac/2016



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:

Name: Christian Brämer

Signature:

Susanne Ulrich

Full Name: Position:

Manager Quality

Full Name: Position:

Senior Manager Regulatory

Affairs, Site Operations,

Germany

Date of Approval:

03-Man-2016

Date of Approval:

S/RC/2016

Date Issued:

03/March/2016.

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

17 Nov 2014

Effective (Date or Lot Number):

03/ Morch 12016

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3L53-25

3L53-01

Declaration of Conformity

Certificate Identification: Legal Manufacturer's Name:

IRIS V4 03L53 LC Abbott Laboratories

Diagnostics Division

Legal Manufacturer's Address:

Abbott Park, IL 60064 USA **GMDN** Code Classification List Numbers Names and Description of Devices and Size Code of Devices Self-declared ARCHITECT C-Peptide Reagent Kit 54130 Self-declared ARCHITECT C-Peptide Calibrators 41836

Self-declared ARCHITECT C-Peptide Controls 41837 3L53-10 Abbott GmbH & Co. KG Authorized European Max-Planck-Ring-2 Representative 65205 Wiesbaden, Germany (Name and Address) Biokit S. A., 08186 Llica d'Amunt, Storage site of technical documentation Barcelona, Spain (Name and Address) Listed in the Technical Documentation Harmonized Standards

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	Signature:	Male Minus
Full Name:	Elizabeth Leibham	Full Name:	Mary Caren Murawski
Position: Date of Approval:	Quality Manager 4/4/2015	Position: Date of Approval:	Regulatory Affairs Manager
Date Issued:	6/9/2015	Place Issued:	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Supersedės:	August 8, 2012	Effective (Date or Lot Number):	6/9/2015

Abbo	ti

Certificate Identification:

02K46 LC

IRIS V2

Legal Manufacturer's Name:

Abbott Laboratories Diagnostics Division

Abbott Park II. 60064 IISA

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:	Plus bether Manne
	1 2/2 / 21/2 / 200

Full Name:

Position:

Quality Manager

Date of Approval:

Date Issued:

Supersedes: May 23, 2005

Position:

Date of Approval:

Place Issued: No Effective (Date or

Lot Number):

5/28/2015

-	
	A TABLE SACRES
	ABBOTT

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

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01P74

Abbott Ireland Diagnostics Division

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
IP74-50	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.

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Signature; Full Name: Position:	Siobhan Wright Quality Manager	Signature: Full Name: Position:	Lorraine Whitney Senior Manager Regulatory Affairs
Date of Approval:	09-JAN-15	Date of Approval:	Q 1 HM 5012
Date Issued:	09 3AN 15	Place Issued	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland,
Supersedes	2: 5410 11	Effective (Lot number or date)	09 JAN 15



Legal Man	ate Identification: Ifacturer's Name; cturer's Address;	Abbott Ireland Diagnostics Division	
		Co. Longford	
		Ireland	
ist Numbers nd Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
K59-20	61078	ARCHITECT Ferritin Reagent Kit	Self-declared

Self-declared

Storage of site technical documentation (Name and Address)		technical Address)	Abbott Ireland Diagnostics Division, Lisnamu Department: Regulatory Affairs	ick, Longford, Co. Longford, Ireland.
Authorized E	European Repres (Name and	Address)	N/A	
7K59-10	41928	AR	CHITECT Ferritin Controls	Self-declared
7K59-01	41927	AR	CHITECT Ferritin Calibrators	Self-declared
7K59-35				
7K59-30				

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

Harmonized Standards Listed in the Technical Documentation

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

Signature:	200 - ist	Signature:	La Con Charles
Full Name:	Kevin Callaghan	Full Name:	Lorraine Whitney
Position: Date of	Quality Manager	Position:	Regulatory Affairs Manager
Approval:	25 Hay 2017	Date of Approval:	25 May 201+
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 2012
			A STATE OF S



	ate Identification:	Declaration of Conformity 7K59	
Legal Manu	facturer's Name:	Abbott Ireland Diagnostics Division	
Legal Manufac	cturer's Address:	Lisnamuck, Longford	
		Co. Longford	
		Ireland	
ist Numbers nd Size Code	GMDN Code	Names and Description of Devices	Classification

of Devices		The state of the s	Classification
7K59-20	61078	ARCHITECT Ferritin Reagent Kit	
7K59-25		The Formula Reagent Kill	Self-declared
7K59-30			
7K59-35			
7K59-01	41927	ARCHITECT Ferritin Calibrators	
7K59-10	41928	ARCHITECT Ferritin Controls	Self-declared
4 (1)			Self-declared
Authorized Eur	opean Repres	entative N/A	

