CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

Digitally signed by Ceaicovschi Tudor
Date: 2023.12.13 14:39:22 EET
Reason: MoldSign Signature
Location: Moldova

Facility ID: F001410

UL Medical Regulatory Services of UL LLC® (UL Solutions) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016
EN ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design and manufacture of in vitro diagnostic reagents for the detection of the blood groups.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

File Number	A12241	Cycle Start Date	May 23, 2023
Certificate Number	1459.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC® (UL Solutions). Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

UL Solutions
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

Facility ID: F001410

Additional Regulatory Requirements

Brazil:
- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:
- Medical Devices Regulations – Part 1- SOR 98/282

File Number	A12241	Cycle Start Date	May 23, 2023
Certificate Number	1459.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC® (UL Solutions). Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

UL Solutions
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

_____

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

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Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom
Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

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Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
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Tel: +44 (0) 118 921 2264
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Email: info@lornelabs.com
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CERTIFICATE

EC Certificate No. 1434-IVDD-075/2022

Full Quality Assurance System
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT, UNITED KINGDOM

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

The list of medical devices covered by this certificate is provided
in the Annex 1 to EC Design-examination Certificate No. 1434-IVDD-074/2022

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 28.04.2022 to 27.05.2025

The date of issue of the Certificate: 28.04.2022

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Issued under the Contract No. MD-004/2022
Application No: 505/2022
Certificate bears the qualified signature.
Warsaw, 28/04/2022
Module H7

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

CERTIFICATE

EC Certificate No. 1434-IVDD-074/2022

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Lorne Laboratories Ltd
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT, UNITED KINGDOM

i.e. *in vitro* diagnostic medical devices
List A

The list of medical devices covered by this certificate is provided in the Annex 1

in terms of design documentation, comply with requirements
of Annex IV (Section 4) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 28.04.2022 to 27.05.2025

The date of issue of the Certificate: 28.04.2022

The date of the first issue of the Certificate: 10.04.2019

CE 1434

Issued under the Contract No. MD-004/2022
Application No: 504/2022
Certificate bears the qualified signature.
Warsaw, 28/04/2022
Module H6/V1

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-074/2022

List of medical devices covered by the certificate:

Anti-A Monoclonal 600010
Anti-B Monoclonal 610010
Anti-A,B Monoclonal 620010
Anti-D Clone 1 Monoclonal 730010
Anti-D Clone 2 Monoclonal 710010
Anti-D Duoclone Monoclonal 740010
Anti-C Monoclonal 690005
Anti-E Monoclonal 691005
Anti-c Monoclonal 692005
Anti-e Monoclonal 693005
Anti-C+D+E Monoclonal 700010
Anti-K Monoclonal 760010

CE 1434

Issued under the Contract No. MD-004/2022
Application No: 504/2022
Certificate bears the qualified signature.
Warsaw, 28/04/2022

Aleksandra Kostrzewa
President

Digitally signed by Aleksandra Kostrzewa

EC DECLARATION OF CONFORMITY

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2-4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products: Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure: Annex III (not including section 6).

Manufacturer: ZAO "Vector-Best"
Address: AHC, Koltsovo,
Novosibirsk Region, 630559, Russia,
Tel. +7 (383) 363 20 60,
Fax: +7 (383) 363 35 55

European authorized representative: Bioron GmbH,
Rheinhorststr. 18, D-67071
Ludwigshafen, Germany.
tel.: +49 (0) 621 5720 915,
fax: +49 (0) 621 5720 916

Date: 2013/04/12

Murat Khusainov
General Director ZAO «Vector-Best»

No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep TTV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1056
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1058
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombiBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombiBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectoHSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectoHSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectoHHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectoHHV-6 - IgG	ELISA kit for determination of IgG to human herpes virus type 6	D-2166
17.	Ureaplasma urealyticum – IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum – IgA-EIA-BEST	ELISA kit for determination of IgA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis – IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus	D-3356

		antigens	
24.	Ascarid-IgG-EIA-BEST	ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lamblia-antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lamblia antibodies	D-3552
26.	Lamblia-IgM-EIA-BEST	ELISA kit for determination of IgM to Lamblia antibodies	D-3554
27.	Lamblia-antigen-EIA-BEST	ELISA kit for determination of Lamblia antigen	D-3556
28.	Helicobacter pylori-CagA-antigen-EIA-BEST	ELISA kit for determination of total antibodies to CagA Helicobacter pylori	D-3752
29.	TSH-EIA-BEST	ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST	ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST	ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST	ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST	ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST	ELISA kit for determination of IgA to Mycoplasma hominis	D-4358
36.	Mycoplasma pneumoniae-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST	ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vectocrimean – CHF – IgG	ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39.	Vectocrimean – CHF – IgM	ELISA kit for determination of IgM to Crimean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST	ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST	ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST	ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST	ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST	ELISA kit for determination of concentration of ferritin	T-6552
47.	IgE total-EIA-BEST	ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST	ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST	ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST	ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST	ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST	ELISA kit for determination of concentration of Interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST	ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST	ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST	ELISA kit for determination of concentration of Interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST	ELISA kit for determination of concentration of Interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST	ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST	ELISA kit for determination of concentration of N-terminal prohormone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST	ELISA kit for determination of concentration of troponin I	A-9106

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 10462 rev. 8

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 SAS GMED SAS

DocuSigned by:
Marjorie PERRIMON
F6FB7BBEC7B144D...

