

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number:

MD 69326

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25

Effective Date: 2024-04-14

Latest Revision Date: 2024-03-26

Expiry Date: 2027-04-13



Page: 1 of 2

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 69326**

Location

Registered Activities

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Sunderland Enterprise Park
Colima Avenue
Sunderland
SR5 3XB
United Kingdom

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



Original Registration Date: 2002-10-25

Effective Date: 2024-04-14

Latest Revision Date: 2024-03-26

Expiry Date: 2027-04-13

Page: 2 of 2

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A Member of the BSI Group of Companies.

Declaration of Conformity

helena
Biosciences Europe

HL-7- 0135 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

| Product Code | Description | GMDN Classification Code |
|--------------|--------------------|--------------------------|
| 5183 | Routine Control SA | 30590 |

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity



HL-7- 0512 DC DOI 2013/08 (4)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

| Product Code | Description | GMDN Classification Code |
|--------------|----------------------|--------------------------|
| 5556 | Clauss Fibrinogen 50 | 55997 |
| 5556H | Clauss Fibrinogen 50 | 55997 |

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 05 Aug 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

helena
Biosciences Europe

HL-7- 0137 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

| Product Code | Description | GMDN Classification Code |
|--------------|-------------------|--------------------------|
| 5186 | Routine Control N | 30590 |

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

helena
Biosciences Europe

HL-7- 0138 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

| Product Code | Description | GMDN Classification Code |
|--------------|-------------------|--------------------------|
| 5187 | Routine Control A | 30590 |

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity



HL-7- 0640DC DOI 2015/07 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

| Product Code | Description | GMDN Classification Code |
|--------------|--------------------|--------------------------|
| 5504R | Calibration Plasma | 55995 |

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 30 Jul 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity



HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

| Product Code | Description | GMDN Classification Code |
|--------------|------------------|--------------------------|
| 5267L | Thromboplastin L | 55983 |

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Laboratories
Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number: **FM 743464**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, Manufacture, Development, Management of Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2018-10-12

Effective Date: 2024-10-13

Latest Revision Date: 2024-09-19

Expiry Date: 2027-10-12

Page: 1 of 2



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **FM 743464**

| Location | Registered Activities |
|--|---|
| Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA | Design, Manufacture, Development, Management of Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments. |
| Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA | Oversight of the Quality Management System for the Abbott Diagnostics Division Sites |
| Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA | QC Inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments. |

Original Registration Date: 2018-10-12

Effective Date: 2024-10-13

Latest Revision Date: 2024-09-19

Expiry Date: 2027-10-12

Page: 2 of 2

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abbott Laboratories
Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number: **MD 743461**

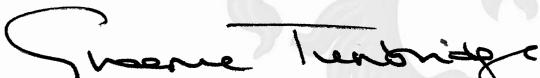
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Manufacture and Distribution of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring.

Design, Development, Manufacture, Installation, Service and Distribution of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems.

Design, Development, Manufacture, Installation, Service and Distribution of In Vitro Diagnostic medical devices including Analyzers, Reagents, and related Accessories for the identification of hematologic parameters.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-06-01

Effective Date: 2024-10-13

Latest Revision Date: 2024-10-03

Expiry Date: 2027-10-12

Page: 1 of 2



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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: MD 743461

Location

Registered Activities

| | |
|--|---|
| Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA | Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments. |
| Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA | Oversight of the Quality Management System for the Abbott Diagnostics Division Sites. |
| Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA | QC inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments. |

Original Registration Date: 2021-06-01

Effective Date: 2024-10-13

Latest Revision Date: 2024-10-03

Expiry Date: 2027-10-12

Page: 2 of 2

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



Declaration of Conformity

Certificate Identification: SC-09H60
Legal Manufacturer's Name: Abbott Laboratories
Legal Manufacturer's Address: Diagnostics Division
Abbott Park, IL 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|----------------------------------|----------------|
| 09H60-01 | 58236 | CELL-DYN Emerald 22 Easy Cleaner | Self-declared |

| | |
|---|--|
| Authorized European Representative (Name and Address) | ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany |
| Storage site of technical documentation (Name and Address) | Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 |
| | Avantor Performance Materials B.V. Teugseweg 20 Deventer, Overijssel Netherlands 7418 AM |
| | Avantor Performance Materials Poland S.A. ul. Sowinskiego 11 44-101 Gliwice, Poland |
| Harmonized Standards | Listed in the Technical Documentation |

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

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

Signature:

Signature:

Full Name:

Kevin Richardson

Full Name:

Mirna DiPano

Position:

Manager, Supplier Quality

Position:

Director of Regulatory Affairs

Date of Approval:

10-July-2017

Date of Approval:

10-July-2017

Date Issued:

JUL 10 2017

Place Issued:

Abbott Santa Clara

Supersedes:

IRIS V1, April 15, 2016

Effective (Date or
Lot Number):

JUL 10 2017



Declaration of Conformity

Certificate Identification:

SC-09H61

Legal Manufacturer's Name:

Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address:

Abbott Park, IL 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|----------------------------------|----------------|
| 09H61-01 | 61165 | CELL-DYN Emerald 22 LYSE | Self-declared |

| | |
|---|---|
| Authorized European Representative (Name and Address) | ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany |
| Storage site of technical documentation (Name and Address) | Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 |
| | BIT Group France Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France |
| Harmonized Standards | Listed in the Technical Documentation |

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

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

Signature:

Signature:

Full Name:

Kevin Richardson

Full Name:

Mirna DiPano

Position:

Manager, Supplier Quality

Position:

Director of Regulatory Affairs

Date of Approval:

10-July-2017

Date of Approval:

10-July-2017

Date Issued:

JUL 10 2017

Place Issued:

