

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

cofrac

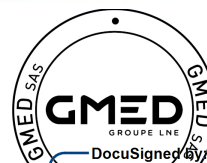


CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

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

Renouvelle le 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 Reglementarios



ELITech Clinical Systems SAS

Zone Industrielle

61500 SEES - France

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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 | GPST-0850 | |
| GLUCOSE HK | GHSL-M490 | |
| GLUCOSE HK SL | GHSL-0600/0250 | 53301 |
| GLUCOSE PAP | GPST-M690 | |
| GLUCOSE PAP SL | GPST-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 | |
| ALT/GPT 4+1 SL | ALSL-0410/0430/0510/0250/0455 | 52923 |
| AMYLASE | AMSL-M430 | |
| AMYLASE ENVOY | AMSL-0850 | 52940 |
| AMYLASE SL | AMSL-0390/0400/0230 | |
| 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 | 52994 |
| CK-MB SL / CKMB | CMSL-0410/0430/0230 | |
| 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 ARSENAZO | CALA-0600/0250/M430 | |
| CALCIUM ENVOY | CALA-0850 | 45789 |
| CHLORIDE | CHLO-0600/0250 | 60037 |
| IRON ENVOY | FEFE-0850 | |
| 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 | |

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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 | IORO-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 selectives 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 |

Vla
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Certificate of Approval

This is to certify that the Management System of:

VitalScientific B.V.

also trading as: **ELITechGroup**

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers and contract manufacturing of ion-selective electrodes (ISE) and erythrocyte sedimentation rate (ESR) analyzers.

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited



Certificate Schedule

| Location | Activities |
|--|---|
| VitalScientific B.V. also trading as: ELITechGroup Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands | ISO 13485:2016 Design, development and manufacturing of clinical chemistry analyzers and contract manufacturing of ion-selective electrodes (ISE) and erythrocyte sedimentation rate (ESR) analyzers. |
| VitalScientific B.V. also trading as: ELITechGroup Kanaaldijk 90, 6956 AX Spankeren, The Netherlands | ISO 13485:2016 Design, development and manufacturing of clinical chemistry analyzers and contract manufacturing of ion-selective electrodes (ISE) and erythrocyte sedimentation rate (ESR) analyzers. |



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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 | | | | ✓ | |

Declaration of CE conformity

Avantor Performance Materials B.V. reg. No. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20
7418 AM Deventer
the Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T. Baker label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III.

The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.