On behalf of the President,
Marjorie PERRIMON
Certification Director

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

GMED_SQ-F-V0-07-2018

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

Renouvelle le certificat 10462-7

ELITech Clinical Systems
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

ELITechGroup
EMPOWERING IVD

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
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

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

Vla

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

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, 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: 2021-10-13
Latest Revision Date: 2022-04-12
Expiry Date: 2024-10-12

...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, 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: 2021-10-13

Latest Revision Date: 2022-04-12

Expiry Date: 2024-10-12

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-06-01
Latest Revision Date: 2022-06-22

Effective Date: 2021-10-13
Expiry Date: 2024-10-12

...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.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan	Design and Development of in vitro diagnostics products including test kits and reagents.

Original Registration Date: 2021-06-01

Effective Date: 2021-10-13

Latest Revision Date: 2022-06-22

Expiry Date: 2024-10-12

Abbott

Declaration of Conformity

Certificate Identification: SC-09H46

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

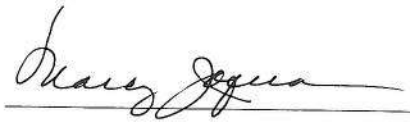
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H46-02	58236	CELL-DYN Emerald CLEANER	**Self-declared**
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	**Self-declared**
09H48-02	58237	CELL-DYN Emerald 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
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:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	02-Dec-2015	Date of Approval:	01 DEC 2015
Date Issued:	DEC 02 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 July 6, 2015	Effective (Date or Lot Number):	DEC 03 2015

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14
Expiry Date: 2024-04-13

...making excellence a habit.™

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: 2021-04-14

Latest Revision Date: 2021-04-13

Expiry Date: 2024-04-13

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

Declaration of Conformity

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

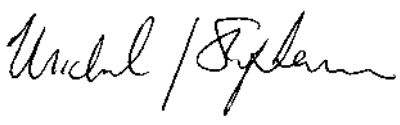
In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

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

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

RUSSIAN FEDERATION

№ 0101475

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ИСО 13485

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС33.17919

Срок действия с 21.03.2022 по 20.03.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС33
ООО «Научно-исследовательский институт проектирования и измерений»
141730, Московская область, город Лобня, улица Борисова, дом 14, корпус 2, помещение 006, офис 1

ВЫДАН
Общество с ограниченной ответственностью «МИНИМЕД»
ИНН: 3234007127 ОГРН: 1023202138332
Адрес: 241520, Брянская обл, Брянский р-н, село Супонево, ул Шоссейная, зд 17А

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА

применительно к видам работ согласно приложению №1 к настоящему сертификату

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ СТАНДАРТА

ГОСТ ISO 13485-2017(ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол РОСС RU.32001.04ИБФ1.ОС33.17919П от 21.03.2022

Проверка подлинности сертификата соответствия

ООО «НИИ ПИ»

Руководитель органа _____ (подпись) К.Р. Василенко (инициалы, фамилия)

Эксперт _____ (подпись) М.Т. Антипин (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2020 г., «В», ТЗ № 974.

RUSSIAN FEDERATION

№ 0101474

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ПромТех Стандарт

ИСО 13485

ПРИЛОЖЕНИЕ № 1

К сертификату соответствия № РОСС RU.32001.04ИБФ1.ОС33.17919
(является неотъемлемой частью сертификата соответствия)

Срок действия с 21.03.2022 по 20.03.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС33

ООО «Научно-исследовательский институт проектирования и измерений»

141730, Московская область, город Лобня, улица Борисова, дом 14, корпус 2, помещение 006, офис 1

Применительно к видам работ: Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики.

ООО «НИИ ПИ»

Руководитель органа _____ (подпись) К.Р. Василенко (инициалы, фамилия)

Эксперт _____ (подпись) М.Т. Антипин (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2020 г., «Б», тз № 974.

МиниМед®
поставщик лабораторий

ООО "МиниМед", 241520, Российская Федерация, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, 17 А

Тел. (4832) 92-97-97, 92-24-52, -53, -55, -56, -57, -58, -60, -61, -62
Многоканальный номер - 8-800-100-48-32
Факс (4832) 92-24-54, 92-24-59, 92-24-61

ИНН 3234007127 www.minimed.ru e-mail: info@minimed.ru

Регистрационное удостоверение № ФСР 2011/11306 от 07.12.2015 г.

Паспорт

Краситель Азур-эозин по Романовскому (МиниМед-Р) ТУ 9398-003-29508133-2011

Серия	*98*	**Дата изготовления**	*03.2023 г.*	**Использовать до**	*03.2024 г.*

1. Назначение

Предназначен для окрашивания форменных элементов крови.

2. Технические требования

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1. Краситель	Темно-синяя сиропообразная жидкость без нерастворимых примесей	*соответствует*
1.2. Буфер фосфатный	Прозрачная бесцветная жидкость	*соответствует*
2. Плотность раствора красителя при комнатной температуре 20±2°С, г/см^3	1,000 – 1,100	*1,01*
3. Время наступления окраски мазка (при разведении красителя 1:19), мин, не более	50	*30*
4. Окраска форменных элементов крови	эритроциты – розовые с серым оттенком, бежево-коричневые	розовые с серым оттенком
	ядра лейкоцитов – фиолетовые	фиолетовые
	цитоплазма лимфоцитов – голубая, серо-голубая;	голубая
	цитоплазма нейтрофилов – бледно-розовая, серо-розовая;	бледно-розовая
	зернистость нейтрофилов – фиолетовая, красно-фиолетовая;	красно-фиолетовая
	зернистость эозинофилов – желто-оранжевая, розово-фиолетовая;	желто-оранжевая
	зернистость базофилов – фиолетовая;	фиолетовая
	тромбоциты – розово-фиолетовые, розово-сине-фиолетовые	розово-фиолетовые

3. Транспортирование и хранение

Транспортирование красителя-фиксатора должно проводиться всеми видами крытого транспорта при температуре от 0 до 25°С в соответствии с правилами перевозки грузов, действующими на данном виде транспорта. Краситель следует хранить при температуре от +5° до +25°С в темном месте, вдали от кислот и щелочей в течение всего срока годности.

