

EU Declaration of Conformity Basic UDI-DI: 038074ARU0445RB **Basic UDI-DI Name:** Albumin BCP2 **Risk Class:** Class B List Number **Product and Trade Name GMDN** Code **EMDN** Code and Size Code 04U4520 Albumin BCP2 59071 W01010201 04U4530 Albumin BCP2 59071 W01010201 Manufacturer Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland (Name and Address) Manufacturer SRN IE-MF-000010070 Authorized Representative N/A (Name and Address) Authorized Representative SRN N/A Produced by (Site of Manufacture) Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland (Name and Address) Notified Body TÜV SÜD Product Service GmbH, (Name and Identification Number) Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123 **Quality Management System** EU Certificate No. Annex IX Chapters I and III, No. V12 054869 0013 **Conformity Assessment Procedure** Including an assessment of the technical documentation for devices concerned on the basis of representative samples **Common Specifications (CS)** N/A

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | David Spellman | Full Name: | Sandra Gallagher |
|-------------------------------|--|---------------------------------|--|
| Function: | Director Quality Assurance/ Site Quality Head | | Manager Regulatory Affairs |
| Signature: | Bill | Signature: | S. Gellagler |
| Date of Approval: | 10 SEP 2024 | Date of Approval: | 04-SEP-2024. |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division Lisnamu | ck, Longford Co. Long | ford Ireland |
| Date Issued: | 10 SEP 2024 | | Lisnamuck, Longford Co. Longford Ireland |
| Supersedes: | 18-May-2023 | Effective (Date or Lot Number): | 10 SEP 2024 |

Page 1 of 9



£.

| Basic UDI-DI: Basic UDI-DI Name: Risk Class: | | 038074ARS0487R5 Alkaline Phosphatase2 Class B | | |
|--|--|---|----------------------------------|-------------------|
| List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code |
| 0458720 | | Alkaline Phosphatase2 | 52929 | W01010105 |
| 04\$8730 | | Alkaline Phosphatase2 | 52929 | W01010105 |
| | Manufacturer Name and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Lo | ongford, Co. Long | gford Ireland |
| | | IE-MF-000010070 | | |
| 0 | ized Representative Name and Address) | ive N/A | | |
| 4-44 . 1 | | N/A | | |
| Produced by (Si | ite of Manufacture) Name and Address) | ture) Abbott Ireland Diagnostics Division Lignamuch Law Coll College | | ford Ireland |
| (Name and Iden | Notified Body tification Number) | TÜV Süd Product Service GmbH Zertifizierstellen, Ridlerstraße 65 • 80339 Munich Germany Notified Body Number 0123 | | |
| | | Quality Management System | EU Certifica | te No |
| Conformity Assessment Procedure | | Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of | No. V12 054869 0013 | |
| Common Specification (COS) | | representative samples N/A | - | |
| Common Specifications (CS) | | IN/A | Contraction of the second second | Ale sole with the |

EU Declaration of Conformity

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | Siobhan Wright | Full Name: | Sandra Gallagher |
|-------------------------------|---|------------------------------------|---|
| Function: | Director Quality Assurance/Site Quality Head | | Manager Regulatory Affairs |
| Signature: | lisblige ionger | Signature: | |
| Date of Approval: | | Date of Approval: | 0 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division Lisnar | nuck, Longford, Co. L | |
| Date Issued: | 16 - Dec - 2021 | Place Issued: | Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: | N/A | Effective (Date or Lot Number): | 16- DEC-2021 |

| Certificate Identification: | 04S88 |
|------------------------------------|---|
| 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 |
|---|-----------|----------------------------------|----------------|
| 04\$8820 | 52925 | Alanine Aminotransferase2 | Setf-declared |
| 0458830 | 52925 | Alanine Aminotransferase2 | Self-declared |

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

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

Siobhan Wright

listrait

(W

Position:

Site Quality Head

Full Name (printed): **Position:**

Signature:

Date of Approval:

17 - SEP-2021

12-2ED-5051

Date Issued:

17- JEP - WI

Approval:

Place Issued:

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

Supersedes:

Not Applicable

Effective Date:

17 - JEP- 2021

Thomas Breslin

Manager Regulatory Affairs

Director Quality Assurance/

Date of

| Certificate Identification: | 04S89 |
|-------------------------------|---|
| Legal Manufacturer's Name: | Abbott Ireland Diagnostics Division |
| Legal Manufacturer's Address: | Lisnamuck, Longford, Co. Longford, Ireland. |
| Department of a reduced. | Line and Benerot, Co. Dongroud, Houside |

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---------------------------|--|----------------|
| 0488920 | 52941 | Amylase2 | Self-declared |
| Authorized Euro Representative (1 | pcan name and address) | Not Applicable | |
| Storage of technical documentation (name and address) | | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. | |
| Harmonized Standards | | Listed in the Technical Documentation | |

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

Siobhan Wright

Position:

Site Quality Head

24-JUN-20

Director Quality Assurance/

fischer Dight

Full Name (printed): Position:

Konaine Christer

Lorraine Whitney Senior Manager Regulatory Affairs

Date of Approval:

24- Jun-20

Approval: Place Issued:

Date of

24 JUN 2020

Date Issued:

Effective Date:

24- JUN-20

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

Supersedes: No

Not Applicable



CE DECLARATION OF CONFORMITY

| Manufacturer: | | | |
|---------------|---------------|---------------------|--|
| Hersteller | Fabricante | BIOKIT, S.A. | |
| Fabricante | Producent | Av. Can Montcau, 7. | |
| Fabricant | Tillverkare | 08186 Lliçà d'Amunt | |
| Produttore | Κατασκευαστής | Barcelona – Spain | |

Biokit hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Biokit erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Biokit declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Biokit déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Biokit dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Biokit declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Biokit erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Biokit bekräftar härmed att produkt(er) listade nedan, vara förenlig(a) med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

Η Biokit με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ενωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:

EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) - Annex III

Standard(s):

Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπα

ISO 13485

1

Name: José Luis Zarroca CEO Biokít, S.A.

Lliçà d'Amunt, 23rd November 2020 R01

Biokit, S.A. Barcelona, Spain

www.biokit.com



| Product(s) | | |
|--------------------|--|--------------|
| Produkt(e) | Produto(s) | 1 . U |
| Producto(s) | Produkt(er) | GMDN code |
| Produit(s | Produkt(er) | in Section 2 |
| Prodotto(i) P/N | Προϊόντα | |
| 6K38-02 | | 50055 |
| | Quantia ASO | 59055 |
| 6K39-02 | Quantia ß2-Microglobulin | 53927 |
| 6K40-02 | Quantia Digitoxin | 59084 |
| 6K41-02 | Quantia Ferritin | 53718 |
| 6K42-02 | Quantia IgE | 61274 |
| 6K44-02 | Quantia RF | 55111 |
| 6K45-03 | Quantia PROTEINS Standard | 30505 |
| 6K46-03 | Quantia ASO Standard | 51744 |
| 6K47-03 | Quantia B2-Microglobulin Standard | 38215 |
| 6K48-02 | Quantia Digitoxin Standard | 55330 |
| 6K49-03 | Quantia Ferritin Standard | 41927 |
| 6K50-03 | Quantia IgE Standard | 53777 |
| 6K52-03 | Quantia RF Standard | 42230 |
| 6K53-02 | Quantia PROTEINS Control | 30506 |
| 6K57-02 | Quantia Digitoxin Control | 38533 |
| 6K54-02 | Quantia ASO RF Control I | 30506 |
| 6K55-02 | Quantia ASO RF Control II | 30506 |
| 6K56-02 | Quantia Ferritin/Myoglobin/IgE Control | 30506 |
| 6K99-02 | Quantia A1-Antitrypsin | 53602 |
| 6L32-43 | Quantia Myoglobin | 59042 |
| 6L33-05 | Quantia Myoglobin Standard | 41733 |
| 6L34-43 | Quantia A-1-AGP | 53606 |
| 7K00-03 | Quantia Lp(a) | 53438 |
| 5P83-02 | Lp(a) Calibrators | 41417 |
| 5P84-11 | Lp(a) Control | 41418 |
| 7K02-02 | Quantia D-Dimer | 47346 |
| 7K02-21 | Quantia D-Dimer Control | 47347 |
| 7K02-11 | Quantia D-Dimer Standard | 47348 |

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

04S90 **Abbott Ireland Diagnostics Division** Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers **GMDN** Code **Names and Description of Devices** Classification and Size Code of Devices 04S9020 52954 Self-declared Aspartate Aminotransferase2 04\$9030 52954 Aspartate Aminotransferase2 Self-declared

| Authorized European Representative (name and address) | Not Applicable |
|--|---|
| Storage of technical documentation (name and address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. |
| Harmonized Standards | Listed in the Technical Documentation |

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC 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.

listhan Diff Signature: Signature: Full Name Full Name Siobhan Wright **Thomas Breslin** (printed): (printed): **Manager Regulatory Affairs Position:** Position: **Director Quality Assurance/** Site Quality Head 17-JEP-2021 Date of Date of Approval: Approval: 17-560-2021 Date Issued: Place Issued: Abbott Ireland Diagnostics Division,

Supersedes:

Not Applicable

Effective Date:

17-5EP-6021

Lisnamuck, Longford, Co. Longford, Ireland.