This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

22 November 2011



Dr. J. Mittendorf
QA & RA Manager

J.T.Baker product list for CE marked products

| Prod.no. | Product | Pack size |
|---|-------------------------------|-----------|
| Reagents for diluting and lysing | | |
| 3961 | Diluid™ 100 Plus | 20 liter |
| 3954 | Diluid 590 | 20 liter |
| 3969 | Diluid 610 | 20 liter |
| 3430.9010 | Diluid Abacus | 10 liter |
| 3430.9020 | Diluid Abacus | 20 liter |
| 3996 | Diluid AC 900 | 20 liter |
| 3996.9010PC | Diluid AC 900 | 10 liter |
| 3476.9020PC | Diluid APR | 20 liter |
| 3957 | Diluid Azide free | 20 liter |
| 3958 | Diluid Azide free | 10 liter |
| 3963.9010 | Diluid III Diff | 10 liter |
| 3963 | Diluid III Diff | 20 liter |
| 3974 | Diluid III Diff Seaccontainer | 20 liter |
| 3459.9020 | Diluid Erma | 20 liter |
| 3483.9020PC | Diluid NR | 20 liter |
| 3439.9020PC | Diluid Mindray | 20 liter |
| 3832.9020 | Diluid Sheath 3200-4000 | 20 liter |
| 3976 | Diluid ST 1600/2000 | 20 liter |
| 3496.9020PC | Diluid M5 | 20 liter |
| 3495.9010PC | Sheath D | 10 liter |
| 3826 | Sheath Fluid 3000/3500 | 20 liter |
| 3826.5000 | Sheath Fluid 3000/3500 | 5 liter |
| 3827.5000PC | LeucoLyse | 5 liter |
| 3998 | CN-free Lyse Diff AC 900 | 5 liter |
| 3744 | CyMet™ 1000 CN free | 5 liter |
| 3773.5000PC | CyMet 4500 CN free | 5 liter |
| 3824 | CyMet 3000 | 10 liter |
| 3823.1000 | CyMet 3200 CN free | 1 liter |
| 3825 | CyMet 3500 CN free | 5 liter |
| 3839.5000PC | CyMet 3500 | 5 liter |
| 3975 | CyMet 530+ CN free | 10 liter |
| 3971 | CyMet 590 CN free | 5 liter |
| 3970 | CyMet 610 CN free | 10 liter |
| 3977 | CyMet 610 CN free | 5 liter |
| 3918.5000 | CyMet 9000 CN free | 5 liter |
| 3431.1000 | CyMet Abacus CN free | 1 liter |
| 3444.1000PE | CyMet Abacus EO | 1 liter |
| 3445.1000PE | CyMet Abacus Baso | 1 liter |
| 3477.0500PE | CyMet APR CN free | 500 ml |
| 3478.1000PE | CyMet APR EO | 1 liter |
| 3479.1000PE | CyMet APR Baso II | 1 liter |
| 3755 | CyMet Automated | 5 liter |
| 3757 | CyMet Automated | 500 ml |
| 3780 | CyMet Automated CN Free | 1 liter |
| 3460.0500 | CyMet Erma | 500 ml |
| 3841.1000PE | CyMet H12 CN Free | 1 liter |
| 3842.1000 | EO Reagent Autocounter | 1 liter |
| 3853.1000 | CyMet H20 | 1 liter |
| 3968 | CyMet III Diff | 1 liter |
| 3964 | CyMet III Diff | 5 liter |
| 3972.1000 | CyMet III Diff CN free | 1 liter |
| 3972.5000 | CyMet III Diff CN free | 5 liter |
| 3740.0500 | CyMet KX CN Free | 500 ml |
| 3852.1000 | CyMet Micro | 1 liter |
| 3852.0500 | CyMet Micro | 500 ml |
| 3857.1000 | CyMet Micro CN free | 1 liter |
| 3857.0500 | CyMet Micro CN free | 500 ml |

| | | |
|--|------------------------------|-------------|
| 3863.1000 | CyMet Micro CN free | 1L micros |
| 3440.0500PE | CyMet Mindray CN Free | 500 ml |
| 3441.0500PE | CyMet Mindray | 500 ml |
| 3480.5000PC | CyMet SF Baso | 5L |
| 3481.5000PC | CyMet SF Diff 1 | 5L |
| 3482.0500PE | CyMet SF Diff 2 | 500 ml |
| 3775.1000 | CyMet ST 1600/2000 | 1 liter |
| 3759.1000 | CyMet ST 1600/2000 CN free | 1 liter |
| 3759.5000 | CyMet ST 1600/2000 CN free | 5 liter |
| 3788 | CyMet STX/STL | 1 liter |
| 3919 | CyMet STX/STL | 5 liter |
| 3484.1000PE | CyMet NR III | 1 liter |
| 3486.1000PE | CyMet NR III, CN Free | 1 liter |
| 3485.1000PE | CyMet NR V | 1 liter |
| 3497.0500PE | CyMet MH CN Free | 500 ml |
| 3489.1000PE | CyMet MBA | 1 liter |
| 3487.1000PE | CyMet MD(I) | 1 liter |
| 3488.0500PE | CyMet MD(II) | 500 ml |
| 3077 | LyzerGlobin™ | 500 ml |
| 3769 | LyzerGlobin | 6 x 15 ml |
| 3771 | LyzerGlobin PCE | 6 x 15 ml |
| 3770 | LyzerGlobin II | 10 x 10 ml |
| 3850 | LyzerGlobin CN free | 6 x 15 ml |
| Cleaners | | |
| 3766.0500 | DetectoTerge | 500 ml |
| 3763 | DetectoTerge | 5 liter |
| 3766 | DetectoTerge | 1 liter |
| 3900 | ProClean™ | 5 liter |
| 3768.1000 | ProClean | 1L micros |
| 3867.1000PE | ProClean Extra | 1L micros |
| 3862.1000 | ProClean Extra | 1 liter |
| 3862.5000 | ProClean Extra | 5 liter |
| 3901 | ProClean Plus | 100 ml |
| 3902.0100PE | ProClean CD | 100 ml |
| 3432.5000 | ProClean Abacus | 5 liter |
| 3946 | Blanking Solution Hgb | 20 liter |
| 3947 | Blanking Solution 1600/2000 | 20 liter |
| 3917 | Hypochlorite 0.5% | 1liter |
| 3917.5000 | Hypochlorite 0.5% | 5 liter |
| 3936.1000 | Hypochlorite 5% | 1liter |
| 3442.5000PE | Rinse Mindray | 5 liter |
| 3915 | Rinsing Solution Serono 9000 | 20 liter |
| 3941.1000PE | HypoChlorite NR | 1 liter |
| 3941.5000PC | HypoChlorite NR | 5 liter |
| 3498.1000PE | ProClean MX5 | 1 liter |
| Reagents for 5-part WBC diff. on STKS and MaxM. | | |
| 3938 | RBCLyse™ | 1 liter |
| 3938G.1000PE | RBCLyse G | 1 liter |
| 3939 | WBCStabilise™ | 500 ml |
| 3492.0090 | RetiCount MH | 6 x 15 ml |
| 3493.0500PE | RetiClear MHG | 500 ml |
| 3493.1000PE | RetiClear MHG | 1 liter |
| 3494.0200PE | RetiCount G | 200 ml |
| 3774 | Reticount™ | 30 ml |
| 3777 | Reticount CD | 15 x 3.5 ml |