4. Гарантии изготовителя

Изготовитель гарантирует соответствие красителя Азур-эозина по Романовскому (МиниМед-Р) требованиям ТУ 9398-003-29508133-2011 при соблюдении потребителем условий транспортирования, хранения и применения в течение всего срока годности.

Начальник ПТО **Бабич В.А.**

Общество с ограниченной ответственностью НАЧАЛЬНИК ПТО г. БРЯНСК БАБИЧ ВА МИНИМЕД

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 декабря 2015 года № ФСР 2011/11306

На медицинское изделие
Краситель Азур-Эозин по Романовскому (МиниМед-Р)
по ТУ 9398-003-29508133-2011

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Место производства медицинского изделия
241520, Брянская область. Брянский район, с. Супонево, пер. Комсомольский, д. 7, корп. 2-а

Номер регистрационного досье **№ РД-9275/51846 от 18.11.2015**

Вид медицинского изделия **232730**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

приказом Росздравнадзора от 07 декабря 2015 года № 9111
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

0015715

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ООО "МиниМед", 241520, Российская Федерация, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, 17 А

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Регистрационное удостоверение № ФСР 2009/03559 от 04.12.2015 г.

Паспорт

Набор реагентов «Масло иммерсионное» по ТУ 9398-011-29508133-2009

Серия	131	Дата изготовления	07.11.2022

1. Назначение

Используется для апохроматических и ахроматических объективов микроскопов всех видов, кроме люминесцентных, предназначенных для работы в видимой области спектра.

2. Технические требования

Наименование показателя	Характеристика и норма по ТУ	Результаты анализа
Внешний вид	Прозрачная бесцветная жидкость со слабым желтоватым оттенком	*соответствует*
Вязкость кинематическая при температуре 20°С, мм²/с	От 220	*1350*
Показатель преломления при температуре 20°С	От 1,5150 до 1,5180	*1,5157*
Коэффициент пропускания масла, %	Не менее 70	*440 нм – 99,1* *540 нм – 100,0*

Иммерсионное масло легко удаляется с поверхности препарата, фронтальной линзы и оправы объектива; инертно к окрашенным и неокрашенным препаратам.

Упаковка – флакон-капельница вместимостью 100,0 мл обеспечивает аккуратное и экономичное нанесение масла на препарат.

Срок годности – 1,5 года с даты изготовления.

3. Транспортирование и хранение

Транспортирование должно проводиться всеми видами крытого транспорта в соответствии с правилами перевозки грузов, действующими на данном виде транспорта. Хранение - в упаковке предприятия-изготовителя в прохладном месте при относительной влажности воздуха не более 80% в местах, защищенных от воздействия прямых солнечных лучей, атмосферных осадков и агрессивных сред в течение всего срока годности.

4. Гарантии изготовителя

Изготовитель гарантирует соответствие качества набора реагентов «Масло иммерсионное» требованиям ТУ 9398-011-29508133-2009 при соблюдении потребителем условий транспортирования, хранения и применения в течение всего срока годности.

Начальник ПТО **Бабич В.А.**

ООО "МиниМед", 241520, Российская Федерация, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, 17 А

Тел. (4832) 92-97-97, 92-24-52, -53, -55, -56, -57, -60, -60, -61, -62
Многоканальный номер - 8-800-100-48-32
Факс (4832) 92-24-54, 92-24-59, 92-24-61

ИНН 3234007127 www.minimed.ru e-mail: info@minimed.ru

Регистрационное удостоверение № ФСР 2011/11702 от 17.08.2011 г.

Паспорт

Пипетка стеклянная к СОЭ-метру ПС/СОЭ-01
ТУ 9443-005-52876351-2002

1. Назначение

Предназначена для измерения высоты столба плазмы крови при определении скорости оседания эритроцитов.

2. Основные технические характеристики

1. Пипетка изготовлена по ТУ 9443-005-52876351-2002.
2. Изделия изготовлены из медицинского стекла по ГОСТ 19808 (НС-1) или химико-лабораторного стекла по ГОСТ 21400 (ХС3).
3. Пипетка представляет собой прямую капиллярную трубку с запаянным нижним торцом. Вдоль капилляра нанесена шкала.
4. Длина пипетки, мм, не более – 174,5. Внешний диаметр, мм – 5 ± 1,0.
5. Внутренний диаметр пипетки, мм – 1,4-1,6 мм.
6. Диапазон измерений высоты столба плазмы, мм – 0-90. Цена деления шкалы, мм -1,0.
7. Допускается слабый цветовой оттенок.
8. Знак утверждения типа наносится на пипетку методом выжигания.

3. Упаковывание, транспортирование и хранение

Упаковка изделий обеспечивает их сохранность при транспортировке. Транспортная упаковка имеет надпись: «Осторожно, стекло». Условия транспортирования изделий - по ГОСТ 15150-69 в крытом транспорте любого вида. Условия хранения - по ГОСТ 15150-69.

4. Требования безопасности

При эксплуатации необходимо соблюдать правила безопасности при работе со стеклянными изделиями. Изделие не должно подвергаться резким ударам в процессе эксплуатации. Рекомендуемые условия эксплуатации: температура окружающей среды от 10 до 35 °С и относительная влажность воздуха при 25°С не более 80%.

