



EDAN

EDAN INSTRUMENTS, INC.

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC

MANUFACTURER: Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District, 518122 Shenzhen, P.R.China

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH
Eiffestrasse 80, 20537 Hamburg Germany

PRODUCT/ MODEL: Hematology Analyzer/ H60, H60S, H66, H66S, H68, H68S,
H69, H69S
Reagents for Hematology Analyzer/ HD600 Diluent, HL600
Lyse, HC600 Cleaner, ED-60D Control H, ED-
60D Control N, ED-60D Control L Hematology
Controls, ED-CAL PLUS Hematology Calibrator.

The accessories are used together with the product.

EDMA[Name/Code]: CC Hardware + accessories + consumables + software/23.01.10.01.00
CBC-Reagents(Cleaning-/Diluting-/Lysing-/Sheat-fluids)/13.01.01.01.00
Blood Multilevel Controls/ 13.01.50.03.00
Whole Blood Calibrators/ 13.01.50.07.00

CLASSIFICATION:General/other device, devices other than those covered by Annex II and devices for performance evaluation, non-self-testing, according to article 9 of IVDD.

CONFORMITY ASSESSMENT ROUTE: Annex III

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO 14971: 2012, IEC 61010-1:2017, IEC 61010-2-101:2018, EN 61326-1:2013, EN 61326-2-6:2013, EN 62304:2006 +A1:2015, EN 62366-1:2015, EN 1041: 2008+A1:2013, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN 13612:2002, EN 13641:2002, EN ISO 17511:2003, EN ISO 23640:2015

CE MARK



START OF CE-MARKING: 2021.8.10

PLACE, DATE OF ISSUE: SHENZHEN, 2021.8.10

SIGNATURE:

NAME **LIU YONGYING**
MANAGEMENT REPRESENTATIVE

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

Latest Revision Date: 2024-09-19

Effective Date: 2024-10-13

Expiry Date: 2027-10-12

Page: 1 of 2



...making excellence a habit.™

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

Latest Revision Date: 2024-09-19

Effective Date: 2024-10-13

Expiry Date: 2027-10-12

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 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

Latest Revision Date: 2024-10-03

Effective Date: 2024-10-13

Expiry Date: 2027-10-12



Page: 1 of 2

...making excellence a habit.™

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

Latest Revision Date: 2024-10-03

Effective Date: 2024-10-13

Expiry Date: 2027-10-12

Page: 2 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.



Declaration of Conformity

Certificate Identification: SC-09H60
 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
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: <u>Kevin Richardson</u>	Full Name: <u>Mirna DiPano</u>
Position: <u>Manager, Supplier Quality</u>	Position: <u>Director of Regulatory Affairs</u>
Date of Approval: <u>10-July-2017</u>	Date of Approval: <u>10-July-2017</u>
Date Issued: <u>JUL 10 2017</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS VI, April 15, 2016</u>	Effective (Date or Lot Number): <u>JUL 10 2017</u>

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:	<u>Kevin Richardson</u>	Full Name:	<u>Mirna DiPano</u>
Position:	<u>Manager, Supplier Quality</u>	Position:	<u>Director of Regulatory Affairs</u>
Date of Approval:	<u>10-July-2017</u>	Date of Approval:	<u>10-July-2017</u>
Date Issued:	<u>JUL 10 2017</u>	Place Issued:	<u>Abbott Santa Clara</u>
Supersedes:	<u>IRIS V1, April 15, 2016</u>	Effective (Date or Lot Number):	<u>JUL 10 2017</u>

Declaration of Conformity

Certificate Identification: SC-09H62
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
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: <u></u>	Signature: <u></u>
Full Name: <u>Kevin Richardson</u>	Full Name: <u>Mirna DiPano</u>
Position: <u>Manager, Supplier Quality</u>	Position: <u>Director of Regulatory Affairs</u>
Date of Approval: <u>10-July-2017</u>	Date of Approval: <u>10-July-2017</u>
Date Issued: <u>JUL 10 2017</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRI S V1, April 15, 2016</u>	Effective (Date or Lot Number): <u>JUL 10 2017</u>

Declaration of Conformity

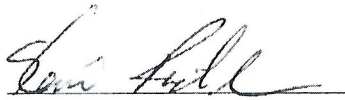

Certificate Identification: SC-09H72
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

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: <u></u> Full Name: <u>Kevin Richardson</u> Position: <u>Manager, Supplier Quality</u> Date of Approval: <u>11-APRIL-2016</u> Date Issued: <u>APR 15 2016</u> Supersedes: <u>N/A</u>	Signature: <u></u> Full Name: <u>Zaman Khan</u> Position: <u>Associate Director, Regulatory Affairs</u> Date of Approval: <u>11-Apr-2016</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>APR 15 2016</u>
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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](http://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/29/2020

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