| Hematology Controls | | |
|----------------------------|---------------------------|------------|
| 3721/3722/3723 | 8 PMC Low/Normal/High | 8 ml |
| 3724/3725/3726 | 8 PMC Low/Normal/High | 2.5 ml |
| 3633/3634/3635 | 8 PMC Low/Normal/High ext | 2.5 ml |
| 3701/3702/3703 | 8 PMC Low/Normal/High | 4.5 ml |
| 3922/3923/3924 | 8 PMC L/N/H Swelab | 4.5 ml |
| 3746 | 8 PMC 1 x L, 1 x N, 1 x H | 3 x 2.5 ml |
| 3747 | 8 PMC 4 x Normal | 4 x 2.5 ml |
| 3748 | 8 PMC 4 x Normal | 4 x 8 ml |
| 3749 | 8 PMC 4 x Low | 4 x 2.5 ml |
| 3751 | 8 PMC 1 x L, 4 x N, 1 x H | 6 x 2.5 ml |
| 3734/3735/3736 | 3-Diff Control L/N/H | 2.5 ml |
| 3630/3631/3632 | 3-Diff Control L/N/H ext | 2.5 ml |
| 3820/3821/3822 | 3-Diff Control L/N/H | 4.5 ml |
| 3752 | 3-Diff Control 4 x Low | 4 x 2.5 ml |
| 3753 | 3-Diff Control 4 x Norm | 4 x 2.5 ml |
| 3754 | 3-Diff Control 4 x High | 4 x 2.5 ml |
| 3782/3783/3784 | CA-Diff Control L/N/H | 4.5 ml |
| 3607/3608/3609 | CA-Diff Control L/N/H | 2.5 ml |
| 3610/3611/3612 | DIA Diff 5 Control L/N/H | 4.5 ml |
| 3731/3732/3733 | XE-Diff Control L/N/H | 4.5 ml |
| 3693/3694/3695 | SF-Diff Control L/N/H | 4.5 ml |
| 3613/3614/3615 | BC Diff 5 Control L/N/H | 4.5 ml |

| | | |
|---|---------------------------------------|------------|
| 3684/3685/3686 | ADV-Diff Control L/N/H | 3.5 ml |
| 3690/3691/3692 | ADV Retic 1/2/3 | 4.0 ml |
| 3828/3829/3830 | CD-Diff Control | 3.0 ml |
| 3838 | CD-Diff Control 2x L _N ,H | 6 x 3.0 ml |
| 3687/3688 | CD 4K Retic 1/2 | 3.0 ml |
| 3892/3893/3894 | AC-Diff Control | 2.5 ml |
| 3896/3897/3898 | K-Diff Control | 2.5 ml |
| 3696/3697 | WBC reduced Plt Control L/H | 3.0 ml |
| 3698/3699 | WBC reduced RBC Control L/H | 3.0 ml |
| Laser controls for Coulter MaxM, GenS and STKS | | |
| 3681/3682/3683 | 5D Control Low /N /H | 5.0 ml |
| Calibration Set for Cell Analysers. | | |
| 3940 | Cal Set 1 | 2 x 2.5 ml |
| 3720 | Platelet Control Ext. value | 5 x 3 ml |
| Phosphate Buffered Saline. | | |
| 3059 | PBS, diluting fluid for bloodgrouping | 20 liter |
| 3059.9010PC | PBS, diluting fluid for bloodgrouping | 10 liter |