5. Сведения об утилизации

Изделие не представляет опасности для окружающей среды, жизни и здоровья людей после окончания срока службы. Порядок утилизации изделия определяется Потребителем.

6. Гарантии изготовителя

Изготовитель: ООО «МиниМедПром», 242600, РФ, Брянская область, г. Дятьково, ул. Ленина, д. 182, корп. 5.

Поставщик: ООО «МиниМед», 241520, РФ, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, 17А.

Изготовитель гарантирует соответствие пипетки стеклянной к СОЭ-метру ПС/СОЭ-01 требованиям ТУ 9443-005-52876351-2002 при соблюдении потребителем условий транспортирования, хранения и эксплуатации. Гарантийный срок эксплуатации — 12 месяцев со дня ввода в эксплуатацию.

7. Свидетельство о приемке

Изделие изготовлено в соответствии с действующей технической документацией и признано годным для эксплуатации.

Начальник ОТК **Грузинцев С.А.**

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 orifizi 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, Is, 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, Is, 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*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2023-10-24	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

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

CERTIFIED COMPANY UNI ISO 9001:2008 & UNI CEI EN ISO 13485:2012

DICHIARAZIONE DI CONFORMITA' CE

CE *DECLARATION OF CONFORMITY*

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

DICHIARA
DECLARES

Che il dispositivo medico diagnostico in vitro di seguito descritto:
That in vitro diagnostic medical devices described as follows:

PROVETTE CON ANTICOAGULANTE, SEPARATORI DI SIERO

BLOOD COLLECTIONS TUBES AND SERUM SEPARATORS

PRODOTTI NON STERILI – *NOT STERILE PRODUCTS*

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

- **Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.**
  Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27Th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.
- **I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.**
  The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.
- **Classificazione EDMA: 1302808000 Coated tubes (Citrate, Heparin etc.)**
  EDMA code: 1302808000 Coated tubes (Citrate, Heparin etc.)
- **La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.**
  The present Declaration was drafted in accordance with annex III to Directive 98/79/EC.

Rilasciato / *Released*
Canelli, 26.07.2015

Duilio BUONO
Responsabile Assicurazione Qualità

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
10110/16	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo rosa per "SEDI-RATE".	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, pink cap for "SEDI-RATE" system.*
10110/PR	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo rosa per "SEDI-RATE".	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, pink cap for "SEDI-RATE" system.*
2000	Provette fondo piatto PP Ø12x56 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø12x56 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2000/1	Provette PP Ø12x56 mm., con K_2EDTA per 1 ml di sangue, tappo verde chiaro, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_2EDTA for 1 ml of blood, light green cap, for paediatric use.*
2000/1/V	Provette PP Ø12x56 mm., con K_2EDTA per 1 ml di sangue, con tappo, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_2EDTA for 1 ml of blood, light with cap, for paediatric use.*
2001	Provette fondo piatto PP Ø16x60 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø16x60 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2002	Provette fondo piatto PP Ø16x60 mm., con K_2EDTA per 5 ml di sangue, tappo verde chiaro.	*PP flat bottom test tubes Ø16x60 mm., with K_2EDTA for 5 ml of blood, light green cap.*
2003	Provette PP Ø12x86 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø12x86 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2004	Provette PP Ø12x86 mm., con K_2EDTA per 5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø12x86 mm., with K_2EDTA for 5 ml of blood, light green cap.*
2005	Provette PP Ø13x75 mm., con K_2EDTA per 2,5 ml di sangue, tappo verde chiaro.	*PP test tubes Ø13x75 mm., with K_2EDTA for 2,5 ml of blood, light green cap.*
2007	Provette PP Ø16x100 mm., con K_2EDTA per 10 ml di sangue, tappo verde chiaro.	*PP test tubes Ø16x100 mm., with K_2EDTA for 10 ml of blood, light green cap.*
2008	Provette PP Ø13x75 mm., con K_2EDTA per 4 ml di sangue, tappo verde chiaro.	*PP test tubes Ø13x75 mm., with K_2EDTA for 4 ml of blood, light green cap.*
2100	Provette fondo piatto PP Ø12x56 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø12x56 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2100/1	Provette PP Ø12x56 mm., con K_3EDTA per 1 ml di sangue, tappo verde scuro, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_3EDTA for 1 ml of blood, dark green cap, for paediatric use.*
2100/1/V	Provette PP Ø12x56 mm., con K_3EDTA per 1 ml di sangue, tappo viola, per uso pediatrico.	*PP test tubes Ø12x56 mm., with K_3EDTA for 1 ml of blood, dark violet cap, for paediatric use.*
2100/TM	Provette fondo piatto PP Ø12x56 mm., con K_3EDTA per 2,5 ml di sangue, con tappo	*PP flat bottom test tubes Ø12x56 mm., with K_3EDTA for 2,5 ml of blood, with cap*
2101	Provette fondo piatto PP Ø16x60 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø16x60 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2102	Provette fondo piatto PP Ø16x60 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP flat bottom test tubes Ø16x60 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2103	Provette PP Ø12x86 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP test tubes Ø12x86 mm., with K_3EDTA for 2,5 ml of blood, dark green cap.*
2104	Provette PP Ø12x86 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP test tubes Ø12x86 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2105	Provette PP Ø13x75 mm., con K_3EDTA per 2,5 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 2,5 ml of blood, dark green cap. Quantity for box 1,000 pieces*
2105/TM	Provetta PP Ø13x75 mm, con K_3EDTA per 2,5ml di sangue, tappo viola.	*PP test tubes Ø13x75 mm, with K_3EDTA for 2,5ml of blood, violet cap.*
2105/VIOLA	Provette PP Ø13x75 mm., con K_3EDTA per 2,5 ml di sangue, tappo viola	*PP test tubes Ø13x75 mm., with K_3EDTA for 2,5 ml of blood, violet cap.*
2107	Provette PP Ø16x100 mm., con K_3EDTA per 10 ml di sangue, tappo verde scuro.	*PP test tubes Ø16x100 mm., with K_3EDTA for 10 ml of blood, dark green cap.*
2108	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood, dark green cap.*
2108/5	Provette PP Ø13x75 mm., con K_3EDTA per 5 ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm., with K_3EDTA for 5 ml of blood, dark green cap.*
2108/TM	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood*
2108/VIOLA	Provette PP Ø13x75 mm., con K_3EDTA per 4 ml di sangue	*PP test tubes Ø13x75 mm., with K_3EDTA for 4 ml of blood*
2200	Provette fondo piatto PP Ø12x56 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP flat bottom test tubes Ø12x56 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap.*
2200/G	Provette fondo piatto PP Ø12x56 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo giallo.	*PP flat bottom test tubes Ø12x56 mm., with KF-Na_2 EDTA for 2,5 ml of blood, yellow cap.*
2201	Provette fondo piatto PP Ø16x60 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap.*
2201/G	Provette fondo piatto PP Ø16x60 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo giallo.	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 2,5 ml of blood, yellow cap.*
2202	Provette fondo piatto PP Ø16x60 mm., con KF+Na_2 EDTA per 5 ml di sangue, tappo arancione.	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 5 ml of blood, orange cap.*
2202/G	Provette fondo piatto PP Ø16x60 mm., con KF+Na_2 EDTA per 5 ml di sangue,	*PP flat bottom test tubes Ø16x60 mm., with KF-Na_2 EDTA for 5 ml of blood,*