Abbott Santa Clara

Supersedes:

IRIS V1, April 15, 2016

Effective (Date or
Lot Number):

JUL 10 2017



Declaration of Conformity

Certificate Identification: SC-09H62
Legal Manufacturer's Name: Abbott Laboratories
Legal Manufacturer's Address: Diagnostics Division
Abbott Park, IL 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|----------------------------------|----------------|
| 09H62-01 | 58237 | CELL-DYN Emerald 22 DILUENT | Self-declared |

| | |
|---|--|
| Authorized European Representative (Name and Address) | ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany |
| Storage site of technical documentation (Name and Address) | Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 |
| | Avantor Performance Materials B.V. Teugseweg 20 Deventer, Overijssel Netherlands 7418 AM |
| | Avantor Performance Materials Poland S.A. ul. Sowinskiego 11 44-101 Gliwice, Poland |
| Harmonized Standards | Listed in the Technical Documentation |

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

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

Signature:

Signature:

Full Name:

Kevin Richardson

Full Name:

Mirna DiPano

Position:

Manager, Supplier Quality

Position:

Director of Regulatory Affairs

Date of Approval:

10-July-2017

Date of Approval:

10-July-2017

Date Issued:

JUL 10 2017

Place Issued:

Abbott Santa Clara

Supersedes:

IRI S V1, April 15, 2016

Effective (Date or
Lot Number):

JUL 10 2017



Declaration of Conformity

Certificate Identification: SC-09H72
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|-------------------------------------|----------------|
| 09H72-01 | 55866 | CELL-DYN 22 Plus Control, Full Pack | Self-declared |
| 09H72-02 | 55866 | CELL-DYN 22 Plus Control, Half Pack | Self-declared |

| | |
|---|--|
| Authorized European Representative (Name and Address) | ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany |
| Storage site of technical documentation (Name and Address) | Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 |
| | Streck 7002 S. 109th Street La Vista, NE 68128 USA |
| Harmonized Standards | Listed in the Technical Documentation |

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

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

Signature:

Signature:

Full Name:

Kevin Richardson

Full Name:

Zaman Khan

Position:

Manager, Supplier Quality

Position:

Associate Director, Regulatory Affairs

Date of Approval:

11 - APRIL - 2016

Date of Approval:

11 - Apr - 2016

Date Issued:

APR 15 2016

Place Issued:

Abbott Santa Clara

Supersedes:

N/A

Effective (Date or Lot Number):

APR 15 2016



Declaration of Conformity

Certificate Identification: SC-09H73
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|----------------------------------|----------------|
| 09H73-01 | 55865 | CELL-DYN 22 Plus Calibrator | Self-declared |

| | |
|---|---|
| Authorized European Representative (Name and Address) | ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany |
| Storage site of technical documentation (Name and Address) | Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 Streck 7002 S. 109th Street La Vista, NE 68128 USA |
| Harmonized Standards | Listed in the Technical Documentation |

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

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

Signature:

Signature:

Full Name:

Kevin Richardson

Full Name:

Zaman Khan

Position:

Manager, Supplier Quality

Position:

Associate Director, Regulatory Affairs

Date of Approval:

11-APR-2016

Date of Approval:

11-Apr-2016

Date Issued:

APR 15 2016

Place Issued:

Abbott Santa Clara

Supersedes:

N/A

Effective (Date or Lot Number):

APR 15 2016

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS
Zone Industrielle
61500 SEES FRANCE

pour les activités
for the activities

Conception, production, contrôle et commercialisation de produits de chimie cliniques
pour le diagnostic in vitro. Validation de la combinaison réactifs et automates.
Distribution d'automates et de produits de chimie cliniques pour le diagnostic in vitro.

*Design, production, control and sales of clinical chemistry products intended to be used
for in vitro diagnostics. Validation of the combination reagents and analyzers.
Distribution of clinical chemistry analyzers and products for in vitro diagnostics.*

réalisées sur le(s) site(s) de
performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité / Effective date : July 25th, 2023 (included)

Valable jusqu'au / Expiry date : July 27th, 2026 (included)

Etabli le / Issued on : July 25th, 2023



GMED_SQ-F-0-07-2018

GMED N° 10462-8

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvellement du certificat 10462-7

On behalf of the President
Marjorie PERRIMON
Certification Director



DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages), conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to *in vitro* diagnostic medical devices and to the public health code.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th, 2023).

DECLARACIÓN CE DE CONFORMIDAD

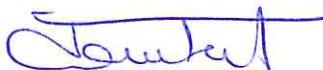
Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico *in vitro* y el código de salud pública.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 12 Mai 2021

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglamentarios



ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General



Société par actions simplifiée au capital de 1.688.392,33 € – SIREN : 318 365 228 – RCS ALENCON