| Number | Product | Content |
|------------------------|-----------------------------------|-----------|
| Stains and Dyes | | |
| 3554.1000PE | Papanicolaou Solution 2A | 1 liter |
| 3554.2500PE | Papanicolaou Solution 2A | 2.5 liter |
| 3554.9200PE | Papanicolaou Solution 2A | 200 liter |
| 3555.1000PE | Papanicolaou Solution 2B | 1 liter |
| 3555.2500PE | Papanicolaou Solution 2B | 2.5 liter |
| 3556.1000PE | Papanicolaou Solution 3B | 1 liter |
| 3556.2500PE | Papanicolaou Solution 3B | 2.5 liter |
| 3556.9200PE | Papanicolaou Solution 3B | 200 liter |
| 3800.1000PE | Eosine-Y Alcoholic | 1 liter |
| 3800.2500PE | Eosine-Y Alcoholic | 2.5 liter |
| 3801.1000PE | Eosin Y 0.5% Aqueous | 1 liter |
| 3801.2500PE | Eosin Y 0.5% Aqueous | 2.5 liter |
| 3871.1000 | Eosine Solution 0.2% ready to use | 1 liter |
| 3871.2500 | Eosine Solution 0.2% ready to use | 2.5 liter |
| 3856.0100 | Giemsa | 0.1 liter |
| 3856.0500 | Giemsa | 0.5 liter |
| 3856.1000 | Giemsa | 1 liter |
| 3856.2500 | Giemsa | 2.5 liter |
| 3870.1000 | Hematoxyline er (Mayer) | 1 liter |
| 3870.2500 | Hematoxyline er (Mayer) | 2.5 liter |
| 3873.1000 | Hematoxyline (Harris, Gill II) | 1 liter |
| 3873.2500 | Hematoxyline (Harris, Gill II) | 2.5 liter |
| 3879.1000 | Leishman | 1 liter |
| 3855.0500 | May Grünwald | 0.5 liter |
| 3855.1000 | May Grünwald | 1 liter |
| 3855.2500 | May Grünwald | 2.5 liter |

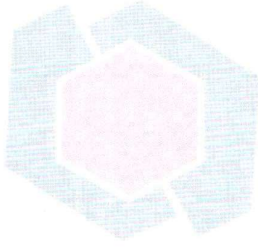
| | | |
|-----------------------|-------------------------------|---------------|
| 3864.1000 | Papanicolaou 2A OG6 | 1 liter |
| 3864.2500 | Papanicolaou 2A OG6 | 2.5 liter |
| 3865.1000 | Papanicolaou 2B Orange II | 1 liter |
| 3865.2500 | Papanicolaou 2B Orange II | 2.5 liter |
| 3866.1000 | Papanicolaou 3B EA 50 | 1 liter |
| 3866.2500 | Papanicolaou 3B EA 50 | 2.5 liter |
| 3876.1000 | Shorr | 1 liter |
| 3878.1000 | Wright | 1 liter |
| Clearing agent | | |
| 3905.2500PE | UltraClear | 2.5 liter |
| 3905.5000PE | UltraClear | 5 liter |
| 3905.9010PE | UltraClear | 10 liter |
| 3905.9200 | UltraClear | 200 liter |
| Mounting media | | |
| 3921.0500 | UltraKitt | 500 ml |
| 3921.0600 | UltraKitt | 6 x 100 ml |
| Fixatives | | |
| 3933.1000 | 10% v/v Buffered Formaldehyde | 1 liter |
| 3933.5000PC | 10% v/v Buffered Formaldehyde | 5 liter |
| 3933.9010 (PE) | 10% v/v Buffered Formaldehyde | 10 liter (PE) |
| 3933.9020 (PE) | 10% v/v Buffered Formaldehyde | 20 liter (PE) |
| 3869.1200 | Cervix Fixative | 12 x 125 ml |
| 3880.1000 | Bouin's Fixative | 1 liter |
| 3058.9010 | Immuno PBS 20x concentrated | 10 liter |