17-SEP-202/



07K61 **Certificate Identification:** Legal Manufacturer's Name: Legal Manufacturer's Address:

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

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|-----------|----------------------------------|----------------|
| 7K61-25 | 60779 | ARCHITECT B12 Reagent Kit | Self-declared |
| 7K61-35 | | | |
| 7K61-01 | 41337 | ARCHITECT B12 Calibrators | Self-declared |
| 7K61-10 | 41338 | ARCHITECT B12 Controls | Self-declared |

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

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC and transposed Irish Regulation S.I. No 304 of 2001 and to the EC Directive 98/79/EC as it is transposed into the laws of the member states.

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

Signature:

liblen wigh

24- APR-19

Full Name:

Siobhan Wright **Director Quality Assurance/Site** Quality Head

Date of Approval:

Position:

UL- APR-19 Date Issued:

Supersedes: 12 OCT 2018

horrare Winhey Signature:

Position:

Senior Manager Regulatory Affairs/

Date of Approval:

12 APR 2019

Place Issued:

Effective (Date or

Lot Number):

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

24- APR-19

Full Name: **Lorraine Whitney**



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

DoC-3L79-SD DELK TPM Abbott GmbH Max-Planck-Ring 2, 65205 Wiesbaden, Germany

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|--|--------------|----------------------------------|----------------|
| 3L79-22 | | | |
| 3L79-32 | 45789 | Calcium | |
| 3L79-42 | | | Self-declared |

| Authorized European Representative (name and address) | N/A | |
|--|--|--|
| Storage site of technical documentation (name and address) | Fisher Diagnostics A Div. of Fisher Scientific Company, LLC A Part of Thermo Fisher Scientific Inc. 8365 Valley Pike Middletown, VA 22645, 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: Position: Claudia Becker Director, Quality Assurance

Date of Approval:

01 Der 2021

Signature:

ure: Mark

Full Name: Position:

Mark Littlefield Associate Director Regulatory Affairs

Date Issued:

Date of Approval:

23-100-2021

23-2000-2021

Place Issued:

Supersedes:

65205 Wiesbaden, Germany

26-FEB-2018

Effective (Date or Lot Number):

OA- Dec- 2021



EC DECLARATION OF CONFORMITY

For in vitro diagnostic medical devices (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy – Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry and immunochemistry, coagulation and rapid tests for immunology and serology" declares, under its own responsibility that the below listed devices comply with all essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (Legislative Decree nr. 322/2000).

It therefore declares and assures, under its own responsibility, that the devices:

- 1. comply with the applicable provisions of the Directive
- 2. are not included in the list A and B of Annex II of the Directive
- 3. are designed, manufactured and placed on the market according to the company certified quality system, in compliance with ISO 9001 and ISO 13485 as per indication expressed in Annex III of the Directive.

DICHIARAZIONE DI CONFORMITÀ CE

per dispositivi medico diagnostici in vitro IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia – Via Robert Koch 2, fabbricante dei dispositivi appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che i dispositivi sotto elencati soddisfano i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che i dispositivi:

- 1. soddisfano le disposizioni applicabili della Direttiva
- 2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
- sono progettati, fabbricati ed immessi in commercio nell'ambito dell'applicazione di un sistema di qualità aziendale dichiarato conforme e certificato secondo le norme ISO 9001 e ISO 13485 come descritto dall'Allegato III della Direttiva.

| Code/Codice | Product Description/Nome prodotto |
|-------------|-----------------------------------|
| 6K26-30 | CRP Vario |
| 6K26-41 | CRP Vario |
| 6K26-10 | CRP Calibrator Set |
| 6K26-12 | CRP Calibrator WR |
| 6K26-14 | CRP Calibrator HS |
| 6K26-21 | CRP Control HS |
| 6K89-30 | Ammonia Ultra |
| 6K91-30 | Ceruloplasmin |
| 4P79-30 | UIBC Liquid |
| 8L24-31 | Creatinine (Enzymatic) |
| 8L24-41 | Creatinine (Enzymatic) |
| 8L25-30 | Lithium |
| 6K89-20 | Ammonia Controls |
| 6K30-10 | Clin Chem Cal |
| 6K31-10 | Plasmaproteins Cal 3x |
| 1P93-30 | Cystatin C |
| 1P93-10 | Cystatin C Calibrator |



ISO 9001:2008 - ISO 13485:2003 - EN ISO 13485:2012 - ISO 13485:2003 CMDCAS - BS OHSAS 18001:2007 - ISO 14001:2004

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. + 39 02 345514.1 Fax + 39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158 Registro delle Imprese di Milano - REA nº 1139796 - Registro AEE nº 1T0804000004820 - Cap. Soc. / Nom. Cap. C 2.500.000 I.v. - sentinel@sentinel.it www.sentineldiagnostics.com



| Code/Codice | Product Description/Nome prodotto |
|-------------|-----------------------------------|
| 1P93-20 | Cystatin C Control Set |
| 6K25-10 | CK-MB Calibrator |
| 6K25-20 | CK-MB Control |
| 6K30-20 | Clin Chem Control 1 |
| 6K30-21 | Clin Chem Control 2 |
| 6K32-20 | Immuno Control 1 |
| 6K32-21 | Immuno Control 2 |
| 6K32-22 | Immuno Control Set |
| 6K90-20 | Bile Acids Controls |
| 6K98-10 | Fructosamine Control 1 |
| 6K98-20 | Fructosamine Control 2 |
| 4P80-30 | Lambda Light Chains |
| 6K24-30 | Cholinesterase |
| 6K25-30 | CK-MB |
| 6K22-30 | Pancreatic Amylase |
| 6K96-30 | Kappa Light Chains |
| 6K23-30 | HBDH |
| 6K90-30 | Bile Acids |
| 6K92-30 | Dibucaine CHE |
| 6K93-30 | Copper |
| 6K94-30 | Fructosamine |
| 6K95-30 | Iron |
| 6K95-41 | Iron |

Furthermore, the manufacturer declares to:

- 1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten (10) years after the production date of the last lot
- 2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoltre di:

- conservare e tenere a disposizione delle Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo almeno di dieci anni dalla data di produzione dell'ultimo lotto
- 2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza postvendita richiesta dalla Direttiva.

Sentinel Ch. SpA A Legal Representative Un Legale Rappresentante Dr. Filippo De Luca

Date/Data 19/06/2015



| Basic UDI-DI: Basic UDI-DI Name: | | 038074ARS0492QW | | | |
|--|-----------------------------------|---|-----------------------|-----------|--|
| | | Cholesterol2 | | | |
| | Risk Class: | Class B | | | |
| List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code | |
| 04S9220 | | Cholesterol2 | 53359 | W01010205 | |
| 04S9230 | | Cholesterol2 | 53359 | W01010205 | |
| (f | Manufacturer Name and Address) | Abbott Ireland Diagnostics Division Lisnamuck, Long | gford Co. Longford In | eland | |
| Manufacturer SRN | | IE-MF-000010070 | | | |
| Authorized Representative | | N/A | | | |
| (Name and Address) | | | | | |
| Authorized Representative SRN | | N/A | | | |
| Produced by (Site of Manufacture) (Name and Address) Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford | | ford Co. Longford Ir | eland | | |
| Notified Body (Name and Identification Number) TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123 | | | | | |
| Conformity Assessment Procedure | | Quality Management System | EU Certificate No. | | |
| | | Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples | No. V12 054869 0013 | | |
| Common Specifications (CS) | | N/A | 1 | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | | Full Name: _Rose | emary McEntire |
|-------------------------------|--|------------------------------------|--------------------------------------|
| Function: | Director Quality Assurance/ Site Quality Head | Function: Man | ager Regulatory Affairs |
| Signature: | Buh | Signature: | . Ne tutine |
| Date of Approval: | 31 001 2024 | Date of Approval: 3 | 10cr 2024 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Lisname | ck, Longford, Co. Longford | Ireland |
| Date Issued: | 31 009 2024 | Place Issued: Lisna | amuck, Longford Co. Longford Ireland |
| Supersedes: | 25-Sep-2023 | Effective (Date or Lot Number): | 31 005 7-84 |

Abbott

Declaration of Conformity

| Certificate Identification: | DOC-7D63-SD DELK TPM |
|-------------------------------|---|
| Legal Manufacturer's Name: | Abbott GmbH |
| Legal Manufacturer's Address: | Max-Planck-Ring 2, 65205 Wiesbaden, Germany |

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|--|--------------|----------------------------------|----------------|
| 7D63-22 7D63-42 | 53006 | Creatine Kinase | Self-declared |
| Authorized European | | N/A | |

| Representative (name and address) | N/A |
|-----------------------------------|---|
| Storage site of technical | Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of |
| documentation (name and address) | Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, 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. Beck

Full Name:

Claudia Becker

Position:

Director Quality Assurance

Date of Approval:

202

Illfini Jenkine Tiffini Jenkins

Manager Regulatory Affairs

Full Name: Tiffin

Position:

Date of Approval:

Signature:

9-111-2021

Date Issued:

65205 Wiesbaden, Germany

Place Issued:

Supersedes:

26-Feb-2018

Effective (Date or Lot Number):