| REACTIFS - REAGENTS - REACTIVOS | RÉFÉRENCES - REFERENCES - REFERENCIAS | Code GMDN |
|--|---|-------------|
| Metabolites divers / Miscellaneous metabolites | | |
| ALBUMIN | ALBU-0600/0700/0250/M830 | |
| ALBUMIN ENVOY | ALBU-0850 | 53597 |
| BILIRUBIN DIRECT 4+1 | BIDI-0600/0250 | 53233 |
| BILIRUBIN TOTAL 4+1 | BITO-0600/0250 | 53229 |
| BILIRUBIN TOTAL & DIRECT 4+1 | BITD-0600 | 53229/53233 |
| CREATININE ENVOY | CRSL-0850 | 53250 |
| CREATININE JAFFE | CRCO-0600/0700 | 53251 |
| CREATININE PAP | CRSL-M490 | |
| CREATININE PAP SL | CRSL-0630/0250 | 53250 |
| DIRECT BILIRUBIN | BIDI-M430 | 53233 |
| DIRECT BILIRUBIN ENVOY | BIDV-0850 | 53233 |
| GLUCOSE ENVOY | GPSL-0850 | |
| GLUCOSE HK | GHSL-M490 | |
| GLUCOSE HK SL | GHSL-0600/0250 | 53301 |
| GLUCOSE PAP | GPSL-M690 | |
| GLUCOSE PAP SL | GPSL-0507/0500/0707/0700/0250/0455/0497 | |
| LACTATE | LACT-0100 | 53342 |
| MICROPROTEIN PLUS | PRTU-0600/0250 | 53481 |
| PHOSPHORUS | PHOS-0600/0230/M430 | |
| PHOSPHORUS ENVOY | PHOS-0850 | 59123 |
| TOTAL BILIRUBIN | BITO-M430 | 53229 |
| TOTAL BILIRUBIN ENVOY | BITV-0850 | 53229 |
| TOTAL PROTEIN | PROB-M830 | |
| TOTAL PROTEIN ENVOY | PROB-0850 | 53985 |
| TOTAL PROTEIN PLUS | PROB-0600/0700/0250 | |
| UREA | URSL-M830 | |
| UREA ENVOY | URSL-0850 | 53587 |
| UREA UV SL | URSL-0427/0420/0500/0507/0250/0455 | |
| URIC ACID | AUML-M830 | |
| URIC ACID ENVOY | AUVD-0850 | |
| URIC ACID MONO SL | AUML-0497/0427/0420/0500/0507/0707/0250 | 53583 |
| URIC ACID SL | AUSL-0250 | |
| URINE PROTEIN | PRTU-M230 | 53481 |
| Enzymes / Enzymes | | |
| ALP (DEA) SL | PASL-0400/0420/0230 | |
| ALP ENVOY | PIVD-0850 | 52928 |
| ALP IFCC | ALPI-0230 | |
| ALT ENVOY | ALSL-0850 | |
| ALT/GPT | ALSL-M490 | 52923 |
| ALT/GPT 4+1 SL | ALSL-0410/0430/0510/0250/0455 | |
| AMYLASE | AMSL-M430 | |
| AMYLASE ENVOY | AMSL-0850 | |
| AMYLASE SL | AMSL-0390/0400/0230 | 52940 |
| AST/GOT | ASSL-M490 | |
| AST ENVOY | ASVD-0850 | 52954 |
| AST/GOT 4+1 SL | ASSL-0410/0430/0510/0250/0455 | |
| CHOLINESTERASE | CHES-0053 | 52971 |
| CK ENVOY | CKSL-0850 | 53003 |
| CK-MB ENVOY | CMSL-0850 | |
| CK-MB SL / CKMB | CMSL-0410/0430/0230 | 52994 |
| CK NAC | CKSL-M230 | |
| CK NAC SL | CKSL-0410/0430/0230 | 53003 |
| GAMMA-GT | GISL-M230 | |
| GAMMA-GT PLUS SL | GISL-0400/0420/0250 | 53027 |
| GGT ENVOY | GISL-0850 | |
| LDH ENVOY | LLSL-0850 | |
| LDH IFCC | LLSL-M230 | 53072 |
| LDH-L SL | LLSL-0400/0420/0230 | |
| LIPASE | LPSL-0250 | |
| LIPASE ENVOY | LPSL-0850 | 53108 |
| LIPASE SL | LPSL-0230 | |
| Electrolytes / Oligo-éléments / Electrolytes / Trace-elements | | |
| CALCIUM ARSENATO | CALA-0600/0250/M430 | |
| CALCIUM ENVOY | CALA-0850 | 45789 |
| CHLORIDE | CHLO-0600/0250 | |
| IRON ENVOY | FEFE-0850 | 60037 |
| IRON FERENE | FEFE-0230/0600/M230 | 54758 |
| MAGNESIUM ENVOY | MAGX-0850 | |
| MAGNESIUM XB | MGXB-0250/0600/M430 | 46795 |
| MAGNESIUM XYLIDYL | MAGX-0230/0600 | |
| Lipides / Lipids | | |
| CHOLESTEROL | CHSL-M690 | |
| CHOLESTEROL ENVOY | CHSL-0850 | 53359 |
| CHOLESTEROL HDL SL 2G | HDLL-0230/0380/0390 | 53391 |
| CHOLESTEROL LDL SL 2G | LDLL-0230/0380/0390 | 53395 |
| CHOLESTEROL SL | CHSL-0507/0500/0700/0707/0250/0455/0497 | 53359 |
| HDL CHOLESTEROL | CHDL-0250/0600/M330 | |
| HDL CHOLESTEROL ENVOY | HDLL-0850 | 53391 |
| LDL CHOLESTEROL | CLDL-0250/M330 | |
| LDL CHOLESTEROL ENVOY | LDLL-0850 | 53395 |
| TRIGLYCERIDES | TGML-M690 | |
| TRIGLYCERIDES ENVOY | TGML-0850 | |
| TRIGLYCERIDES MONO SL NEW | TGML-0427/0425/0515/0700/0517/0707/0497 | 53460 |
| TRIGLYCERIDES SL | TGML-0250/0455 | |