22 November 2011

Conformity Declarations

Archem Diagnostics Systems

Declares in our own responsibility conformity of the products listed below according to the essential requirements in other IVD products the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive)



archem
DIAGNOSTICS



 **archem**
SAĞLIK SAN. VE TİC. ANONİM ŞTİ.
Mahmutbey Mah. Halkalı Cad. No:124/42
Bağcılar/İST/ Tel:444 08 92 Fax:0212 629 98 89
Güneşli V.D.:0730790980



archem
DIAGNOSTICS

Archem Sağlık San. ve Tic. A.Ş.

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| | |
|------------|------------------------|
| ZA17B4-R1 | D-Dimer Reagent |
| ZA17B4-R2 | D-Dimer Reagent |
| ZA17B20-R1 | D-Dimer Reagent |
| ZA17B20-R2 | D-Dimer Reagent |
| PR21B1-R1 | Procalcitonin Reagent |
| PR21B1-R2 | Procalcitonin Reagent |
| 5110M | PlasmaDiluent III |
| 5121M | StromaLyse III |
| 5131M | CleanAr |
| 5120R | StromaLyse |
| 9020R | CleanAr |
| 5310C | PlasmaDiluent C |
| 5321C | StromaLyse C |
| 5330C | CleanAr |
| 5340C | Concentrated Cleanacer |
| 5910MN | PlasmaDiluent III |
| 5911MN | PlasmaDiluent III |
| 5950MN | DS Dilüent |
| 5920MN | StromaLyse |
| 5921MN | StromaLyse MN |
| 5930MN | CleanAr |
| 5931MN | CleanAr |
| 5940MN | Concentrated Cleanacer |
| 5941MN | PROBE CleanAr |
| 5810AB | PlasmaDiluent |
| 5811AB | PlasmaDiluent |
| 5820AB | StromaLyse ABB |
| 5821AB | StromaLyse ABB |
| 5830AB | CleanAr |
| 5831AB | CleanAr |
| 5840AB | Concentrated Cleanacer |
| 5611SW | PlasmaDiluent |
| 5621SW | StromaLyse SW |
| 5631SW | CleanAr |
| 6410DN | PlasmaDiluent |
| 6411DN | PlasmaDiluent |
| 6420DN | StromaLyse DN |
| 6421DN | StromaLyse DN |
| 6430DN | CleanAr |
| 6431DN | CleanAr |
| 6440DN | Concentrated Cleanacer |

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| | |
|--------|------------------------|
| 5410A | PlasmaDiluent A |
| 5411A | PlasmaDiluent A |
| 5420A | StromaLyse A |
| 5421A | StromaLyse A |
| 5430A | CleanAr |
| 5431A | CleanAr |
| 5440A | Concentrated Cleanacer |
| 7310ER | PlasmaDiluent |
| 7311ER | PlasmaDiluent |
| 7320ER | StromaLyse E |
| 7321ER | StromaLyse E |
| 7322ER | StromaLyse E |
| 7330ER | CleanAr |
| 7340ER | Concentrated Cleanacer |
| 6011MD | PlasmaDiluent III |
| 6020MD | StromaLyse MD |
| 6021MD | StromaLyse MD |
| 6031MD | Cleaner MD Sample |
| 6030MD | CleanAr |
| 6040MD | Concentrated Cleanacer |
| 6211HY | PlasmaDiluent |
| 6220HY | StromaLyse HY |
| 6221HY | StromaLyse HY |
| 6231HY | CleanAr HY |
| 6240HY | Concentrated Cleanacer |
| 5211R | PlasmaDiluent |
| 5220R | StromaLyse HY |
| 5221R | StromaLyse HY |
| 6510ML | PlasmaDiluent |
| 6511ML | PlasmaDiluent |
| 6520ML | StromaLyse DIFF |
| 6521ML | M REF CONC |
| 8111AR | PlasmaDiluent |
| 8110AR | PlasmaDiluent |
| 8112AR | PlasmaDiluent C |
| 8120A | StromaLyse |
| 8121A | StromaLyse |
| 8130A | CleanAr |
| 8131A | CleanAr |
| 8132A | CleanAr |
| 8140A | Concentrated Cleanacer |