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ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
	tappo giallo.	*yellow cap.*
2203	Provette PP Ø12x86 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP test tubes Ø12x86 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap.*
2204	Provette PP Ø12x86 mm., con KF+Na_2 EDTA per 5 ml di sangue, tappo arancione.	*PP test tubes Ø12x86 mm., with KF-Na_2 EDTA for 5 ml of blood, orange cap.*
2205	Provette PP Ø13x75 mm., con KF+Na_2 EDTA per 2,5 ml di sangue, tappo arancione.	*PP test tubes Ø13x75 mm., with KF-Na_2 EDTA for 2,5 ml of blood, orange cap. Quantity for box 1,000 pieces*
2205/TG	Provetta PP Ø13x75 mm, con KF+NA_2 EDTA per 2,5ml di sangue, tappo grigio.	*PP test tubes Ø13x75 mm, with KF+NA_2 EDTA for 2,5ml of blood, grey cap.*
2207	Provette PP Ø16x100 mm., con KF+Na_2 EDTA per 10 ml di sangue, tappo arancione.	*PP test tubes Ø16x100 mm., with KF-Na_2 EDTA for 10 ml of blood, orange cap.*
2208	Provette PP Ø13x75 mm., con KF+Na_2 EDTA per 4 ml di sangue, tappo arancione.	*PP test tubes Ø13x75 mm., with KF-Na_2 EDTA for 4 ml of blood, orange cap.*
2300	Provette fondo piatto PP Ø12x56 mm., con Sodio Eparina per 2,5 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Heparin for 2,5 ml of blood, violet cap.*
2301	Provette fondo piatto PP Ø16x60 mm., con Sodio Eparina per 2,5 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Heparin for 2,5 ml of blood, violet cap.*
2302	Provette fondo piatto PP Ø16x60 mm., con Sodio Eparina per 5 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Heparin for 5 ml of blood, violet cap.*
2303	Provette PP Ø12x86 mm., con Sodio Eparina per 2,5 ml di sangue, tappo viola.	*PP test tubes Ø12x86 mm., with Sodium Heparin for 2,5 ml of blood, violet cap.*
2304	Provette PP Ø12x86 mm., con Sodio Eparina per 5 ml di sangue, tappo viola.	*PP test tubes Ø12x86 mm., with Sodium Heparin for 5 ml of blood, violet cap.*
2305	Provette fondo piatto PP Ø13x75 mm., con Sodio Eparina per 2,5 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø13x75 mm., with Sodium Heparin for 2,5 ml of blood, violet cap.*
2307	Provette PP Ø16x100 mm., con Sodio Eparina per 10 ml di sangue, tappo viola.	*PP test tubes Ø16x100 mm., with Sodium Heparin for 10 ml of blood, violet cap.*
2308	Provette fondo piatto PP Ø13x75 mm., con Sodio Eparina per 4 ml di sangue, tappo viola.	*PP flat bottom test tubes Ø13x75 mm., with Sodium Heparin for 4 ml of blood, violet cap.*
2400	Provette fondo piatto PP Ø12x56 mm., con Litio Eparina per 2,5 ml di sangue, tappo blu.	*PP flat bottom test tubes Ø12x56 mm., with Lithium Heparin for 2,5 ml of blood, blue cap.*
2400/1	Provette PP Ø12x56 mm., con Litio Eparina per 1 ml di sangue, tappo blu, per uso pediatrico.	*PP test tubes Ø12x56 mm., with Lithium Heparin for 1 ml of blood, blue cap, for paediatric use.*
2400/TV	Provette fondo piatto PP Ø12x56 mm., con Litio Eparina per 2,5 ml di sangue, tappo verde.	*PP flat bottom test tubes Ø12x56 mm., with Lithium Heparin for 2,5 ml of blood, green cap.*
2401	Provette fondo piatto PP Ø16x60 mm., con Litio Eparina per 2,5 ml di sangue, tappo blu.	*PP flat bottom test tubes Ø16x60 mm., with Lithium Heparin for 2,5 ml of blood, blue cap.*
2402	Provette fondo piatto PP Ø16x60 mm., con Litio Eparina per 5 ml di sangue, tappo blu.	*PP flat bottom test tubes Ø16x60 mm., with Lithium Heparin for 5 ml of blood, blue cap.*
2403	Provette PP Ø12x86 mm., con Litio Eparina per 2,5 ml di sangue, tappo blu.	*PP test tubes Ø12x86 mm., with Lithium Heparin for 2,5 ml of blood, blue cap.*
2404	Provette PP Ø12x86 mm., con Litio Eparina per 5 ml di sangue, tappo blu.	*PP test tubes Ø12x86 mm., with Lithium Heparin for 5 ml of blood, blue cap.*
2404/TV	Provette PP Ø12x86 mm., con Litio Eparina per 5 ml di sangue, tappo verde.	*PP test tubes Ø12x86 mm., with Lithium Heparin for 5 ml of blood, green cap.*
2404/VERDE	Provette PP Ø12x86 mm., con Litio Eparina per 5 ml di sangue, tappo verde.	*PP test tubes Ø12x86 mm., with Lithium Heparin for 5 ml of blood, green cap.*
2405	Provette PP Ø13x75 mm., con Litio Eparina per 2,5 ml di sangue, tappo blu.	*PP test tubes Ø13x75 mm., with Lithium Heparin for 2,5 ml of blood, blue cap.*
2405/TV	Provetta PP Ø13x75 mm, con Litio Eparina per 2,5ml di sangue, tappo verde scuro.	*PP test tubes Ø13x75 mm, with Lithium Heparin for 2,5ml of blood, dark green cap.*
2407	Provette PP Ø16x100 mm., con Litio Eparina per 10 ml di sangue, tappo blu.	*PP test tubes Ø16x100 mm., with Lithium Heparin for 10 ml of blood, blue cap.*
2408	Provette PP Ø13x75 mm., con Litio Eparina per 4 ml di sangue, tappo blu.	*PP test tubes Ø13x75 mm., with Lithium Heparin for 4 ml of blood, blue cap. Quantity for box 1,000 pieces*
2408/VERDE	Provette PP Ø13x75 mm., con Litio Eparina per 4 ml di sangue, tappo blu.	*PP test tubes Ø13x75 mm., with Lithium Heparin for 4 ml of blood, blue cap. Quantity for box 1,000 pieces*
2500	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile verde, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable green cap, for 3 ml of blood.*
2500*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile verde, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable green cap, for 3 ml of blood.*
2500/N	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile neutro, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable neutral cap, for 3 ml of blood.*
2500/N*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile neutro, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable neutral cap, for 3 ml of blood.*
2500/SE	Provette in PP con K3 EDTA tappo perforabile verde, senza tappo	*PP test tubes Ø13x75 mm., with K_3EDTA, without cap, for 3 ml of blood.*
2500/SE/V	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue, senza etichetta.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood, without label*
2500/V	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood.*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