10- Jun - 2021

m-2021



| | | EU Declaration of Conformity | | |
|---------------------------------|---|---|----------------------|-----------|
| Bas | Basic UDI-DI: ic UDI-DI Name: Risk Class: | 038074ARS0495R4 Creatinine2 Class B | | |
| List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code |
| 0489520 | | Creatinine2 | 53251 | W01010207 |
| C | Manufacturer Name and Address) | Abbott Ireland Diagnostics Division Lisnamuck, Long | ford Co. Longford In | reland |
| | Manufacturer SRN IE-MF-000010070 | | | |
| | ized Representative Name and Address) | | | |
| Authorized F | Representative SRN | N N/A | | |
| | ite of Manufacture) Name and Address) | Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland | | |
| (Name and Ider | Notified Body ntification Number) | TÜV SÜD Product Service GmbH, | | |
| Conformity Assessment Procedure | | Quality Management System | EU Certificate No. | |
| | | Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples | No. V12 054869 0013 | |
| Common Specifications (CS) N/A | | N/A | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | David Spellman | Full Name: | Sandra Gallagher |
|-------------------------------|--|---------------------------------|--|
| Function: | Director Quality Assurance/ Site Quality Head | Function: | Manager Regulatory Affairs |
| Signature: | isell | Signature: | S. Gellagler |
| Date of Approval: | 10 SEP 2024 | Date of Approval: | 09- SEP- 2024 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division Lisnamuc | ck, Longford Co. Long | gford Ireland |
| Date Issued: | 10 SEP LORY | | Lisnamuck, Longford Co. Longford Ireland |
| Supersedes: | 13-Mar-2023 | Effective (Date or Lot Number): | 10 SEP 2024 |

Page 1 of 9



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

Abbott

DoC-8G63-SD DELK TPM Abbott GmbH Max-Planck-Ring 2, 65205 Wiesbaden, Germany

| List Numbers and GMDN Size Code of Devices Code | | Names and Description of Devices | Classification |
|--|-------|----------------------------------|----------------|
| 8G63-22 | 53236 | Direct Bilirubin | Self-declared |

| Authorized European Representative (name and address) | N/A |
|--|---|
| Storage site of technical documentation (name and address) | Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada. |
| 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. Leves

Signature:

Full Name:

Position:

Claudia Becker

Full Name:

Jeffen Jentins

Tiffini Jenkins

11-111-2021

Position: Man

Manager Regulatory Affairs

65205 Wiesbaden, Germany

Date of Approval:

22 Jul 2021

Director Quality Assurance

Date Issued:

Date of Approval:

22- Jul - 2021

Place Issued:

Supersedes:

26-Feb-2018

Effective (Date or Lot Number):

22- Jul-202h



.

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 | 61078 | ARC | CHITECT Ferritin Reagent Kit | Self-declared |
| 7K59-25 | | | | |
| 7K59-30 | | | | |
| 7K59-35 | | | | |
| 7K59-01 | 41927 | ARC | CHITECT Ferritin Calibrators | Self-declared |
| 7K59-10 | 41928 | ARCHITECT Ferritin Controls | | Self-declared |
| Authorized Eu | opean Representa (Name and Add | | N/A | |
| Storage of site technical documentation (Name and Address) | | | Abbott Ireland Diagnostics Division, Lisnamuck, Lo Department: Regulatory Affairs | ongford, Co. Longford, Ireland |
| | Harmonized Stand | lards | 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: | 1.Solver Wigh | Signature: | foncine Colistery |
|----------------------|--|------------------------------------|---|
| Full Name: | Siobhan Wright | Full Name: | Lorraine Whitney |
| Position: | Director Quality Assurance/ Site Quality Head | Position: | Senior Manager Regulatory Affairs |
| Date of Approval: | 24 - APR-19 | Date of Approval: | 19 AVR 2019 |
| Date Issued: | 24-APR-19 | Place Issued: | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: | 25-May-2017 | Effective (Date or Lot Number): | 24- APR-15 |



EU Declaration of Conformity 038074ARP0174PC

| Basic UDI-DI: | 038074ARP0174PC | and the second se | |
|------------------------------------|-----------------------------|---|--|
| UDI-DI Name: | Folate | | |
| Risk Class: | Class B | | |
| | Product and Trade Name | GMDN Code | EMDN Code |
| ARCHITECT Folate Reagent Kit | | 60982 | W0102070103 |
| ARCHITECT Folate RBC Lysis Diluent | | 54455 | W01029003 |
| ARCHITECT Folate Manual Diluent | | 58237 | W01029003 |
| ARCHITECT Folate Calibrators | | 41931 | W0102152206 |
| ARCHITECT Folate Controls | | 41932 | W0102152006 |
| Folate Lysis Reagent | | 54455 | W01029003 |
| | UDI-DI Name: Risk Class: | UDI-DI Name: Folate Risk Class: Class B Product and Trade Name ARCHITECT Folate Reagent Kit ARCHITECT Folate RBC Lysis Diluent ARCHITECT Folate Manual Diluent ARCHITECT Folate Calibrators ARCHITECT Folate Controls | Folate Folate Risk Class: Folate Class B GMDN Code Product and Trade Name GMDN Code ARCHITECT Folate Reagent Kit 60982 ARCHITECT Folate RBC Lysis Diluent 54455 ARCHITECT Folate Manual Diluent 58237 ARCHITECT Folate Calibrators 41931 ARCHITECT Folate Controls 41932 |

| (Name and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | |
|---|--|---|
| Manufacturer SRN | IE-MF-000010070 | |
| Authorized Representative (Name and Address) | N/A | |
| Authorized Representative SRN | N/A | |
| Produced by (Site of Manufacture) (Name and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | |
| Notified Body (Name and Identification Number) | TÜV Süd Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123 | |
| Conformity Assessment Procedure | Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples | EU Certificate No. No. V12 054869 0013 |
| Common Specifications (CS) | N/A | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | David Spellman | Full Name: | Sandra Gallagher |
|-------------------------------|--|------------------------|------------------------------------|
| P | Director Quality Assurance/Site Quality | Function | Manager Regulatory Affairs |
| Function: | Head | - | |
| Signature: | Bull | Signature: | S. Callage |
| Date of Approval: | 23 JAN 2024 | Date of Approval: | 19-JAN-2024 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division Lisnam | uck, Longford, Co. Lon | gford Ireland |
| Date Issued: | 23 JAN 2024 | Place Issued: | Lisnamuck, Longford, Co. Longford, |
| Supersedes: | | Effective (Date | 23 5AN 2024 |

Page 1 of 9

Harmonized Standards

transposed into the laws of the member states.

| Legal Manufacturer's Address: | | Lisnamuck, Longford, Co. Longford, Ireland | 1. |
|--|--------------------------|---|-----------------|
| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
| 04T0020 | 53030 | Gamma-Glutamyl Transferase2 | Self-declared |
| 04T0030 | 53030 | Gamma-Glutamyl Transferase2 | Self-declared |
| Authorized Euro Representative (n | pean ame and address) | Not Applicable | |
| Storage of technical documentation (name and address) | | Abbott Ireland Diagnostics Division, Lisnamuck Longford, Ireland. | , Longford, Co. |

Declaration of Conformity

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

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 the manufacturer.

| Signature: Full Name (printed): Position: | Liblo My Siobhan Wright Director Quality Assurance/ Site Quality Head | Signature: Full Name (printed): Position: | Thomas Breslin Manager Regulatory Affairs |
|--|--|--|---|
| Date of Approval: | 09-569-2021 | Date of Approval: | 09 - Sep - 2021 |
| Date Issued: | 09-509-2021 | Place Issued: | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. |
| Supersedes: | Not Applicable | Effective Date: | 09 - Sep - 2021 |

Certificate Identification: Legal Manufacturer's Name:

04T00 Abbott Ireland Diagnostics Division

5

.



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

DoC-3L82-SD DELK TPM Abbott GmbH Max-Planck-Ring 2, 65205 Wiesbaden, Germany

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|--|--------------|----------------------------------|----------------|
| 3L82-22 | 52201 | | |
| 3L82-42 | 53301 | Glucose | Self-declared |

| Authorized European Representative (name and address) | N/A |
|--|---|
| Storage site of technical | Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward |
| documentation (name and address) | Island C1E 2B9, Canada. |
| 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. Jeans

Full Name:

Position:

Full Name:

Signature:

Date of Approval:

Date Issued:

22- Jul- 2021

65205 Wiesbaden, Germany

Place Issued:

Supersedes:

26-Feb-2018

Effective (Date or Lot Number):

22- Jul- 2021

Date of Approval:

CC /ul 2021

Tiffini Jenkins Manager Regulatory Affairs

Juppini Jenkino

Position:

11-Jul-2021

Director Quality Assurance

Claudia Becker



| | Basic UDI-DI: | | 038074LFD0007KK | and an and a second | | |
|--|---|-------------------------------------|---|--|-------------|--|
| | Basic UDI-DI Name: | | Immunoglobulin A | | | |
| | | Risk Class: | Class B | | | |
| | List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code | |
| | 09D9824 | 09D9824 Immunoglobulin A | | 53758 | W0102010101 | |
| | (N | Manufacturer Jame and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | | Ireland | |
| | | Manufacturer SRN | IE-MF-000010070 | | | |
| | Authorized Representative (Name and Address) | | N/A | | | |
| | Authorized Representative SRN | | N/A | | | |
| | Produced by (Site of Manufacture) (Name and Address) | | Abbott Ireland Diagnostics Division, Lisnamuck, Long | gford, Co. Longford | Ireland | |
| | (Name and Ident | Notified Body tification Number) | TÜV SÜD Product Service GmbH, Certification Body Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123 | , | | |
| | | | Quality Management System | | | |
| | Conformity Asso | essment Procedure | Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples | EU Certificate No No. V12 054869 0 | | |
| | Common S | Specifications (CS) | N/A | | | |
| | | | | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | David Spellman | Full Name: | Sandra Gallagher |
|-------------------------------|--|------------------------------------|--|
| Function: | Director Quality Assurance/ Site Quality Head | Function: | Manager Regulatory Affairs |
| Signature: | Buh | Signature: | S. Calles les |
| Date of Approval: | 24 Nov 2023 | Date of Approval: | 24-NOV-2023 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Lisnam | uck, Longford, Co. Lor | ngford Ireland |
| Date Issued: | 24 Nov 2023 | Place Issued: | Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: | 06-April-2022 | Effective (Date or Lot Number): | 24 Nov 2023 |

