ABBOTT

# Declaration of Conformity

**Certificate Identification:** 2J94

**Legal Manufacturer's Name:** Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 2J94-21 | 59058 | Detergent B | Self-declared |

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

Position: Site Director, Quality Assurance

Date of Approval: December 4, 2014

Date Issued: December 4, 2014

Supersedes: New

Digitally signed by Ceaicovschi Tudor
Date: 2021.03.19 16:25:59 EET
Reason: MoldSign Signature
Location: Moldova

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: December 4, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): December 4, 2014

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 3P39

**Legal Manufacturer's Name:** Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 3P39-21; 3P39-41 | 53583 | Uric Acid | Self-declared |

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

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 6K01

**Legal Manufacturer's Name:** Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 6K01-20 | 56676 | Acid Wash | Self-declared |

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

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 11, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

Abbott

# Declaration of Conformity

**Certificate Identification:** 7D81
**Legal Manufacturer's Name:** Abbott Laboratories Diagnostic 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 |
|---|---|---|---|
| 7D81-21 | 52954 | Aspartate Aminotransferase | **Self-declared** |

| | |
|---|---|
| **Authorized European Representative (name and address)** | Abbott GmbH & Co. KG<br>Max-Planck-Ring 2<br>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: Thomas Creel

Full Name: **Thomas Creel**

Position: **Director, Site QA**

Date of Approval: 15-Oct-2018

Signature:

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 15-OCT-2018

Date Issued: 15-OCT-2018

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: 08-SEP-2017

Effective (Date or Lot Number): 15-OCT-2018

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 7D53
**Legal Manufacturer's Name:** Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 7D53-23 | 53599 | Albumin BCG | Self-declared |

| | |
|---|---|
| **Authorized European Representative (Name and Address)** | Abbott<br>Max-Planck-Ring 2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (Name and Address)** | Abbott<br>1921 Hurd Drive<br>Irving, TX 75038<br>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: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 9-3-2015
Date Issued: 9-3-2015
Supersedes: November 5, 2014

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 9-3-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 9-3-2015

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 9D31
**Legal Manufacturer's Name:** Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 9D31-20 | 58236 | Alkaline Wash | Self-declared |

| | |
|---|---|
| **Authorized European Representative (Name and Address)** | Abbott<br>Max-Planck-Ring 2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (Name and Address)** | Abbott<br>1921 Hurd Drive<br>Irving, TX 75038<br>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: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

Abbott

# Declaration of Conformity

**Certificate Identification:** DoC-*7D55*-SD DELK
**Legal Manufacturer's Name:** Abbott GmbH & Co. KG
**Legal Manufacturer's Address:** Max-Planck-Ring 2, 65205 Wiesbaden, Germany

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 7D55-22 | 52929 | Alkaline Phosphatase | **Self-declared** |
| 7D55-32 | 52929 | Alkaline Phosphatase | **Self-declared** |

| | |
|---|---|
| **Authorized European Representative (name and address)** | N/A |
| **Storage site of technical documentation (name and address)** | Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, 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: Diana Romero
Full Name: **Diana Romero**
Position: **Director Quality Assurance**
Date of Approval: 22-MAY-2017

Signature:
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 22-MAY-2017
Date Issued: 22-MAY-2017
Place Issued: 65205 Wiesbaden, Germany
Supersedes: Not applicable
Effective (Date or Lot Number): 22-MAY-2017

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 7D58

**Legal Manufacturer's Name:** Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 7D58-21 | 52941 | Amylase | Self-declared |

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

Position: Site Director, Quality Assurance

Date of Approval: 9-3-2015

Date Issued: 9-3-2015

Supersedes: November 5, 2014

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: 9-3-2015

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): 9-3-2015

Abbott

# Declaration of Conformity

**Certificate Identification:** 7D56
**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 |
|---|---|---|---|
| 7D56-21 | 52925 | Alanine Aminotransferase | Self-declared |

| | |
|---|---|
| **Authorized European Representative (name and address)** | Abbott GmbH & Co. KG<br>Max-Planck-Ring 2<br>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: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 8-SEP-2017

Date Issued: 8-SEP-2017

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: September 3, 2015

Effective (Date or Lot Number): 8-SEP-2017

Biokit
A Werfen Company

# CE DECLARATION OF CONFORMITY

| **Manufacturer:** | | |
|---|---|---|
| *Hersteller*<br>*Fabricante*<br>*Fabricant*<br>*Produttore* | *Fabricante*<br>*Producent*<br>*Tillverkare*<br>*Κατασκευαστής* | **BIOKIT, S.A.**<br>**Av. Can Montcau, 7.**<br>**08186 Lliçà d'Amunt**<br>**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*