V6

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| REACTIFS - REAGENTS - REACTIVOS | RÉFÉRENCES - REFERENCES - REFERENCIAS | Code GMDN |
|---|---------------------------------------|-----------|
| Contrôles-Calibrants-Standards / Controls-Calibrators-Standards | | |
| CHOLESTEROL HDL 2G CALIBRATOR | HDLL-0011/0041 | 44696 |
| CHOLESTEROL LDL 2G CALIBRATOR | LDLL-0011/0041 | 41728 |
| CHOLESTEROL Standard 200 mg/dL | CHOL-0055 | 44698 |
| CK-MB CONTROL | CKMB-0900 | 44693 |
| ELICAL 2 | CALI-0550 | 47868 |
| ELITROL I | CONT-0060 | 47869 |
| ELITROL II | CONT-0160 | |
| GLUCOSE Standard 100 mg/dL | GLUP-0055 | 41818 |
| HDL LDL CALIBRATOR | HLCA-0041 | 47868 |
| ISE CONTROL I | ISCT-0046 | 47869 |
| ISE CONTROL II | ISCT-0047 | |
| MICROPROTEIN PLUS Standard 100 mg/dL | PRTU-0022 | 53482 |
| TRIGLYCERIDES Standard 200 mg/dL | TRIG-0055 | 44702 |
| UREA Standard 50 mg/dL | URUV-0055 | 53588 |
| URIC ACID Standard 6 mg/dL | ACUR-0055 | 44704 |
| Protéines spécifiques / Specific proteins | | |
| ANTI-STREPTOLYSIN O | ASLO-0250 | 59055 |
| CRP IP | ICRP-0400/M230 | 53705 |
| CRP IP CALIBRATOR SET | ICRP-0043 | 41838 |
| CRP IP CONTROL I | ICRP-0046 | 41839 |
| CRP IP CONTROL II | ICRP-0047 | |
| CRP WR | CRPW-0230 | 53705 |
| CRP WR CALIBRATOR SET | CRPW-0043 | 41838 |
| CRP WR CONTROL | CRPW-0045 | 41839 |
| CRP WR ENVOY | CRPW-0850 | 53705 |
| FERRITIN | IFRT-0230 | 53718 |
| FERRITIN CALIBRATOR | IFRT-0042 | 41927 |
| HAPTOGLOBIN IP | IHAP-0400 | 53737 |
| HbA1c | HBAC-0240 | 59090 |
| HbA1c CALIBRATOR SET | HBAC-0043 | 53315 |
| HbA1c CONTROL L + H | HBAC-0049 | 44435 |
| IgA IP | IIGA-0400 | 53760 |
| IgG IP | IIGG-0400 | 53787 |
| IgM IP | IIGM-0400 | 53795 |
| μALBUMIN IP | IMAL-0400 | 53475 |
| μALBUMIN IP CALIBRATOR SET | IMAL-0043 | 53477 |
| μALBUMIN IP CONTROL I | IMAL-0046 | 53478 |
| μALBUMIN IP CONTROL II | IMAL-0047 | |
| OROSOMUCOID IP | IROO-0400 | 53606 |
| PREALBUMIN IP | IPAL-0400 | 53957 |
| PROTEIN IP CALIBRATOR SET | IPRO-0043 | 53593 |
| RF CALIBRATOR | IRFA-0042 | 42230 |
| RHEUMATOID FACTOR | IRFA-0230 | 55111 |
| RHEUMATOLOGY CONTROL I | IRCT-0046 | 47869 |
| RHEUMATOLOGY CONTROL II | IRCT-0047 | |
| TRANSFERRIN IP | ITRF-0400 | 59041 |
| Vitamines/Vitamins | | |
| VITAMIN D | VITD-0250 | 54476 |
| VITAMIN D CALIBRATOR SET | VITD-0043 | 54474 |
| VITAMIN D CONTROL SET | VITD-0049 | 54475 |
| ISE Solutions pour électrodes sélectives d'ions / ISE Solutions for ion-selective electrodes | | |
| ISE BASELINE SOLUTION ENVOY | ISBA-0850 | 59238 |
| ISE CALIBRATORS | ISCA-0250 | 52867 |
| ISE CALIBRATOR ENVOY | ISCV-0850 | |
| ISE CLEANER/CONDITIONER | ISCC-0280 | 59058 |
| ISE DILUENT | ISDI-0250 | 58237 |
| ISE DILUENT ENVOY | ISDV-0850 | |
| ISE REFERENCE SOLUTION | ISRS-0800 | 59238 |
| ISE REFERENCE SOLUTION ENVOY | ISRS-0850 | |
| Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments | | |
| ACID SOLUTION for ELITech Clinical Systems Analyzers | SLHC-5900 | 59058 |
| SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers | SLNA-5900 | 59058 |
| SYSTEM SOLUTION | SLSY-5905 | 58236 |
| SYSTEM SOLUTION for ELITech Clinical Systems Analyzers | SLSY-5900 | |
| WASH SOLUTION A | SOLA-M163 | 59058 |
| WASH SOLUTION B | WASH SOLUTION B | 59058 |
| Tests d'agglutination / Agglutination tests | | |
| CRP LATEX | LXCR-0112 | 53707 |

VIA
CG

ELITechGroup B.V.
P.O.Box 100
6950 AC Dieren
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands
T: +31 313 430 500
F: +31 313 427 807
info.ecsnl@elitechgroup.com
www.elitechgroup.com
Chamber of Commerce 09175642

To: Whom it May Concern

Regulatory status of parts & accessories

As mentioned on the current Declarations of Conformity of our Clinical Chemistry Analyzers also the accessories conform to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC). This applies to the parts and accessories as mentioned in the attached list.

'IVD accessory' means an article which, whilst not being an IVD medical device, is intended specifically by its manufacturer to be used together with an IVD device to enable that IVD device to be used in accordance with its intended purpose.

ELITechGroup B.V.