Page 1 of 9



| 038074LFD0009KP |
|------------------|
| Immunoglobulin G |
| Class C |
| |

| List Number and Size Code | Product and Trade Name | GMDN Code | EMDN Code | |
|------------------------------|------------------------|-----------|-------------|--|
| 09D9924 | Immunoglobulin G | 53787 | W0102010105 | |
| 0757721 | minunogiobumi o | 55707 | 1010201010 | |

| Manufacturer (Name and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | | |
|---|--|--|--|
| Manufacturer SRN | IE-MF-000010070 | | |
| Authorized Representative (Name and Address) | N/A | | |
| Authorized Representative SRN | N/A | | |
| Produced by (Site of Manufacture) (Name and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | | |
| Notified Body (Name and Identification Number) | | | |
| Conformity Assessment Procedure | Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples | EU Certificate No. No. V12 054869 0013 | |
| Common Specifications (CS) | N/A | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | David Spellman | Full Name: | Sandra Gallagher |
|-------------------------------|---|---------------------------------|---|
| Function: | Director Quality Assurance/Site Quality Head | Function: | Manager Regulatory Affairs |
| Signature: | But | Signature: | S. Culles for |
| Date of Approval: | 11 Oct 2023 | Date of Approval: | 18 - SEP-2023 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Lisnam | ick, Longford, Co. Lor | gford Ireland |
| Date Issued: | 11 Oct 2023 | Place Issued: | Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: | 05-MAY-2022 | Effective (Date or Lot Number): | 11 Det 2023 |



| 038074LFD0011KA | | | |
|--|--|--|--|
| Immunoglobulin M Class B | | | |
| Product and Trade Name | GMDN Code | EMDN Code | |
| Immunoglobulin M | 53793 | W0102010107 | |
| Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | | | |
| IE-MF-000010070 | | | |
| N/A | | | |
| N/A | | | |
| Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | | | |
| TÜV Süd Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123 | | | |
| Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples | EU Certificate No No. V12 054869 0 | 1949-10 | |
| N/A | | | |
| | Immunoglobulin M Class B Product and Trade Name Immunoglobulin M Abbott Ireland Diagnostics Division, Lisnamuck, Lon, IE-MF-000010070 N/A N/A Abbott Ireland Diagnostics Division, Lisnamuck, Lon, TÜV Süd Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123 Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples | Immunoglobulin M Class B Product and Trade Name GMDN Code Immunoglobulin M 53793 Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford IE-MF-000010070 N/A N/A N/A Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford TÜV Süd Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123 EU Certificate Note Note Note Note Note Note Note No | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | David Spellman | Full Name: | Sandra Gallagher |
|-------------------------------|---|---------------------------------|--|
| Function: | Director Quality Assurance / Site Quality Head | Function: | Manager Regulatory Affairs |
| Signature: | Bull | Signature: | 3. Callafer |
| Date of Approval: | 28 July 2023 | Date of Approval: | 27-341-2023 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Lisnamu | ick, Longford, Co. Lor | ngford Ireland |
| Date Issued: | 28 July 2023 | Place Issued: | Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: | 06-Apr-2022 | Effective (Date or Lot Number): | 28 July 2023 |

Page 1 of 9



| | E | EU Declaration of Conformity | | | |
|---|--|---|--------------------|-----------|--|
| Basi | Basic UDI-DI: c UDI-DI Name: Risk Class: | 038074ART0402QE Iron2 Class B | | | |
| List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code | |
| 04T0220 | | Iron2 | 54758 | W01010216 | |
| 04T0230 | | Iron2 | 54758 | W01010216 | |
| Manufacturer Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland (Name and Address) Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | | | Ireland. | | |
| | Manufacturer SRN | IE-MF-000010070 | | | |
| Authorized Representative (Name and Address) | | | | | |
| Authorized R | epresentative SRN | N/A | | | |
| | te of Manufacture) Name and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland. | | | |
| Notified Body (Name and Identification Number) TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich Germany Notified Body Number 0123 | | | | | |
| | | Quality Management System | EU Certificate No. | | |
| Conformity Ass | essment Procedure | Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples | No. V12 054869 0 | 013 | |
| Common | Specifications (CS) | N/A | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | David Spellman | Full Name: | Rosemary McEntire |
|-------------------------------|---|------------------------------------|--|
| Function: | Director Quality Assurance/Site Quality Head | Function: | Manager Regulatory Affairs |
| Signature: | Buch | Signature:C | L'alifertine |
| Date of Approval: | 21 Nov 2023 | Date of Approval: | 21 NOV 2023 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division Lisnamu | ıck, Longford, Co. Lon | gford Ireland |
| Date Issued: | 21 Nov 2023 | Place Issued: | Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: | 09 December 2021 | Effective (Date or Lot Number): | 21 Nov 2023 |



| Basic UDI-DI: Basic UDI-DI Name: | | _038074ART0403QG | | | |
|---|---|---|---|-----------|--|
| | | Lactate Dehydrogenase2 | | | |
| | Risk Class: | Class C | | | |
| List Number and Size Code | | Product and Trade Name GMDN Code | | EMDN Code | |
| 04T0320 | | Lactate Dehydrogenase2 | 53072 | W01010119 | |
| 04T0330 | | Lactate Dehydrogenase2 | 53072 | W01010119 | |
| 0 | Manufacturer Name and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Lor | igford, Co. Longford | Ireland | |
| | Manufacturer SRN | | | | |
| Authori | zed Representative | N/A | | | |
| . (1 | Name and Address) | | | | |
| Authorized R | epresentative SRN | N/A | | | |
| | te of Manufacture) Name and Address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | | | |
| Notified Body (Name and Identification Number) | | TÜV Süd Product Service GmbH Zertifizierstellen, Ridlerstraße 65 • 80339 Munich Germany Notified Body Number 0123 | | | |
| Conformity Assessment Procedure | | Quality Management System Annex IX Chapters I and III, | EU Certificate No. No. V12 054869 00 | | |
| | | Including an assessment of the technical documentation for devices concerned on the basis of representative samples | | | |
| Common Specifications (CS) | | N/A | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | Siobhan Wright | Full Name: | Sandra Gallagher | |
|-------------------------------|--|------------------------------------|---|--|
| Function: | Director Quality Assurance/Site Quality Head | Function: | Manager Regulatory Affairs | |
| Signature: | lischan parge | | 3. Culler ler | |
| Date of Approval: | 14-DEC-2021 | Date of Approval: | 13- DEC-2021 | |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland | | | |
| Date Issued: | 14- DEC - 2021 | | Lisnamuck, Longford, Co. Longford, Ireland | |
| Supersedes: | N/A | Effective (Date or Lot Number): | 14-082-2021 | |

Abbott

| Certificate Identification: | 7D80 |
|-------------------------------|--|
| Legal Manufacturer's Name: | Abbott Laboratories Diagnostics Division |
| Legal Manufacturer's Address: | Abbott Park, Illinois 60064 USA |

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|--------------|----------------------------------|----------------|
| 7D80-31 | 53114 | Lipase | Self-declared |

| Authorized European | Abbott GmbH & Co. KG |
|--|---|
| Representative (name and address) | Max-Planck-Ring 2 |
| | 65205 Wiesbaden, Germany |
| Storage site of technical documentation (name and address) | Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038 |
| 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:

Erik Muegge

Position:

QA Manager Ops

Date of Approval:

8-SEP-2017

Signature:

Full Name: Position:

Assoc. Director Regulatory Affairs

Date of Approval:

Resource of Regulatory A

Date Issued:

8-SEV-2017 8-SEP-2017

Abbott Laboratories 1921 Hurd Drive Irving, TX 75038

Mark Littlefield

Supersedes:

Place Issued:

_November 17, 2014_____

Effective (Date or Lot Number):

8-SEP-2017

Certificate Identification: Legal Manufacturer's Name: 3E16 Abbott Laboratories Diagnostics Division Abbott Park, Illinois 60064 USA

List Numbers
and Size Code
of DevicesGMDN CodeNames and Description of DevicesClassification3E16-0253109Lipase CalibratorSelf-declared

| Authorized European | Abbott |
|---------------------------|---------------------------------------|
| Representative | Max-Planck-Ring 2 |
| (Name and Address) | 65205 Wiesbaden, Germany |
| Storage site of technical | Abbott |
| documentation | 1921 Hurd Drive |
| (Name and Address) | Irving, TX 75038 |
| | 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:

Diana Romero

Full Name:

Position: Site Director, Quality Assurance

Diana Romero

Date of Approval:

Date Issued:

9-3-2015

9-3-2015

Supersedes: November 5, 2014

Signature:

Full Name:

Position: Associate Director, Regulatory Affairs

Date of Approval:

Place Issued:

Abbott Laboratories 1921 Hurd Drive Irving, TX 75038

9-3-2015

Mark Littlefield

Effective (Date or Lot Number):

9-3-2015



Certificate Identification: Legal Manufacturer's Name: Legal Manufacturer's Address: 03P68 Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford, Ireland.