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Annex 1 to Declaration of Conformity 98/79/CE

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2500/V*	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 3 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 3 ml of blood.*
2500/V/2	Provette PP Ø13x75 mm, con K_3EDTA, con tappo perforabile viola, per 2 ml di sangue.	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 2 ml of blood.*
2500/V/SG	Provette in PP con K3 EDTA sterili,tappo perf,viola	*PP test tubes Ø13x75 mm., with K_3EDTA, with pierceable violet cap, for 2 ml of blood, sterile*
2501	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,4ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,4 ml, yellow cap for coagulation.*
2502	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo giallo per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, yellow cap for coagulation*
2503	Provette in PP Ø16x100 mm, con Sodio Citrato 0,4ml, tappo giallo	*PP test tubes Ø16x100 mm., with Sodium Citrate 0,4 ml, yellow cap*
2505	Provette PP Ø12x56 mm, con Sodio Citrato 0,4ml, tappo giallo.	*PP test tubes Ø12x56 mm., with Sodium Citrate 0,4 ml, yellow cap*
2505/1	Provette PP Ø12x56 mm, con Sodio Citrato 0,1ml, tappo giallo per coagulazione uso pediatrico.	*PP test tubes Ø12x56 mm., with Sodium Citrate 0,1 ml, yellow cap for coagulation, for paediatric use.*
2508	Provette PP Ø13x75 mm, con Sodio Citrato 0,4ml, tappo giallo per coagulazione.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,4 ml, yellow cap for coagulation*
2508/BLU	Provette PP Ø13x75 mm, con Sodio Citrato 0,4ml, tappo blu per coagulazione.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,4 ml, blue cap for coagulation*
2511	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,5ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,5 ml, yellow cap for coagulation.*
2512	Provette PP Ø12x86 mm, con Sodio Citrato 0,5ml, tappo giallo per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,5 ml, yellow cap for coagulation.*
2512/TB	Provette PP Ø12x86 mm, con Sodio Citrato 0,5ml per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,5 ml for coagulation.*
2513	Provette PP Ø16x100 mm, con Sodio Citrato 0,5ml, tappo giallo per coagulazione.	*PP test tubes Ø16x100 mm., with Sodium Citrate 0,5 ml, yellow cap for coagulation.*
2515/BLU	Provette PP Ø13x75 mm, con Sodio Citrato 0,5ml, tappo blu	*PP test tubes Ø113x75 mm., with Sodium Citrate 0,5 ml, yellow cap*
2515/TB/F	Provette PP Ø13x75 mm, con Sodio Citrato 0,5ml, tappo blu	*PP test tubes Ø113x75 mm., with Sodium Citrate 0,5 ml, yellow cap*
2520	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, yellow cap for coagulation.*
2520/TB	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml, tappo blu per coagulazione.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, blue cap for coagulation.*
2520/TR	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml per coagulazione.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml for coagulation.*
2521	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,25ml, tappo giallo per coagulazione.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,25 ml, yellow cap for coagulation.*
2522	Provette PP Ø12x86 mm, con Sodio Citrato 0,25ml, tappo giallo per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,25 ml, yellow cap for coagulation.*
2522/R	Provette PP Ø12x86 mm, con Sodio Citrato 0,25ml, tappo rosa per coagulazione.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,25 ml, pink cap for coagulation.*
2525	Provette PP Ø13x75 mm, con Sodio Citrato 0,25ml, tappo giallo per coagulazione.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,25 ml, yellow cap for coagulation.*
2525/2	Provetta PP Ø13x75 mm, con 0,20 ml di Sodio Citrato per coagulazione, tappo giallo	*PP test tubes Ø13x75 mm, with 0,20ml of Sodium Citrate for coagulation, yellow cap.*
2525/32/BLU	Provette in PP tappo blu con 0,25ml di Sodio Citrato 3,2%,	*PP test tubes Ø13x75 mm, with 0,25ml of Sodium Citrate for coagulation, blue cap.*
2600	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml, tappo rosa per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, pink cap for ESR.*
2600/1	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,1ml, tappo rosa per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,1 ml, pink cap for ESR.*
2600/TN	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,25ml, tappo nero per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, black cap for ESR.*
2601	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,25ml, tappo rosa per VES.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,25 ml, pink cap for ESR.*
2602	Provette PP Ø12x86 mm, con Sodio Citrato 0,25ml, tappo rosa per VES.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,25 ml, pink cap for ESR.*
2603	Provette PP Ø16x100 mm, con Sodio Citrato 0,25ml, tappo rosa	*PP test tubes Ø16x100 mm., with Sodium Citrate 0,25 ml, pink cap*
2605	Provette PP Ø13x75 mm, con Sodio Citrato 0,25ml, tappo rosa per VES.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,25 ml, pink cap for ESR.*
2610	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,4ml, tappo rosa per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,4 ml, pink cap for ESR.*
2610/G	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,4ml, tappo giallo per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,4 ml, yellow cap for ESR.*
2611	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,4ml, tappo rosa per VES.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,4 ml, pink cap for ESR.*
2612	Provette PP Ø12x86 mm, con Sodio Citrato 0,4ml, tappo rosa per VES.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,4 ml, pink cap for ESR.*