Adriaan P. Intveld
Manager Quality Assurance & Regulatory Affairs

| Part number | Description | IVD medical device | IVD accessory | general laboratory use | spare part | supporting part |
|-------------|------------------------------|--------------------|---------------|------------------------|------------|-----------------|
| 1540-001 | Anti-Slip sheet | | | | | ✓ |
| 2206-007 | Cooling Liquid (1 L) | | | | | ✓ |
| 3062-021 | Sample cup (1000 pcs) | | ✓ | | | |
| 3062-033 | Sample tube 6 ml (500 pcs) | | | | | ✓ |
| 3062-040 | Water container 10 L | | | | | ✓ |
| 3062-041 | Water container 5 L | | | | | ✓ |
| 3066-155 | Syringe 100 µl | | ✓ | | | |
| 3066-156 | Syringe 1 ml | | ✓ | | | |
| 3069-040 | Keyboard Dust cover | | | | | ✓ |
| 3069-047 | Keyboard Dust cover | | | | | ✓ |
| 3070-518 | Cap holder | | | | | ✓ |
| 3070-538 | Cap rotor Left | | | | | ✓ |
| 3070-539 | Cap rotor right | | | | | ✓ |
| 3201-002 | Dichromate 8 Abs (25ml) | | ✓ | | | |
| 3365-192 | USB Stick | | | | | ✓ |
| 3374-003 | Mains cable (USA) | | | | | ✓ |
| 3374-059 | Pumpunit cable | | ✓ | | | |
| 3374-066 | Mains cable | | | | | ✓ |
| 3374-097 | Serial Null-modem cable | | | | | ✓ |
| 3374-286 | USB Extension cable | | | | | ✓ |
| 4804-038 | Reagent identification Disc | | | | | ✓ |
| 6001-826 | Diluted Waste container | | ✓ | | | |
| 6001-827 | Concentrated Waste container | | ✓ | | | |
| 6001-860 | Water container | | ✓ | | | |
| 6001-861 | Tube assy (analyser) | | ✓ | | | |
| 6001-872 | Tube assy (cooling unit) | | ✓ | | | |
| 6002-102 | Assorter unit | | | | ✓ | |
| 6002-386 | System software on CD | | ✓ | | | |
| 6002-706 | Reaction Rotor set (3 pcs) | | ✓ | | | |
| 6002-726 | System Disc | | ✓ | | | |
| 6002-817 | Bottle 30 ml (20 pcs) | | ✓ | | | |
| 6002-818 | Bottle 15 ml (20 pcs) | | ✓ | | | |
| 6002-904 | Water container 5 L | | ✓ | | | |
| 6002-910 | Assorter unit | | | | ✓ | |
| 6002-913 | External tubing | | ✓ | | | |
| 6003-074 | System software on USB stick | | ✓ | | | |
| 6003-444 | Diluted Waste Container 5 L | | ✓ | | | |
| 6003-466 | Keyboard Support option | | | | | ✓ |
| 6003-797 | CW Waste Container 2 L | | ✓ | | | |
| 6003-808 | Assorter unit | | | | ✓ | |



CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifici naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, IIs, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.

Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.

Marketing of invasive and non-invasive medical devices of class IIa, IIs, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date

1998-07-23

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2023-10-24

Data di Scadenza
Expiration Date

2026-10-29

Settore IAF 14 - 29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifici naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile.

Commercializzazione di dispositivi medici invasivi e non di classe IIa, IIs, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.

Design and manufacturing of diagnostic-medical devices for laboratories of analysis and non-sterile class I medical devices.

Marketing of invasive and non-invasive medical devices of class IIa, IIs, I and in vitro diagnostics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date

2007-10-30

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2023-10-24

Data di Scadenza
Expiration Date

2026-10-29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

DATA SHEET



CUVETTES FOR COAGULOMETER TECO®, DIAMED®, DIALAB®

In polystyrene with high optical transparency.

| Cod. | Type | Vol. ml | Dim. mm |
|------|---------|---------|--------------------|
| 5951 | 1 cell | 0.8 | Ø 10 x 23.4 |
| 5961 | 2 cells | 0.6 | Ø 10 x 23.4 x 29.7 |

SCHEDA TECNICA PRODOTTO TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
24.04.2024



ARTICOLO: **5 ML CYLINDRICAL TEST TUBE IN PP**
 ITEM: **PROVETTA CILINDRICA 5 ML IN PP**

DESCRIZIONE / DESCRIPTION



PROVETTA CILINDRICA DA 5ML, NON GRADUATA, SENZA BORDO, Ø 13 x 75 MM

Prodotta in polipropilene medica (PP), particolarmente trasparente ed infrangibile. Dispositivo latex free

5ML. CYLINDRICAL TEST TUBE, NOT GRADUATED, WITHOUT RIM, Ø 13 x 75 MM

Manufactured in medical polypropylene (PP) very transparent and unbreakable. Latex free device

Prodotto con marchio CE conforme al Regolamento (UE) 2017/746 (IVDR)

CE Marked product - manufactured in compliance with Regulation (EU) 2017/746 (IVDR)

| CARATTERISTICHE PRINCIPALI | | TECHNICAL FEATURES |
|----------------------------|----------------------------------|------------------------------------|
| Stato microbiologico | NON STERILE / NOT STERILE | <i>Microbiological status</i> |
| Materiale impiegato | POLIPROPILENE / POLYPROPYLENE | <i>Raw material</i> |
| Temperature tollerate | MIN -10°C MAX +121°C | <i>Temperature range</i> |
| Volume (ml) | 5,0 | <i>Volume (ml)</i> |
| Dimensioni provetta (mm) | Ø 13 x 75 | <i>Dimensions - test tube (mm)</i> |
| Spessore (mm) | 1,0 | <i>Thickness (mm)</i> |
| Peso provetta (gr) | 2,2 | <i>Weight - test tube (gr)</i> |
| Validità del prodotto | 5 ANNI / YEARS | <i>Shelf life</i> |



Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
 Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
 E-Mail: info@aptaca.com – Website: www.aptaca.com

| | | | | | | | Scatola / Box | | |
|------------|----------------------------|-----------------|---------------|-----------|---|-------------------|---|------------|--|
| REF. | Tappo Cap | Etichetta Label | UDI-DI | R.D.M. | Confezione interna Internal packing | Quantità Quantity | Dimensioni Dimensions | Peso (Kg.) | |
| 1375/MO | | | 8055776092140 | 2330631/R | Sacchetti da 1.000 pcs Bags of 1,000 pcs | 4.000 pcs | 55,5 x 42,5 x 34 cm 0,087 m ³ | 10,3 | |
| 1375/MO/T | ✓ Azzurro Light blue | | 8055776092157 | 2330632/R | Sacchetti da 1.000 pcs Bags of 1,000 pcs | 4.000 pcs | 55,5 x 42,5 x 34 cm 0,087 m ³ | 12,7 | |
| 1375/MO/TB | ✓ Bianco White | | 8059575192476 | 2378906/R | Sacchetti da 1.000 pcs Bags of 1,000 pcs | 4.000 pcs | 55,5 x 42,5 x 34 cm 0,087 m ³ | 12,7 | |
| 1375/MO/TE | ✓ Azzurro Light blue | ✓ | 8055776092164 | 2330633/R | Sacchetti da 1.000 pcs Bags of 1,000 pcs | 4.000 pcs | 55,5 x 42,5 x 34 cm 0,087 m ³ | 12,8 | |

DESTINAZIONE D'USO / INTENDED PURPOSE

Dispositivo Medico Diagnostico in Vitro “contenitore di campione” atto a contenere un campione biologico umano (sangue, urine, feci, pus, espettorato, saliva, sperma, cellule, unghie, capelli) al fine di effettuare esami diagnostici di laboratorio. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**

Classificazione Nazionale Dispositivi Medici (CND) / European Medical Device Nomenclature (EMDN) > W050301020102 (Provette senza additivi in materiale plastico per analisi).

Classificazione EDMA > 51091001 - Other containers for samples of human origin

Basic UDI-DI (Global Model Number – GMN): 805577609F102TESTUBES01QU

*In Vitro Diagnostic Medical Device “specimen receptacles” adapted to contain a human biological sample (blood, urine, faeces, pus, sputum, saliva, semen, cells, nails, hair) to perform in vitro diagnostic analysis laboratory. **For professional use only.***

National classification of medical devices (CND) / European Medical Device Nomenclature (EMDN) > W050301020102 (Samples analyses, plastic tubes without additives).

EDMA code > 51091001 - Other containers for samples of human origin

Basic UDI-DI (Global Model Number – GMN): 805577609F102TESTUBES01QU

AVVERTENZE PER L'USO / OPERATING INSTRUCTIONS

- Destinato esclusivamente ad uso professionale –

Utilizzare esclusivamente per effettuare analisi diagnostiche di laboratorio su campioni biologici umani in contesti sanitari.

Dispositivo senza funzione di misura.

L'eventuale presenza di scala graduata è da intendersi a scopo indicativo e senza funzione metrologica

Non variare la destinazione d'uso. In caso di dubbio circa la destinazione d'uso, Vi preghiamo di contattare il Fabricante.

Prima dell'utilizzo controllare la perfetta chiusura del dispositivo se applicabile

Manipolare utilizzando dispositivi di protezione individuale: pericolo di contaminazione

Dopo il prelievo conservare il campione come prescritto dalla metodica analitica e consegnare al Laboratorio entro il tempo massimo previsto dalla stessa.

Non utilizzare il Dispositivo in caso di evidenti segni di rottura, lesioni, fessurazioni che potrebbero compromettere il corretto uso

Non avvicinare il Dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare

Non utilizzare e smaltire il Dispositivo scaduto o con la confezione non integra

Non riutilizzare: Dispositivo monouso. L'eventuale riutilizzo potrebbe causare la contaminazione del campione.

Nel caso di dispositivo sterile (radiazioni ionizzanti) o asettico: stato microbiologico garantito a confezione integra. Non ri-sterilizzare

Utilizzare il Dispositivo unicamente con accessori compatibili e/o in dotazione (tappi, supporti, ecc.)

Non esporre direttamente ai raggi solari; proteggere dall'umidità (U.R. max 75% a 26°C)

Conservare in luogo asciutto, temperatura min. -10°C (14°F) max +50°C (122°F)

Smaltire secondo le normative vigenti, pericolo di infezione.

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.

Provette: velocità di rotazione in centrifuga (max 20 minuti, temperatura ambiente): PMMA r.p.m 3.000 (R.C.F. min 1.500 x g) – PS r.p.m 3.000 (R.C.F. min 1.500 x g) – PP r.p.m 5.000 (R.C.F. min 4.000 x g) – TPX r.p.m 4.500 (R.C.F. min 3.200 x g).

- For professional use only -

Use only for laboratory diagnostic analysis of human biological samples in healthcare settings.

Device without measuring function.

Any presence of a graduated scale is intended for indicative purposes and without a metrological function.

Do not vary the intended purpose of the device. Please contact the Manufacturer in the evenience of doubts concerning the intended purpose.

Before use check the perfect closure of the device if applicable.

Handle using personal protective equipment: risk of contamination.

After collection, store the sample as prescribed by the analytical method and deliver to the Laboratory within the maximum time specified by the same.

Do not use the Device in case of evident signs of breakage, injuries, cracks that could compromise its correct use.

Keep out of flame or heat sources which might damage the device.

Do not use after expiry date or if packing is opened.

Do not re-use: Disposable Device. Any reuse could cause sample contamination.

If sterile (ionizing radiations) or aseptic Device: Microbiological status in undamaged pack.