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| | |
|--------|------------------------|
| 6710S | PlasmaDiluent |
| 6711S | PlasmaDiluent |
| 6720S | StromaLyse E |
| 6721S | StromaLyse E |
| 6730S | CleanAr |
| 6740S | Concentrated Cleanacer |
| 5111M | PlasmaDiluent III |
| 5120M | StromaLyse III |
| 5130M | CleanAr |
| 5125B | StromaLyse B |
| 5128B | StromaLyse EOS |
| 5140M | Concentrated Cleanacer |
| 7110N | PlasmaDiluent III |
| 7111N | PlasmaDiluent III |
| 7210N | StromaLyse |
| 7211N | StromaLyse |
| 7220N | CleanAr |
| 7230N | Concentrated Cleanacer |
| 7010P | PlasmaDiluent |
| 7011P | PlasmaDiluent |
| 7020P | StromaLyse |
| 7021P | StromaLyse |
| 7030P | CleanAr |
| 7031P | CleanAr |
| 7040P | Concentrated Cleanacer |
| 5311C | PlasmaDiluent C |
| 5320C | StromaLyse C |
| 5325C | StromaLyse ALFA |
| 5231R | CleanAr |
| 5240R | Concentrated Cleanacer |
| 7310S | PlasmaDiluent |
| 7320S | StromaLyse |
| 7321S | StromaLyse |
| 7330S | CleanAr HY |
| 7340S | Concentrated Cleanacer |
| 8210DW | PlasmaDiluent |
| 8220DW | StromaLyse |
| 8221DW | StromaLyse |
| 8230DW | CleanAr |
| 8240DW | Concentrated Cleanacer |
| 8310HX | PlasmaDiluent |


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Appendix to
Conformity Declarations
Archem Diagnostic Systems



Archem Sağlık San. ve Tic. A.Ş.
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Conformity also declared with all applicable harmonized standards, especially the following:

EN ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purpose.

EN ISO 14971: Medical devices — Application of risk management to medical devices.

EN ISO 17511: In vitro diagnostic medical devices — Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials.

EN ISO 18113-1: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements.

EN ISO 18113-2: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for Professional use.

Other standards applied:

EN ISO 9001: Quality management systems

Note: Standards are used in this issue that is valid at date of issue of this conformity declaration.

Commercial Director

Erkan Uca
06.10.2022


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Güvenli Y.B.:0730790980



Archem Diagnostic Industry Inc.

Mahmutbey Mah. Halkalı Cad. No:124 Bağcılar, İSTANBUL TURKEY
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TECHNICAL DATA SHEET



CENTRIFICHEM® SAMPLE CUPS

Multi-purpose sample cups with excellent optical properties. Material: polystyrene.

| Cod. | Vol. ml | Dim. mm | Compatibility |
|--------|---------|---------|--|
| 1024/V | 0.25 | Ø 14x16 | CentrifiChem®, Beckman® Synchron® and similar. |
| 1022/V | 2 | Ø 16x24 | Beckman® Access®, Hyland Laser Beam Analyzer, IL - Instrumentation Laboratory® ACL®, Olympus® AU400 / AU600 / AU640 / AU2700 / AU5400, Sysmex® CA 540 and similar. |



Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity


Product Name:

EasyLyte Analyzer and accessories per attachment

Model/Type:

Na/K, Na/K/Cl, Na/K/Li,
Na/K/Cl/Li, Na/K/Ca/pH,
Na/K/Cl/Ca/Li

Manufacturer

 Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA
Single Registration Number (SRN): US-MF-000037250

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and their corresponding amendments.

Place and Date: Bedford, Massachusetts, USA, 26 May 2022

Signature:



Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs



Medica Corporation
 5 Oak Park Drive
 Bedford, Massachusetts 01730
 Tel 781 275 4892
 Fax 781 275 2731
 www.medicacorp.com

| Catalog No. | EasyLyte Analyzer and Accessories | EDMA Code | Class |
|-------------|--|-------------|---|
| 2004 | EasyLyte Analyzer, Na/K | 21 07 11 02 | General IVD device, not listed in IVDD Annex II and not intended for self-testing |
| 2014 | EasyLyte Analyzer, Na/K/Cl | 21 07 11 02 | |
| 2015 | EasyLyte Analyzer, Na/K/Li | 21 07 11 02 | |
| 2016 | EasyLyte Analyzer, Na/K/Ca/pH | 21 07 11 02 | |
| 2021 | EasyLyte Analyzer, Na/K/Cl/Li | 21 07 11 02 | |
| 2030 | EasyLyte Analyzer, Na/K/Cl/Ca/Li | 21 07 11 02 | |
| C2004 | EasyLyte Analyzer, Na/K | 21 07 11 02 | |
| C2014 | EasyLyte Analyzer, Na/K/Cl | 21 07 11 02 | |
| C2015 | EasyLyte Analyzer, Na/K/Li | 21 07 11 02 | |
| C2016 | EasyLyte Analyzer, Na/K/Ca/pH | 21 07 11 02 | |
| C2030 | EasyLyte Analyzer, Na/K/Cl/Ca/Li | 21 07 11 02 | |
| L2014 | EasyLyte Analyzer, Na/K/Cl | 21 07 11 02 | |
| L2015 | EasyLyte Analyzer, Na/K/Li | 21 07 11 02 | |
| L2016 | EasyLyte Analyzer, Na/K/Ca/pH | 21 07 11 02 | |
| L2021 | EasyLyte Analyzer, Na/K/Cl/Li | 21 07 11 02 | |
| 2101 | EasyLyte K+ Electrode | 11 04 01 06 | |
| 2102 | EasyLyte Na+ Electrode | 11 04 01 07 | |
| 2103 | EasyLyte Reference Electrode | 11 04 04 01 | |
| 2113 | EasyLyte Cl- Electrode | 11 04 01 03 | |
| 2106 | EasyLyte Lithium Electrode | 11 04 01 04 | |
| 2150 | EasyLyte Ca++ Electrode | 11 04 01 02 | |
| 2151 | EasyLyte pH Electrode | 11 70 31 02 | |
| 2152 | EasyLyte Disposable Reference Electrode | 11 04 04 01 | |
| 2109 | EasyLyte Solutions Pack, 400mL | 11 04 04 02 | |
| 2120 | EasyLyte Solutions Pack, 800mL | 11 04 04 02 | |
| 2112 | EasyLyte Plus Solutions Pack, 400mL | 11 04 04 02 | |
| 2121 | EasyLyte Plus Solutions Pack, 800mL | 11 04 04 02 | |
| 2115 | EasyLyte Lithium Solutions Pack, 400mL | 11 04 04 02 | |
| 2122 | EasyLyte Lithium Solutions Pack, 800mL | 11 04 04 02 | |
| 2114 | EasyLyte Calcium Solutions Pack, 400mL | 11 04 04 02 | |
| 2123 | EasyLyte Calcium Solutions Pack, 800mL | 11 04 04 02 | |
| 2026 | EasyLyte Na/K/Cl/Li Solutions Pack, 800mL | 11 04 04 02 | |
| 2028 | EasyLyte Na/K/Cl/Li Solutions Pack, 400mL | 11 04 04 02 | |
| 2124 | EasyLyte Na/K/Cl/Ca/Li Solutions Pack, 800mL | 11 04 04 02 | |



Medica Corporation
 5 Oak Park Drive
 Bedford, Massachusetts 01730
 Tel 781 275 4892
 Fax 781 275 2731
 www.medicacorp.com

| Catalog No. | EasyLyte Analyzer and Accessories | EDMA Code | Class |
|-------------|--|-------------|---|
| 2814 | EasyQC Bi-Level Quality Control Kit | 11 50 02 04 | General IVD device, other than listed in IVDD Annex II and other than intended for self-testing |
| 2815 | EasyQC Tri-Level Quality Control Kit | 11 50 02 04 | |
| L2026 | EasyLyte Solutions Pack, Na/K/Cl/Li, 800mL | 11 04 04 02 | |
| L2112 | EasyLyte Solutions Pack, Na/K/Cl, 400mL | 11 04 04 02 | |
| L2121 | EasyLyte Solutions Pack, Na/K/Cl, 800mL | 11 04 04 02 | |
| L2122 | EasyLyte Solutions, Na/K/Li Pack, 800mL | 11 04 04 02 | |
| L2123 | EasyLyte Solutions Pack, Na/K/Ca/pH, 800mL | 11 04 04 02 | |
| | | | |



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 |