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|-----------|----------------------------------|----------------|
| 03P6824 | 46795 | Magnesium | Self-declared |
| 03P6834 | 46795 | Magnesium | Self-declared |

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

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC 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.

| | 1 | | 1 |
|----------------------|---|----------------------|-----------------------------|
| Signature: | tisha triget | Signature: | - Conaise Clistey |
| Full Name: | Siobhan Wright | Full Name: | Lorraine Whitney |
| Position: | Director Quality Assurance/Site Quality Head | Position: | Director Regulatory Affairs |
| Date of Approval: | 20- JAN - 2021 | Date of Approval: | 20 344 2021 |
| Date Issued: | 20- JAN-2021 | Place Issued: | AIDD Longford |
| Supersedes: | 27 April 2020 | Effective (Date) | 20 - JAN - 2021 |



Certificate Identification: Legal Manufacturer's Name: Legal Manufacturer's Address: DOC-1E66-SD DELK TPM Abbott GmbH Max-Planck-Ring 2, 65205 Wiesbaden, Germany

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|----------------|
| 1E66-05 | 41830 | Bilirubin Calibrator | Self-declared |
| Authorized European Representative (name | | N/A | |
| Storage site of technical Microgenics Corpor 46500 Kato Road | | Microgenics Corporation 46500 Kato Road Fremont, CA 94538 USA | |
| Harmonized Standard | Denized 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:

Date of Approval:

C. Teck

Signature:

Juffin Jenkins

Tiffini Jenkins

Position:

Position:

Date of Approval:

15-Jun-2021

65205 Wiesbaden, Germany

Manager Regulatory Affairs

23- Jun - 2021

Place Issued:

Effective (Date or

Lot Number):

Supersedes:

26-Feb-2018

23- Jun - 2021

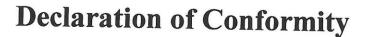
23 Jun 2021

Claudia Becker Director Quality Assurance

Full Name:

Date Issued:

Abbott



DOC-1E78-SD DELK TPM

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

Abbott

Abbott GmbH Max-Planck-Ring 2, 65205 Wiesbaden, Germany

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|--|--------------|---|----------------|
| 1E78-04 | 30505 | Specific Proteins Multiconstituent Calibrator | Self-declared |

| Authorized European Representative (name and address) | N/A |
|--|--|
| Storage site of technical documentation (name and address) | NITTOBO MEDICAL CO., LTD. MEDICAL DEVELOPMENT CENTER, 1 Shiojima, Fukuhara, Fukuyama-Machi, Koriyama- City, Fukushima-Pref. 963- 8061 Japan. |
| 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:

C. Beckers

Signature:

Full Name:

liffin gentins

Tiffini Jenkins

Position:

Director Quality Assurance

Claudia Becker

Position:

Manager Regulatory Affairs

Date of Approval:

<u>22 Jul 2021</u>

Date Issued:

Date of Approval:

22- Mul- 2021

Place Issued:

65205 Wiesbaden, Germany

13-Sep-2019

Supersedes:

Effective (Date or Lot Number):

22- Jul- 2021

| Certificate Identification: | 04V15 |
|-------------------------------|---|
| 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 |
|---|-----------|-----------------------------------|----------------|
| 04V1501 | 47868 | Consolidated Chemistry Calibrator | Self-declared |

| Authorized European Representative (name and address) | N/A |
|--|--|
| Storage of technical documentation (name and address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland and Randox Laboratories Ltd, 30 Randalstown Road, Antrim, Co. Antrim, BT41 4FL, UK |
| 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

(printed):

Position:

Signature: Full Name (printed): Position:

Siobhan Wright Director Quality Assurance/

Site Quality Head

__09 September 2021

Date of Approval:

Supersedes:

15-DEC-2021

Date Issued: 15 - DEC - 2021

Approval: Place Issued:

Date of

Effective (Date or Lot Number): Themas Breslin

Manager Regulatory Affairs

15 - DEC - 2021

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

15-DEC-2021



TECHNOPATH CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY

Category

Manufacturer Techno-path Manufacturing Ltd. Fort Henry Business Park, Ballina, Co. Tipperary, Ireland

Product(s):

Expiry Date:

Product Name

Multichem S Plus Multichem S Plus Multichem S Plus **Multichem S Plus Multichem S Plus Multichem S Plus**

GMDN: **Conformity Route: Quality Management System:** QMS Certification No.: Issued By:

Unassayed/single level Unassayed/single level Assayed/single level

Unassayed/single level 05P79-10 05P79-11 05P79-12 05P78-10

Catalogue Number

Assayed/single level 05P78-11 Assayed/single level 05P78-12

47869 Annex III Self-Declared EN ISO 13485:2016 Q51038520004 Rev 01 TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany 12 February 2025

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from Ag (Day) FEB (Month) 2022 (Year)



Signed for and on behalf of Techno-path Manufacturing Ltd.,

Bernd Hass,

Ballina, Co.Tipperary 18- FEIS -- 2022, Place and Date of Issue

Bernd Hass, Place a SVP of Quality and Regulatory Affairs Techno-path Manufacturing Ltd.

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

| 3 | |
|-------------------------|---|
| Standard | Title |
| EN ISO15223-1:2016 | Symbols to be used with medical device labels, labelling |
| | and information to be supplied. |
| EN ISO13485:2016 | Medical devices – Quality management systems – |
| | Requirements for regulatory purposes |
| EN 13612:2002 + AC:2002 | Performance evaluation of in vitro diagnostic medical |
| | devices |
| EN 13641:2002 | Elimination or reduction of risk of infection related to in |
| | vitro diagnostic reagents |
| EN 13975:2003 | Sampling procedures used for acceptance testing of in |
| | vitro diagnostic medical devices – statistical aspects |
| ISO 14971:2019 | Medical devices – Application of risk management to |
| | medical devices |
| EN ISO 18113-1:2011 | In vitro diagnostic medical devices – Information supplied |
| | by the manufacturer (labelling) – Part 1: Terms, definitions |
| | and general requirements |
| EN ISO 18113-2:2011 | In vitro diagnostic medical devices – Information supplied |
| | by the manufacturer (labelling) – Part 2: In vitro diagnostic |
| | reagents for professional use |
| EN 23640:2015 | In vitro diagnostic medical devices - Evaluation of stability |
| | of in vitro diagnostic reagents |

DC003



TECHNOPATH CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY



Manufacturer

Techno-path Manufacturing Ltd. Fort Henry Business Park, Ballina, Co. Tipperary, Ireland

Product(s):

Product Name Multichem IA Plus Category Assayed/tri-level Catalogue Number 05P76-10

| GMDN: | 47869 |
|----------------------------|---|
| Classification: | Annex II List B |
| Conformity Route: | Annex IV |
| Quality Management System: | EN ISO 13485:2016 |
| QMS/CE Certification No.: | V11038520001 |
| Issued By: | TÜV SÜD, Ridlerstraße 65, 80339 Munich, |
| | Germany |
| Expiry Date: | 26 May 2024 |
| Notified Body Number: | 0123 |

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 3/(Day) 0/(Month) 20 (Year)

Signed for and on behalf of Techno-path Manufacturing Ltd.,

Hu

Bernd Hass, VP of Quality and Regulatory Affairs Techno-path Manufacturing Ltd. Ballina, Co.Tipperary 31 - 01 - 20. Place and Date of Issue



TECHNOPATH CLINICAL DIAGNOSTICS

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

| Standard | Title | |
|-------------------------|---|--|
| EN ISO15223-1:2016 | Symbols to be used with medical device labels, labelling | |
| | and information to be supplied. | |
| EN ISO13485:2016 | Medical devices – Quality management systems – | |
| | Requirements for regulatory purposes | |
| EN 13612:2002 + AC:2002 | Performance evaluation of in vitro diagnostic medical | |
| | devices | |
| EN 13641:2002 | Elimination or reduction of risk of infection related to in | |
| * | vitro diagnostic reagents | |
| EN 13975:2003 | Sampling procedures used for acceptance testing of in in | |
| | vitro diagnostic medical devices – statistical aspects | |
| EN ISO 14971:2012 | Medical devices – Application of risk management to | |
| | medical devices | |
| EN ISO 18113-1:2011 | In vitro diagnostic medical devices – Information supplied | |
| | by the manufacturer (labelling) – Part 1: Terms, definitions | |
| | and general requirements | |
| EN ISO 18113-2:2011 | In vitro diagnostic medical devices – Information supplied | |
| | by the manufacturer (labelling) – Part 2: In vitro diagnostic | |
| | reagents for professional use | |
| EN 23640:2015 | In vitro diagnostic medical devices - Evaluation of stability | |
| | of in vitro diagnostic reagents | |
| SOR/98-282, May 7, 1998 | Canada Medical Device Regulations | |



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

DOC-7D71-SD DELK TPM Abbott GmbH Max-Planck-Ring 2, 65205 Wiesbaden, Germany

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|--|--------------|----------------------------------|----------------|
| 7D71-23 | | | |
| 7D71-32 | 52891 | Phosphorus | Self-declared |

| Authorized European Representative (name and address) | N/A |
|--|--|
| 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, 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:

Position:

C. Berras

Claudia Becker

Signature:

Full Name:

Auffini fentine

Tiffini Jenkins

Manager Regulatory Affairs

11-Jul-2021

Date Issued:

2-111-2021

Place Issued:

65205 Wiesbaden, Germany

26-Feb-2018

Effective (Date or Lot Number):

22- 141-2021

Date of Approval:

22 Jul 2021

Director Quality Assurance Position:

Date of Approval:

Supersedes:



| Basic UDI-DI: Basic UDI-DI Name: Risk Class: | | 038074ART0409QU Total Bilrubin2 Class C | | | | | | | | |
|---|-----------------------------------|---|---------------------|------------|--|------------------------------|--|------------------------|-----------|-----------|
| | | | | | | List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code |
| | | | | | | 04T0920 | | Total Bilirubin2 | 53229 | W01010203 |
| 04T0930 | | Total Bilirubin2 | | W01010203 | | | | | | |
| (N | Manufacturer Name and Address) | Abbott Ireland, Diagnostics Division, Lisnamuck, Long | gford, Co. Longford | , Ireland. | | | | | | |
| Manufacturer SRN | | IE-MF-000010070 | | | | | | | | |
| Authorized Representative | | N/A | | | | | | | | |
| (Name and Address) | | | | | | | | | | |
| Authorized Representative SRN | | N/A | | | | | | | | |
| Produced by (Site of Manufacture) (Name and Address) | | Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. | | | | | | | | |
| | Notified Body | | | | | | | | | |
| (Name and Identification Number) | | Ridlerstraße 65, 80339 Münich, Germany | | | | | | | | |
| | | Notified Body Number 0123 | | | | | | | | |
| | | Quality Management System | EU Certificate No | 0. | | | | | | |
| | | Annex IX Chapters I and III, | V12 054869 0013 | | | | | | | |
| Conformity Assessment Procedure | | Including an assessment of the technical documentation for devices concerned on the basis of representative samples | | | | | | | | |
| Common | Specifications (CS) | N/A | | | | | | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| E 11 M | David Spellman | E II N | Rosemary McEntire |
|-------------------------------|--|---------------------------------|---|
| Full Name: | Director Quality Assurance/ Site Quality | Full Name: | Manager Regulatory Affairs |
| Function: | Head | Function: | |
| Signature: | Bull | Signature: ^c | R. al tatile |
| Date of Approval: | 26 APR 2024 | Date of Approval: | 24 APR 2024 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Lisnamu | uck, Longford, Co. Lor | ngford, Ireland |
| Date Issued: | 26 Apr 2024 | Place Issued: | Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: | 16-Dec-2021 | Effective (Date or Lot Number): | 26 for 2029 |

Page 1 of 9



| Certificate Identification: | 04U44 | |
|-------------------------------|---|--|
| 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 |
|---|-----------|----------------------------------|----------------|
| 04U4420 | 53989 | Total Protein2 | Self-declared |
| 04U4430 | 53989 | Total Protein2 | Self-declared |

| Authorized European Representative (name and address) | Not Applicable |
|--|--|
| Storage of technical documentation (name and address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. |
| Harmonized Standards | Listed in the Technical Documentation |

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC 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

(printed):

Position:

Signature: Full Name (printed): Position:

iblis which Siobhan Wright

Site Quality Head

Director Quality Assurance/

Date of Approval:

Date Issued:

24 - JUN-20

Place Issued:

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

Not Applicable Supersedes:

Effective (Date or Lot Number):

24- JUN-20

24 JUN 2020

powaice (ditrey

Senior Manager Regulatory Affairs

Lorraine Whitney

24- JUN-20 Date of Approval:

 Certificate Identification:
 04T10

 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 |
|---|-----------|----------------------------------|----------------|
| 04T1020 | 53462 | Triglyceride2 | Self-declared |
| 04T1030 | 53462 | Triglyceride2 | Self-declared |

| Authorized European Representative (name and address) | Not Applicable |
|--|--|
| Storage of technical documentation (name and address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. |
| Harmonized Standards | Listed in the Technical Documentation |

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC 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: | listohan whigh | Signature: | the |
|----------------------|-----------------------------|-------------------------|---|
| Full Name (printed): | Siobhan Wright | Full Name (printed): | Thomas Breslin |
| Position: | Director Quality Assurance/ | Position: | Manager Regulatory Affairs |
| | Site Quality Head | | |
| Date of Approval: | 24-JUN-2021 | Date of Approval: | 25 - JUNE - 2021 |
| Date Issued: | 24-JUN-2021 | Place Issued: | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. |
| Supersedes: | Not Applicable | Effective Date: | 25 - JUNE -2021 |

J ABBOTT

| Declaration | of Conformity |
|-------------|---------------|
| | |
| | |

Certificate Identification: Legal Manufacturer's Name: Legal Manufacturer's Address: 04T12 Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford, Ireland.

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|-----------|----------------------------------|----------------|
| 04T1220 | 53590 | Urea Nitrogen2 | Self-declared |
| 04T1230 | 53590 | Urea Nitrogen2 | Self-declared |

| Authorized European Representative (name and address) | Not Applicable |
|--|---|
| Storage of technical documentation (name and address) | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. |
| Harmonized Standards | Listed in the Technical Documentation |

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC 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 (printed): hobhan Dugh Siobhan Wright

Position:

Director Quality Assurance/ Site Quality Head

22- Feb-2021

22 - Keb-2021

Date of Approval:

Date Issued:

Supersedes:

23 June 2020

Signature: Full Name (printed): Position:

Date of Approval:

22 Feb 2021

honaice Mitey

Director Regulatory Affairs

Lorraine Whitney

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

Effective Date:

Place Issued:

22 Feb 2021



Certificate Identification:

| Legal Manufacturer's Name: Legal Manufacturer's Address: | | Abboll Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford, Ireland. | | |
|---|-----------|---|----------------|--|
| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification | |
| 04T1320 | 53583 | Uric Acid2 | Self-deciared | |
| 04T1330 | 53583 | Uric Acid2 | Self-declared | |
| Authorized European Representative (name and address) | | Not Applicable | | |
| Storage of technical documentation (name and address) | | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. | | |
| Harmonized Standards | | Listed in the Technical Documentation | | |

Declaration of Conformity

Abbott Imland Diagonatian Division

04T13

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 (printed): Position:

bla Mich Siebban Wright

Director Quality Assurance/ Site Quality Head Signature: Full Name (printed): Position:

Cowaine Chitney

Lorraine Whitney Director Regulatory Affairs

24 Sep 2020

Date of

Approval:

24-SEP-20

Date of Approval:

Date Issued:

24-568-20

Place Issued:

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

Supersedes:

Not Applicable

Effective Date:

24-SEP-10

Abbott

Declaration of Conformity

Certificate Identification: Legal Manufacturer's Name: Legal Manufacturer's Address: DoC-09P08- AIDD Sligo Abbott Ireland Diagnostics Division Finisklin Business Park, Sligo, Ireland

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|--|---------------------------|--|----------------|
| 09P0825 | 54393 | TRAb Reagent Kit | Self-declared |
| 09P0835 | 54393 | TRAb Reagent Kit | Self-declared |
| 09P0801 | 42079 | TRAb Calibrators | Self-declared |
| 09P0810 | 42080 | TRAb Controls | Self-declared |
| Authorized Euro Representative (1 | pean name and address) | N/A | |
| Storage site of technical documentation (name and address) | | Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs. | |
| Harmonized Standards | | Listed in the Technical Documentation | |

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

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

Signature: Full Name: Joe Murray Noel Haren Director Quality Assurance/Site Position: Manager Regulatory Affairs Quality Head 15 Jun 2021 Date of Approval: Date of Approval: Jun 202

Signature:

Full Name:

Position:

Date Issued:

15 Jun 2021

Place Issued:

AIDD Sligo

Supersedes:

Not applicable

Effective (Date or Lot Number):

15 Jun 2021



| Basic UDI-DI: | 038074LFD0017KN | | | | |
|---|---|----------------------|-------------|--|--|
| Basic UDI-DI Name: | Transferrin | | | | |
| Risk Class: | Class B | | | | |
| List Number and Size Code | Product and Trade Name | GMDN Code | EMDN Code | | |
| 01E0424 | Transferrin | 59041 | W0102010307 | | |
| 01E0444 | | | | | |
| Manufactur (Name and Addres | | gford, Co. Longford, | Ireland | | |
| Manufacturer SR | N IE-MF-000010070 | IE-MF-000010070 | | | |
| Authorized Representati (Name and Addres | | | | | |
| Authorized Representative SR | N/A | | | | |
| Produced by (Site of Manufactur (Name and Addres | Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland | | | | |
| Notified Boo (Name and Identification Numbe | Notified BodyTÜV Süd Product Service GmbH, Certification Body,Identification Number)Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123 | | | | |
| | Quality Management System | EU Certificate No |). | | |
| | Annex IX Chapters I and III, | No. V12 054869 0 | 013 | | |
| Conformity Assessment Procedu | Including an assessment of the technical documentation for devices concerned on the basis of representative samples | | | | |
| Common Specifications (C | 5) N/A | | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | David Spellman | Full Name: | Sandra Gallagher |
|-------------------------------|--|---------------------------------|--|
| Function: | Director Quality Assurance/ Site Quality Head | Function: | Manager Regulatory Affairs |
| Signature: | All | Signature: | S. Callagler |
| Date of Approval: | 150EC 2023 | Date of Approval: | 15-DEC-2023 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Lisnamud | ek, Longford, Co. Lou | ngford Ireland |
| Date Issued: | 15 DEc 2023 | Place Issued: | Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: | 30 June 2022 | Effective (Date or Lot Number): | 15 DEC 2023 |