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

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2615	Provette PP Ø13x75 mm, con Sodio Citrato 0,4ml, tappo rosa per VES.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,4 ml, pink cap for ESR.*
2615/TN	Provetta PP Ø13x75 mm, con 0,4ml di Sodio Citrato per VES, tappo nero.	*PP test tubes Ø13x75 mm, with 0,4ml of Sodium Citrate for ESR, black cap.*
2620	Provette fondo piatto PP Ø12x56 mm, con Sodio Citrato 0,5ml, tappo rosa per VES.	*PP flat bottom test tubes Ø12x56 mm., with Sodium Citrate 0,5 ml, pink cap for ESR.*
2621	Provette fondo piatto PP Ø16x60 mm, con Sodio Citrato 0,5ml, tappo rosa per VES.	*PP flat bottom test tubes Ø16x60 mm., with Sodium Citrate 0,5 ml, pink cap for ESR.*
2622	Provette PP Ø12x86 mm, con Sodio Citrato 0,5ml, tappo rosa per VES.	*PP test tubes Ø12x86 mm., with Sodium Citrate 0,5 ml, pink cap for ESR.*
2625	Provette PP Ø13x75 mm, con Sodio Citrato 0,5ml, tappo rosa per VES.	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,5 ml, pink cap for ESR.*
2632	Provette Ø12x56 mm in PP, con 0,25ml di Sodio Citrato x 1 ml di sangue	*PP test tubes Ø12x56 mm., with Sodium Citrate 0,25 ml, pierceable black rubber cap for ESR.*
2635	Provette Ø13x75 mm in PP, con 0,4ml di Sodio Citrato x 1,6ml di sangue	*PP test tubes Ø13x75 mm., with Sodium Citrate 0,4 ml, pierceable black rubber cap for ESR.*
2661/E/TB	Provette Ø16 x 100 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
2662/E	Provette Ø16 x 100 mm. in PP, con gel separatore + acceleratore	*PP test tubes with separating gel + clot accelerator, Ø16 x 100 mm*
2662/E/TB	Provette Ø16 x 100 mm. in PMMA, con gel separatore + acceleratore, tappo basso	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, low cap*
2662/TB	Provette Ø16 x 100 mm. in PMMA, con gel separatore + acceleratore, tappo basso, senza etichetta	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, low cap, without label*
2662/TM	in prov.16x100 in metacr. x 10 ml di sangue t/marrone	*PMMA test tubes with separating gel + clot accelerator, Ø16 x 100 mm, low cap, without label*
2663/E/TB	Provette Ø13x75 mm. in PP, con granuli separatori + acceleratore, tappo basso	*PP test tubes with separating granules + clot accelerator, Ø13x75 mm, low cap*
2664/E/TB	Provette Ø12x86 mm. in PP, con granuli separatori + acceleratore, tappo basso	*PP test tubes with separating granules + clot accelerator, Ø12x86 mm, low cap*
2665/E	Provette Ø13 x 75 mm. in PP, con gel separatore + acceleratore	*PP test tubes with separating gel + clot accelerator, Ø13 x 75 mm*
2665/E/TB	Provette Ø13 x 75 mm. in PMMA, con gel separatore + acceleratore, tappo basso	*PP test tubes with separating gel + clot accelerator, Ø13 x 75 mm, low cap*
2665/TB	gel separ.+acc. in prov.13x75 pmma per 5 ml sangue	*PMMA test tubes with separating gel + clot accelerator, Ø13 x 75 mm, low cap*
2666/E/TB	Provette Ø16 x 100 mm, in PP, con gel separatore + acceleratore, con etichetta, tappo basso	*PP test tubes with separatine gel + clot accelerator, Ø16 x 100 mm., with label, low cap.*
2666/TB	gel separ.+acc.in prov.16x100 pp x 10 ml di sangue	*PP test tubes with separatine gel + clot accelerator, Ø16 x 100 mm., with label, low cap.*
2668/E	Provette Ø12 x 86 mm. in PP, con gel separatore + acceleratore	*PP test tubes with separating gel + clot accelerator, Ø12 x 86 mm*