*Name: José Luis Zarroca*
*CEO*
*Biokit, S.A.*

Lliçà d'Amunt, 23rd November 2020
*R01*

Biokit
A Werfen Company

| **Product(s)**<br>*Produkt(e)*<br>*Producto(s)*<br>*Produit(s*<br>*Prodotto(i)* | *Produto(s)*<br>*Produkt(er)*<br>*Produkt(er)*<br>*Προϊόντα* | *GMDN code* |
|---|---|---|
| **P/N** | | |
| 6K38-02 | 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 ß2-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 |

Biokit, S.A.
Barcelona, Spain
Av. Can Montcau 7
08186 Lliçà d'Amunt
Tel. +34 93 860 9000
www.biokit.com

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 1E66

**Legal Manufacturer's Name:** Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 1E66-04 | 41830 | Bilirubin Calibrator | Self-declared |

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

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: November 5, 2014

Supersedes: September 28, 2006

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

Abbott

# Declaration of Conformity

**Certificate Identification:** 8G63
**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 |
|---|---|---|---|
| 8G63-21 | 53236 | Direct Bilirubin | Self-declared |

| | |
|---|---|
| **Authorized European Representative (name and address)** | Abbott GmbH & Co. KG<br>Max-Planck-Ring 2<br>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: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: September 3, 2015
Effective (Date or Lot Number): 8-SEP-2017

Abbott

# Declaration of Conformity

**Certificate Identification:** 7D81
**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 |
|---|---|---|---|
| 6L45-21 | 53229 | Total Bilirubin | Self-declared |
| 6L45-41 | 53229 | Total Bilirubin | Self-declared |

| | |
|---|---|
| **Authorized European Representative (name and address)** | Abbott GmbH & Co. KG<br>Max-Planck-Ring 2<br>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: Thomas Creel

Full Name: **Thomas Creel**

Position: **Director, Site QA**

Date of Approval: 12-Oct-2018

Signature: Mark Littlefield

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 12-OCT-2018

Date Issued: 12-OCT-2018

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Supersedes: September 8,2017

Effective (Date or Lot Number): 12-OCT-2018

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 3L79

**Legal Manufacturer's Name:** Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 3L79-21;3L79-31; 3L79-41 | 45789 | Calcium | Self-declared |

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

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 31, 2012

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

Abbott

# Declaration of Conformity

**Certificate Identification:** 7D62
**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 |
|---|---|---|---|
| 7D62-21 | 53362 | Cholesterol | Self-declared |

| | |
|---|---|
| **Authorized European Representative (name and address)** | Abbott GmbH & Co. KG<br>Max-Planck-Ring 2<br>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: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 8-SEP-2017
Date Issued: 8-SEP-2017
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Supersedes: 9-3-2015
Effective (Date or Lot Number): 8-SEP-2017

Abbott

# Declaration of Conformity

**Certificate Identification:** DoC-7D63-SD DELK TPM
**Legal Manufacturer's Name:** Abbott GmbH & Co. KG
**Legal Manufacturer's Address:** Max-Planck-Ring 2, 65205 Wiesbaden, Germany

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 7D63-22<br>7D63-42 | 53006 | Creatine Kinase | **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: **Erik Muegge**

Position: **Mgr. Quality Operations Assurance**

Date of Approval: _26-FEB-2018_____

Signature: 

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: _26-FEB-2018_____

Date Issued: _26-FEB-2018_____

Place Issued: 65205 Wiesbaden, Germany

Supersedes: Not Applicable

Effective (Date or Lot Number): _26-FEB-2018_____

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 3L81

**Legal Manufacturer's Name:** Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 3L81-22; 3L81-32; 3L81-41 | 53251 | Creatinine | Self-declared |

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

Position: Site Director, Quality Assurance

Date of Approval: November 5, 2014

Date Issued: 11-5-2014

Supersedes: July 16, 2013

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

# Declaration of Conformity

**Certificate Identification:** 1J72
**Legal Manufacturer's Name:** Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---|---|---|---|
| 1J72-20 | 59058 | Detergent A | Self-declared |

| | |
|---|---|
| **Authorized European Representative (Name and Address)** | Abbott<br>Max-Planck-Ring 2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (Name and Address)** | Abbott<br>1921 Hurd Drive<br>Irving, TX 75038<br>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: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015