Page 1 of 9



| Basic UDI-DI: | | 038074DAL0004FU | * | | |
|-----------------------------------|-----------------------|--------------------------------------|--|-------------|--|
| Ba | isic UDI-DI Name: | Detergent A | | | |
| | Risk Class: | Class A | ······································ | | |
| List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code | |
| 1J72-20 | Detergent A | | 59058 | W0201010185 | |
| | Manufacturer | Abbott Laboratories | | | |
| | (Name and Address) | 1915 Hurd Drive | | | |
| | | Irving, TX 75038 USA | | | |
| | Manufacturer SRN | US-MF-000017777 | | | |
| Autho | orized Representative | Abbott Gmb11 | | | |
| | (Name and Address) | Max-Planck-Ring 2 | | | |
| | | 65205 Wiesbaden, Germany | | | |
| Authorized | Representative SRN | DE-AR-000009457 | - <u></u> | | |
| Produced by (Site of Manufacture) | | Sekisui Diagnostics P.E.I. Inc. | | ***** | |
| (Name and Address) | | | | | |
| | | Charlotte town, Prince Edward Island | | | |
| | | CANADA CIE 2B9 | | | |
| Conformity Assessment Procedure | | Annex II and III | | | |
| | | | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

| Full Name: | Kevin Richardson | Full Name: | Melissa Vaughan |
|--------------------|---|------------------------------------|------------------------------|
| | Director, Instrument Quality | Function: | Director, Regulatory Affairs |
| Signature: | Far fihal | Signature: | Melina Vaughan |
| Signed for, and on | 20 - JULY - 2023 Abbott Laboratorics, 1915 Hurd Drive, Irving, TX 75038 USA | | 19 Mily 2023 |
| Date Issued: | 20-July-2023 | Place Issued: | lrving, Texas |
| Supersedes: | 20-May-2022 | Effective (Date or Lot Number): | 20-July-2023 |

EU Declaration of Conformity



| | | EU Declaration of Comornity | | |
|-----------------------------------|-----------------------|-------------------------------------|--------------|-------------|
| | Basic UDI-DI: | 038074DAL0004FU | | |
| Ba | sic UDI-DI Name: | Detergent B | | |
| | Risk Class: | Class A | | |
| List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code |
| 2J94-22 | Detergent B | | 59058 | W0201010185 |
| | Manufacturer | Abbott Laboratories | | |
| (Name and Address) | | 1915 Hurd Drive | | |
| | | Irving, TX 75038 USA | | |
| | Manufacturer SRN | US-MF-000017777 | | |
| Auth | orized Representative | Abbott GmbH | | |
| | (Name and Address) | Max-Planck-Ring 2 | | |
| | | 65205 Wiesbaden, Germany | | |
| Authorized Representative SRN | | DE-AR-000009457 | | |
| Produced by (Site of Manufacture) | | Sekisui Diagnostics P.E.I. Inc. | | |
| (Name and Address) | | 70 Watts Avenue | | |
| | | Charlottetown, Prince Edward Island | | |
| | | CANADA C1E 2B9 | | |
| Conformity / | Assessment Procedure | Annex II and III | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

| Full Name: | Thomas Creel | Fuil Name: | Michele Smith-Waheed |
|-----------------------------|--|---|--|
| Function: | Sr. Director, Instrument and Automation Quality | Function: | Associate Director, Regulatory Affairs |
| Signature: / | homes Curl | Signature: | Underhand |
| Signed for, and on | 20 - May - 2022 Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038 | Date of Approval: | Ungewahud 20-Mry-2022 |
| Date Issued: Supersedes: | 20- Mpy -2022 N/A | Place Issued: Effective (Date or Lot Number): | Irving, Texas 20-Mpy -2022 |

EU Declaration of Conformity



| Basic UDI-DI: Basic UDI-DI Name: | | 038074DA1 0004LU | | | |
|-------------------------------------|-----------------------|--------------------------|-----------|-------------|--|
| | | Acid Wash | | | |
| | Risk Class: | Class A | | | |
| List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code | |
| 6K01-20 | 0 ARCHITECT Acid Wash | | 56676 | W0201010185 | |
| | Manufacturer | Abbott Laboratories | | | |
| | (Name and Address) | 1915 Hurd Drive | | | |
| | | Irving, TX 75038 USA | | | |
| ····· | Manufacturer SRN | Abbott GinbH | | | |
| Autho | prized Representative | | | | |
| | (Name and Address) | | | | |
| | | 65205 Wiesbaden, Germany | | | |
| Authorized Representative SRN | | DE-AR-000009457 | | | |
| Produced by (Site of Manufacture) | | Fisher Diagnostics | | | |
| (Name and Address) | | | | | |
| | . , | Middletown, VA 22645 USA | | | |
| Conformity Assessment Procedure | | Annex II and III | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

| Full Name: | Kevin Richardson | Full Name: | Melissa Vaughan |
|-------------------|---|------------------------------------|------------------------------|
| Function: | Director, Instrument Quality | Function: | Director, Regulatory Affairs |
| Signature: | Jein Richard | Signature: | Melissa Vaughan |
| Date of Approval: | 20- JULY-2023 | Date of Approval: | 19 grey 2023 |
| | Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038 USA | | 0 [|
| Date Issued: | 20-July-2023 | · 632.22 | Irving, Texas |
| Supersedes: | 20-May-2022 | Effective (Date or Lot Number): | 20-July-2023 |



| Basic UDI-DI: | 038074DAL0004FU | | |
|---------------------------|---|---|---|
| ic UDI-DI Name: | Water Bath Additive | | |
| Risk Class: | Class A | | |
| | Product and Trade Name | GMDN Code | EMDN Code |
| Water Bath Additive | | 56676 | W0201010185 |
| Manufacturer | Abbott Laboratories | | |
| (Name and Address) | 1915 Hurd Drive | | |
| | Irving, TX 75038 USA | | |
| Manufacturer SRN | US-MF-000017777 | | |
| rized Representative | Abbott GmbH | | |
| (Name and Address) | Max-Planck-Ring 2 | | |
| | 65205 Wiesbaden, Germany | | |
| Representative SRN | DE-AR-000009457 | | |
| Site of Manufacture) | Sekisui Diagnostics P.E.I. Inc. | | |
| (Name and Address) | 70 Watts Avenue | | |
| 97. - | Charlottetown, Prince Edward Island | | |
| | CANADA CIE 2B9 | | |
| sessment Procedure | Annex II and III | | |
| | ic UDI-DI Name: Risk Class: Water Bath Additive Manufacturer Name and Address) Manufacturer SRN ized Representative Name and Address) Representative SRN site of Manufacture) Name and Address) | Water Bath Additive Risk Class: Class A Product and Trade Name Water Bath Additive Manufacturer Abbott Laboratories Name and Address) 1915 Hurd Drive Irving, TX 75038 USA US-MF-000017777 ized Representative Abbott GmbH Name and Address) DE-AR-00009457 Site of Manufacture) Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown, Prince Edward Island CANADA CIE 2B9 Path Additive | Water Bath Additive GMDN Class A Product and Trade Name GMDN Code Soforo Soforo Water Bath Additive 56676 Manufacturer Abbott Laboratories Soforo Name and Address) 1915 Hurd Drive Irving, TX 75038 USA Manufacturer SRN US-MF-000017777 Soforo ized Representative Abbott GmbH Max-Planck-Ring 2 Name and Address) 65205 Wiesbaden, Germany Soforo Representative SRN DE-AR-000009457 Site of Manufacture) Sekisui Diagnostics P.E.I. Inc. Name and Address) 70 Watts Avenue Charlottetown, Prince Edward Island CANADA CIE 2B9 |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

| Full Name: | Thomas Creel | |
|------------|--------------|--|
| | | |

Quality

Function:

Signature:

Date of Approval: <u>JU-MRi</u>, <u>JO22</u> Signed for, and on Abbott Laboratories, 1915 Hurd Drive, behalf of: Irving, TX 75038

Sr. Director, Instrument and Automation

Full Name: Michele Smith-Waheed

Function: Associate Director, Regulatory Affairs

Signature:

Date of Approval:

20-MRy - 2022

20 - Mpy - 2022 Date Issued: Supersedes: N/A 0

| Place Issued: | Irving, Texas | |
|-----------------|---------------|--|
| Effective (Date | | |
| r Lot Number): | 20- Mpy -2022 | |
| | | |



| | | EU Declaration of Confor | mity | | |
|---|-------------------|--|-----------|-------------|--|
| Basic UDI-DE: | | 038074DAL0004FU | | | |
| B | asic UDI-DI Name: | Alkaline Wash | | | |
| | Risk Class: | Class A | | | |
| List Number and Size Code | | Product and Trade Name | GMDN Code | FMDN Code | |
| 9D31-20 | ARCHITECT Alka | linc Wash | 58236 | W0201010185 | |
| Manufacturer (Name and Address) | | Abbott Laboratories 1915 Hurd Drive Irving, 1X 75038 USA | | 141 | |
| | Manufacturer SRN | US-MI-000017777 | | | |
| Authorized Representative (Name and Address) | | Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany | | | |
| Authorized Representative SRN | | DF-AR-000009457 | | | |
| Produced by (Site of Manufacture) (Name and Address) | | Fisher Diagnostics 8365 Valley Pike Middletown, VA 22645 USA | | | |
| Conformity Assessment Procedure | | Annex II and III | | | |
| | | | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

| Full Name: | Kevin Richardson | Full Name: | Melissa Vaughan |
|--------------------|---|------------------------------------|------------------------------|
| Function: | Director, Instrument Quality | Function: | Director, Regulatory Affairs |
| Signature: | Jein hichal | Signature: | · Melina Vaughan |
| Signed for, and on | 20-5449-2023 Abbott Laboratorics, 1915 Hurd Drive, Irving, TX 75038 USA | | 19 mly 2023 |
| Date Issued: | 20-July - 2023 | | Irving, Texas |
| Supersedes: | 20-May-2022 | Effective (Date or Lot Number): | 20-July-2023 |