Authorized European Representative (Name and Address)	
Storage of site technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. Department: Regulatory Affairs
	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 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:	Signature: Full Name: Position: Date of Approval:	Lorraine Whitney Regulatory Affairs Manager 25 May Zort
Date Issued: 25 May 2017	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes: 22 1901 2014	Effective (Date or Lot Number):	- 25 - 7ay 2011



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:

Signature:

Dr. Holger Kost

Position: Head of Quality

Position:

2017-11-21

Date of Approval:

Date of Approval:

Date Issued:

Full Name:

Place Issued:

Supersedes:

23 Sep 2015

Susanne Ulrich

Effective (Date or Lot Number):

65205 Wiesbaden, Germany

Senior Manager Regulatory Affairs Site Operations Germany

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: Full Name: J. Cochoruky

Stefanie Leschonsky

Manager Quality Position:

Signature:

Full Name:

Susanne Ulrich Position:

Senior Manager Regulatory Affairs Site Operations Germany

Date of Approval:

13. Nov. 2014

Date of Approval:

Date Issued:

10/ NOV / 2019

17. NOV 2014

Place Issued:

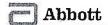
65205 Wiesbaden, Germany

Supersedes:

29 Jan 2013

Effective (Date or Lot Number):

MADE VON FA



Certificate Identification:

DoC-7C18-AIDD Sligo

Legal Manufacturer's Name: Legal Manufacturer's Address: Abbott Ireland Diagnostics Division 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	N/A
Representative (name and address)	
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
	UL International (UK) Ltd Wonersh House, The Guildway,
	Old Portsmouth Road, Guildford, Surrey, GU3 1LR
Notified Body number	0123 (TÜV SÜD Product Service GmbH) & 0843 (UL International (UK) Ltd)
Approval Certificate No.	V1 0019220008 (TÜV SÜD Product Service GmbH) & 361 (UL International (UK) Ltd)
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland.
	Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation



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

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Signature:

Se Lemy

Signature:

Lorraine Whitney

Full Name: Position: Joe Murray Director Quality Assurance/Site Full Name: Lorraine Whi

Senior Manager Regulatory Affairs

Date of Approval:

2 a Mar 19

Date of Approval:

Position:

KA March 2019

Date Issued:

29 March 2019

Supersedes:

11 Jan 2017

Quality Head

Place Issued:

AIDD Sligo

Effective (Date or Lot Number):

30 March 2019

Legal Man	rate Identification: ufacturer's Name: acturer'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
IL56-40	Not Available	ARCHITECT Probe Conditioning Solution	Self-declared
5C54-58	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 Buffe	. 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
Auf	horized European	N/A	
Representative			
	ame and Address) ge site of technical	Abbott Ireland Diagnostics Division, Pinisklin Busin	ness Park, Sligo, County Sligo, Ireland.
(N	documentation	Department: Regulatory Affairs.	
(Name and Address) Harmonized Standards		Listed in the Technical Documentation	
marking, confort Council of 27 Oc states.	n with the applicate tober 1998 on in Yes is made in accordant	te that the in vitro diagnostic medical devices desple provisions of the EC Directive 98/79/EC of the vitro Diagnostic Medical Devices as they are transce with Annex III of the IVD Directive and is issued. Signature:	te European Parliament and of the insposed into the laws of the inembe
		P. CAN.	J
Full Name: Position:	TAIRE I THINGS		Lorraine Whitneyenior Manager Regulatory Affairs
Position;			OLY JULY 2014
Date of Annewal	<u> </u>	And the state of t	0 (3# 69 2814
Date of Approval:		Place Issued:	AIDD Sligo
Date of Approval: Date Issued:	07 Jul	Effective (Date or	VIDO augo



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

ARCH Sys Acc LC	IRIS V3
Abbott Laboratories	
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	-11885

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 manufactufer.

Signature

Full Name _Lauren Sieber_

Position^e

Product Quality Assurance

Manager

Date of Approval

5 28 2015

Date Issued:

Supersedes:

June 13, 2013

Signature

Full Name:

Deborah Hinkley

Position:

Regulatory Affairs

Director!

Date of Approval

Place Issued:

Abbott Ilaboratories

Diagnostics Division

Abbon Hark II. 00004 USA 04/04/11/5

Effective (Date or Lot Number):



This document certifies that:

Sergiu Sorocovici

has completed

Architect i2000SR

Level 1 / 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

Level 1 / Level 2
Application, Operation, Troubleshooting
from 9 February 2015 to 13 February 2015

Trainer: Athanasios Plakas

Date: 13 Feb 2015