Do not re-sterilize.

Use the Device only with compatible and / or supplied accessories (caps, supports, etc.)

Do not put under direct sun rays; store in a dry, cool place (U.R. max 75% at 26°C)

Store in dry place, temperature range: min. -10°C (14°F) max +50°C (122°F)

Disposal according to applicable regulations, risk of infection.

Before use with particular substances check the resistance/compatibility chart in our catalogue.

Test tubes: centrifuge rotation speed (max 20 minutes, room temperature):

PMMA r.p.m 3.000 (R.C.F. min 1.500 x g) – PS r.p.m 3.000 (R.C.F. min 1.500 x g) – PP r.p.m 5.000 (R.C.F. min 4.000 x g) – TPX r.p.m 4.500 (R.C.F. min 3.200 x g).



Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

SIMBOLI UTILIZZATI SULL'IMBALLO / PACKING SYMBOLS (UNI EN CEI ISO 15223-1)



Marchio CE
CE Mark



Data di produzione
Date of manufacture



Codice articolo
Catalogue number



Non sterile
Non-sterile



Dispositivo Medico Diagnostico in Vitro
In Vitro diagnostic medical device



Data di scadenza
Use-by date



Fabbricante
Manufacturer



Proteggere dall'umidità
Keep dry



Consultare le istruzioni per l'uso
Consult instructions for use



Lotto
Batch code



Monouso
Do not re-use



Non esporre ai raggi del sole
Keep away from sunlight



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Holder of Certificate: **Nova Biomedical Corporation**

200 Prospect Street
Waltham MA 02454
USA

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; The provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology, In-Vitro Diagnostic General Use Consumables; and Distribution of Lancets.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 02

Report No.: 72198686

Valid from: 2024-10-25
Valid until: 2027-10-24

Date, 2024-10-04

Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q5 020747 0242 Rev. 02

Applied Standard(s):

ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

Nova Biomedical Corporation

200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; the provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology and In-Vitro Diagnostic General Use Consumables.

Nova Biomedical Corporation

39 Manning Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care test strips.

Nova Biomedical Corporation

165 Lexington Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care Instruments

Nova Biomedical Corporation

4 Enterprise Road, Billerica MA 01821, USA

Production of In-Vitro Diagnostic Instruments including Near Patient / Point of Care; Distribution of Finished Goods; Distribution of Lancets.

**Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC
In Vitro Diagnostic Medical Device Directive (IVDD)**

Product name: Nova Stat Profile Prime Plus Analyzer System including Reagents, Calibrators and Controls

Catalog Numbers: List Attached (Two Pages)

Classification: Other/General

Manufacturer: Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454 USA

Representative: William Jacques, Director of Regulatory and Quality

Authorized Representative: Nova Biomedical GmbH
Hessenring 13 A, Geb. G
64546 Mörfelden-Walldorf
Germany
Tel: +49 6105 4505-0

Conformity Assessment Route: Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

EN 50581:2012 Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances

EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

EN 61010-2:101:2015 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Signature:



William Jacques, Director of Regulatory and Quality



Date: Jul/24/2020

List of Catalog Items Covered:

| Catalog Number | Product Name | Global Medical Device Nomenclature (GMDN) Name | GMDN Number | DIMDI EDMS Code |
|----------------|--|---|-------------|-----------------|
| 57400 | Stat Profile Prime Plus® Analyzer | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |
| 59508 | Stat Profile Prime Plus® Analyzer (Remanufactured) | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |
| 57820 | Stat Profile Prime Plus MicroSensor Card™ with COOX | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |
| 57821 | Stat Profile Prime Plus MicroSensor Card™ BUN, Creatinine | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |
| 57822 | Stat Profile Prime Plus MicroSensor Card™ with COOX (High Volume) | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |
| 57823 | Stat Profile Prime Plus Reference Cartridge | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |
| 57825 | Stat Profile Prime Plus Calibrator Cartridge 100 Sample | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57826 | Stat Profile Prime Plus Calibrator Cartridge 200 Sample | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57827 | Stat Profile Prime Plus Calibrator Cartridge 300 Sample | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57828 | Stat Profile Prime Plus Calibrator Cartridge 400 Sample | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57829 | Stat Profile Prime Plus Calibrator Cartridge 500 Sample | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57831 | Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat / BUN | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57832 | Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat / BUN | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57833 | Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat / BUN | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57834 | Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat / BUN | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57835 | Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat / BUN | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 52859 | 11-04-04-03-00 |
| 57838 | Stat Profile Prime Plus Auto QC Cartridge 160 Sample | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 57839 | Stat Profile Prime Plus Auto QC Cartridge 320 Sample | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 57840 | Stat Profile Prime Plus Auto QC Cartridge 480 Sample | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 57841 | Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat / BUN | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 57842 | Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat / BUN | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 57843 | Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat / BUN | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 57844 | Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1, 2, 3 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 57845 | Stat Profile Prime Plus Ampuled Controls Chemistry Levels 4,5 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 58379 | Stat Profile Prime Plus BUN, Creatinine - Blank Sensor Card | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |
| 58642 | Stat Profile Prime Plus MicroSensor Card™ | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |
| 58643 | Stat Profile Prime Plus MicroSensor Card™ (High Volume) | Point-of-care single channel clinical chemistry analyzer IVD | 56681 | 21-02 |

| Catalog Number | Product Name | Global Medical Device Nomenclature (GMDN) Name | GMDN Number | DIMDI EDMS Code |
|----------------|--|--|-------------|-----------------|
| 55229 | Nova Linearity Level 1,2,3,4 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-01-00 |
| 56198 | Linearity Standard Set G Multipack | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-90-00 |
| 61656 | Nova Linearity Creatinine/BUN/Hct Levels 1,2,3,4 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 52860 | 11-50-90-90-00 |



**Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC
In Vitro Diagnostic Medical Device Directive (IVDD)**

Product name: Nova Stat Profile Prime Analyzer System Family including Reagents, Calibrators and Controls

Catalog Numbers: List Attached (two pages)

Classification: Other/General

Near Manufacturer: Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454 USA

Representative: William Jacques, Director of Regulatory and Quality

Authorized Representative: Nova Biomedical GmbH
Hessenring 13 A, Geb. G
64546 Mörfelden-Walldorf
Germany
Tel: +49 6105 4505-0

Conformity Assessment Route: Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016 **Medical devices. Quality management systems. Requirements for regulatory purposes**

EN ISO 14971:2012 **Medical devices – Application of risk management to medical devices**

EN 61010-1:2010 **Safety requirements for electrical equipment for measurement, control, and laboratory use -Part 1: General requirements**

EN 61010-2:101:2015 **Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**

Signature:

William Jacques, Director of Regulatory and Quality



Date: Jul/22/2020

List of Catalog items covered:

| Catalog Number | Product Name | GMDN Number | Global Medical Device Nomenclature (GMDN) Name | DIMDI EDMS Code |
|----------------|--|-------------|--|-----------------|
| 14631 | Power Cord Int 230V | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 38846 | Nova Biomedical Capillary Tube Clot Catcher | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 38883 | Stat Profile Critical Care Xpress Syringe Clot Catcher | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 42032 | Prime Sensor Card CCS | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 42033 | Prime Sensor Card CCS Comp | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 42043 | Prime Reference Cartridge | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 52484 | Prime Pump Harness | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 52582 | Prime Probe S Line 100 ul | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 52616 | Prime Tubing L1 L2 L3 | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 52617 | Prime Tubing Harness ABG/CCS | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 52669 | Prime Safety Sample Port 5 Pk | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 52703 | Prime Acc Pack | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 52856 | Prime CCS | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 52857 | Prime CCS Comp | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 53418 | Remanufactured Prime CCS | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 53420 | Remanufactured Prime CCS Comp | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 53656 | Prime CCS w/Scanner | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 53657 | Prime CCS Comp w/Scanner | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 53666 | Remanufactured Prime CCS w/ Scanner | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 53667 | Remanufactured Prime CCS Comp w/ Scanner | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 55263 | Prime Sensor Card CCS (High Volume) | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 55264 | Prime Sensor Card CCS Comp (High Volume) | 56672 | Point-of-Care blood gas/haemoximetry analyser IVD | 21-02-02 |
| 42031 | Prime Sensor Card ABG | 56671 | Point-of-Care blood gas analyzer IVD | 21-02-02 |
| 52855 | Prime ABG | 56671 | Point-of-Care blood gas analyzer IVD | 21-02-02 |
| 53421 | Remanufactured Prime ABG | 56671 | Point-of-Care blood gas analyzer IVD | 21-02-02 |
| 53655 | Prime ABG w/ Scanner | 56671 | Point-of-Care blood gas analyzer IVD | 21-02-02 |
| 53665 | Remanufactured Prime ABG w/ Scanner | 56671 | Point-of-Care blood gas analyzer IVD | 21-02-02 |
| 55262 | Prime Sensor Card ABG (High Volume) | 56671 | Point-of-Care blood gas analyzer IVD | 21-02-02 |
| 25217 | Linearity Standard Set A Levels 1,2,3,4 Multipack | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 55229 | Nova Linearity Level 1,2,3,4 | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 56198 | Linearity Standard Set G Multipack | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-90-00 |

| Catalog Number | Product Name | GMDN Number | Global Medical Device Nomenclature (GMDN) Name | DIMDI EDMS Code |
|----------------|--|-------------|---|-----------------|
| 45150 | Prime Auto QC Cartridge CCS 200 Sample | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 52714 | Prime Ampuled Control ABG/CCS | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 52864 | Prime Auto QC Cartridge CCS 300 Sample | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 53107 | Prime Auto QC Cartridge ABG 200 Sample | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 53108 | Prime Auto QC Cartridge ABG 300 Sample | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 53455 | Prime Auto QC Cartridge CCS 100 Sample | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 53456 | Prime Auto QC Cartridge ABG 100 Sample | 52860 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, control | 11-50-90-01-00 |
| 52427 | Prime Calibrator Cartridge CCS Comp 300 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 52861 | Prime Calibrator Cartridge CCS Comp 100 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 52862 | Prime Calibrator Cartridge CCS 100 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 52863 | Prime Calibrator Cartridge CCS 300 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53104 | Prime Calibrator Cartridge ABG 100 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53105 | Prime Calibrator Cartridge CCS Comp 400 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53359 | Prime Calibrator Cartridge ABG 300 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53360 | Prime Calibrator Cartridge ABG 200 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53364 | Prime Calibrator Cartridge CCS 200 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53365 | Prime Calibrator Cartridge CCS Comp 200 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53463 | Prime Calibrator Cartridge ABG 400 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53464 | Prime Calibrator Cartridge ABG 500 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53465 | Prime Calibrator Cartridge ABG 600 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53466 | Prime Calibrator Cartridge CCS 400 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53467 | Prime Calibrator Cartridge CCS 500 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53468 | Prime Calibrator Cartridge CCS 600 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53469 | Prime Calibrator Cartridge CCS Comp 500 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 53470 | Prime Calibrator Cartridge CCS Comp 600 Sample | 52859 | Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator | 11-04-04-03-00 |
| 52865 | Stat Profile Prime Calibrator Flush Fixture | 56672 | Point-of-Care blood gas/haemoximetry analyzer IVD | 21-02-02 |