Page 1 of 9



| | Basic UDI-DI: | 038074SLI0002T5 | 1 | | |
|------------------------------|--|---|---------|-----------|-------------|
| Ba | sic UDI-DI Name: | ARCHITECT Probe Conditioning Solution | 1 | | |
| | Risk Class: | Class A | <u></u> | | |
| List Number and Size Code | | Product and Trade Name | | GMDN Code | EMDN Code |
| 1L56-40 | ARCHITECT Probe | Conditioning Solution | | 59058 | W0201020185 |
| | Manufacturer (Name and Address) | Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland | i | | |
| | Manufacturer SRN | IE-MF-000009849 | | | |
| Autho | rized Representative (Name and Address) | N/A | | | Ŷ. |
| Authorized | Representative SRN | N/A | | | |
| | Site of Manufacture) (Name and Address) | Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland | | x 4 | e e |
| Conformity A | ssessment Procedure | Annex II and III | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | Noel Haren | Full Name: | Joe Murray |
|-------------------------------|--|---------------------------------|----------------------------|
| Function: | Manager Regulatory Affairs | . Function: | Director Quality Assurance |
| Signature: | D.2en | Signature: | See Auning |
| Date of Approval: | 15 Jul 2022 | Date of Approval: | 15 Jul 2022 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Sligo | | |
| Date Issued: | 15 Jul 2022 | Place Issued: | Sligo, Ireland |
| Supersedes: | 23 May 2022 | Effective (Date or Lot Number): | 15 Jul 2022 |

Basic UDI-DI: 03 Basic UDI-DI Name: AF

038074DAL0005FW ARCHITECT Septum Class A

| | Risk Class: | Class A | | | |
|--|----------------------|--------------------------------------|-----------|------------------------------|--|
| List Number and Size Code | | Product and Trade Name | GMDN Code | EMDN Code | |
| 4D18-03 | ARCHITECT Septur | n | 56676 | W0201020185 | |
| | | | | | |
| | | | | | |
| | Manufacturer | Abbott Laboratories | | ł | |
| (Name and Address) | | 1915 Hurd Drive | | | |
| | | Irving, TX 75038 USA | | | |
| | Manufacturer SRN | US-MF-000017777 | | | |
| Autho | rized Representative | Abbott GmbH | | | |
| | (Name and Address) | Max-Planck-Ring 2 | | | |
| | | 65205 Wiesbaden, Germany | | | |
| Authorized Representative SRN DE-AR-000009457 | | | | | |
| | | MGS Germantown A Division of MGS Gro | up NA Inc | | |
| (Name and Address) W190 N11701 Moldmakers Way | | | | | |
| | | Germantown, WI 53022 USA | | | |
| Conformity Assessment Procedure Annex II and III | | | | - And - Series - Contraction | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

| Full Name: | Thomas Creel | Full Name: | Michele Smith-Waheed |
|-------------------------------|--|------------------------------------|--|
| Function: | Sr. Director, Instrument and Automation Quality | Function: | Associate Director, Regulatory Affairs |
| Signature: | Plomas Curl | Signature: | Miswaheed |
| Date of Approval: | 31-Aug-2022 | Date of Approval: | 02- Sept-2022 |
| Signed for, and on behalf of: | Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 | | |
| Date Issued: | | Place Issued: | Irving, Texas |
| Supersedes: | 24 May 2022 | Effective (Date or Lot Number): | 02-Sept-2022 |
| | | | / |



EU Declaration of Conformity

| | Basic UDI-DI: | 038074SLI0002T5 | 1 | | |
|---|------------------------------------|---|-----------|-------------|--|
| Basic UDI-DI Name: | | ARCHITECT Concentrated Wash Buffer | | | |
| | Risk Class: | Class A | £ | | |
| List Number and Size Code | · · · | Product and Trade Name | GMDN Code | EMDN Code | |
| 6C54-58 | ARCHITECT Conce | entrated Wash Buffer | , 58236 | W0201020185 | |
| 6C54-82 | ARCHITECT Conce | entrated Wash Buffer | 58236 | W0201020185 | |
| 6C54-88 | ARCHITECT ARM | Concentrated Wash Buffer | 58236 | W0201020185 | |
| | Manufacturer (Name and Address) | Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland | ί. | 5 | |
| | Manufacturer SRN | IE-MF-000009849 | | | |
| Authorized Representative (Name and Address) | | N/A | | | |
| Authorized Representative SRN | | N/A | ř, | a.5 | |
| Produced by (Site of Manufacture) | | Abbott Ireland | 4. | | |
| (Name and Address) | | Diagnostics Division Finisklin Business Park Sligo, Ireland | * 14 | | |
| Conformity Assessment Procedure | | Annex II and III | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | Noel Haren | Full Name: | Joe Murray |
|-------------------------------|--|---------------------------------|--------------------------------|
| Function: | Manager Regulatory Affairs | Function: | Director Quality Assurance |
| Signature: | NR | Signature: | See Aunas |
| Date of Approval: | 15 Jul 2022 | Date of Approval: | 15 Jul 2022 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Sligo | an An air an an an | transation as set on a Million |
| | 15 Jul 2022 | Place Issued: | Sligo, Ireland |
| | 23 May 2022 | Effective (Date or Lot Number): | 15 Jul 2022 |

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| Ba | Basic UDI-DI: sic UDI-DI Name: Risk Class: | 038074SLI0002T5 ARCHITECT Trigger Sol Class A | ution | | | |
|---|--|---|-------|---|-----------|-------------|
| List Number and Size Code | · · · | Product and Trade Na | ne | | GMDN Code | EMDN Code |
| 6C55-63 | ARCHITECT Trigge | er Solution | | | , 58793 | W0201020185 |
| 6C55-85 | ARCHITECT Trigge | er Solution | | | 58793 | W0201020185 |
| | Manufacturer (Name and Address) | Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland | | č | | |
| | Manufacturer SRN | IE-MF-000009849 | 1 | | | 3 |
| | rized Representative (Name and Address) | N/A | | | | |
| Authorized Representative SRN | | N/A | * | | 5 | 4 |
| Produced by (Site of Manufacture) (Name and Address) | | Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland | | | 8 | 2 |
| Conformity Assessment Procedure | | Annex II and III | | | | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | Noel Haren | Full Name: | Joe Murray |
|-------------------------------|--|---------------------------------|----------------------------|
| Function: | Manager Regulatory Affairs | Function: | Director Quality Assurance |
| Signature: | vien | Signature: | Soe Anny |
| | 15 Jul 2022 | Date of Approval: | 15 Jul 2022 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Sligo | | |
| Date Issued: | 15 Jul 2022 | | Sligo, Ireland |
| Supersedes: | 23 May 2022 | Effective (Date or Lot Number): | 15 Jul 2022 |

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| | Basic UDI-DI: | 038074SLI0002T5 | ÷ | | , |
|---|--|---|-----|------------|-------------|
| Basic UDI-DI Name: | | ARCHITECT Pre-Trigger Solution | | | |
| | Risk Class: | Class A | | | |
| List Number and Size Code | | Product and Trade Name | | GMDN Code | EMDN Code |
| 6E23-65 | ARCHITECT Pre-Tr | igger Solution | | 61163 | W0201020185 |
| 6E23-82 | ARCHITECT Pre-Trigger Solution | | | 61163 | W0201020185 |
| | Manufacturer (Name and Address) | Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland | i | | |
| | Manufacturer SRN | IE-MF-000009849 | | | Υ |
| | rized Representative (Name and Address) | N/A | | | 1.1 |
| Authorized Representative SRN | | N/A | | | |
| Produced by (Site of Manufacture) (Name and Address) | | Abbott Ireland Diagnostics Division Finisklin Business Park | | <i>k</i> ' | d a |
| | | Sligo, Ireland | | | |
| Conformity Assessment Procedure | | Annex II and III | 1.4 | • | |

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

| Full Name: | Noel Haren | Full Name: | Joe Murray |
|-------------------------------|--|---------------------------------|----------------------------|
| Function: | Manager Regulatory Affairs | Function: | Director Quality Assurance |
| Signature: | N.2l | Signature: | Se Numy |
| | 15 Jul 2022 | | 15 Jul 2022 |
| Signed for, and on behalf of: | Abbott Ireland Diagnostics Division, Sligo | | |
| Date Issued: | 15 Jul 2022 | Place Issued: | Sligo, Ireland |
| Supersedes: | 23 May 2022 | Effective (Date or Lot Number): | 15 Jul 2022 |

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038074DAL0005FW

Basic UDI-DI: Basic UDI-DI Name

ARCHITECT Reaction Vessels

| υ | ע-וע | rame: |
|---|------|-------|
| | Riel | Class |

Class A List Number **GMDN** Code EMDN Code **Product and Trade Name** and Size Code 7C15-03 ARCHITECT Reaction Vessels 56676 W0201020185 Manufacturer Abbott Laboratories (Name and Address) 1915 Hurd Drive Irving, TX 75038 USA **Manufacturer SRN** US-MF-000017777 Authorized Representative Abbott GmbH (Name and Address) Max-Planck-Ring 2 65205 Wiesbaden, Germany **Authorized Representative SRN** DE-AR-000009457 Produced by (Site of Manufacture) NYPRO CHICAGO (Name and Address) 955 Tri-State Parkway Gurnee, IL 60031 USA **Conformity Assessment Procedure** Annex II and III

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices, and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

| Full Name: | Thomas Creel Sr. Director, Instrument and Automation | Full Name: | Michele Smith-Waheed |
|---|---|---|--|
| Function: | | Function: | Associate Director, Regulatory Affairs |
| Signature: | Chomus Cul | Signature: | MSWaherl |
| Date of Approval: Signed for, and on behalf of: | 3/-Aug-2022 Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 | Date of Approval: | 02- Sept- 2022 |
| Date Issued: Supersedes: | 02-Sept-2022 24 May 2022 | Place Issued: Effective (Date or Lot Number): | Irving, Texas |
| - | Let Muy 2022 | - | |