2668/E/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore + acceleratore, tappo basso	*PMMA test tubes with separating gel + clot accelerator, Ø12 x 86 mm, low cap*
2668/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore + acceleratore, tappo basso, senza etichetta	*PMMA test tubes with separating gel + clot accelerator, Ø12 x 86 mm, low cap, without label*
2678/E/TB	Provette con gel+acceleratore per 5ml di sangue, in PP,	#N/D
2700	Provette Ø13x75 mm in PP con 0,3ml di Sodio Citrato per coagulazione, tappo azzurro in gomma perforabile	*PP test tubes Ø13x75 mm with 0.3ml of Sodium Citrate for coagulation, with light blue cap in pierceable cap.*
2700/2	Provette in PP tappo azzurro perforabile con 0,2 ml di	*PP test tubes Ø13x75 mm with 0.2ml of Sodium Citrate for coagulation, with light blue cap in pierceable cap.*
2705	Provette in PP tappo blu con 0,35 ml di Sodio Citrato	*PP test tubes Ø13x75 mm with 0.35 ml of Sodium Citrate for coagulation, with blue cap*
2710	Provette Ø12x56 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø12x56 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2711	Provette Ø16x60 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø16x60 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2712	Provette Ø12x86 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø12x86 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
2715	Provette Ø13x75 mm in PP con 0,25 ml di Sodio Citrato, tappo rosa, doppia freccia di riempimento per VES e coagulazione	*PP test tubes Ø13x75 mm with 0.25ml of Sodium Citrate, pink cap, two blood level for ESR and coagulation*
3553/E	Provette Ø16 x 100 mm in PMMA, con acceleratore	*PMMA test tubes with clot accelerator, Ø16x100 mm*
3555/E	Provette Ø13 x 75 mm in PMMA, con acceleratore	*PMMA test tubes with clot accelerator, Ø13 x 75 mm*
3556/E	Provette Ø16 x 100 mm in PP, con acceleratore	*PP test tubes with clot accelerator, Ø16 x 100 mm*
3558/E	Provette Ø12 x 86 mm in PMMA, con acceleratore	*PMMA test tubes with clot accelerator, Ø12 x 86 mm*
3771/E/TB	Provette Ø16 x 100 mm. in PP, con gel separatore, tappo rosso basso	*PP test tubes with separating gel, Ø16 x 100 mm, with low red cap*
3772/E/TB	Provette Ø13x75 mm. in PP, con gel separatore, tappo rosso basso	*PP test tubes with separating gel, Ø13x75 mm, red low cap*
3773/E	Provette Ø16 x 100 mm. in PP, con gel separatore	*PP test tubes with separating gel, Ø16 x 100 mm*
3773/E/TB	Provette Ø16 x 100 mm. in PMMA, con gel separatore, tappo basso	*PMMA test tubes with separating gel, Ø16 x 100 mm, low cap*
3773/TB	gel separatore in prov. 16x100 pmma per 10 ml di sangue	*PMMA test tubes with separating gel, Ø16 x 100 mm, low cap*
3774/E/TB	Provette Ø12x86 mm. in PP, con gel separatore, tappo basso	*PP test tubes with separating gel, Ø12x86 mm, low cap*

NUOVA APTACA s.r.l.
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3775/E	Provette Ø13 x 75 mm. in PP, con gel separatore	*PP test tubes with separating gel, Ø13 x 75 mm*
3775/E/TB	Provetta Ø13 x 75 mm. in PMMA, con gel separatore, tappo basso	*PMMA test tubes with separatine gel, Ø13 x 75 mm, low cap*
3776/E/TB	Provetta Ø16 x 100 mm. in PP, con gel separatore, tappo basso marrone	*PP test tubes with separatine gel Ø 16 x 100 mm, brown low cap.*
3776/TB	gel separatore in prov. 16x100 pp+etichetta x 10 ml di sangue	*PP test tubes with separatine gel Ø 16 x 100 mm, low cap.*
3778/E	Provette Ø12 x 86 mm. in PP, con gel separatore	*PP test tubes with separating gel, Ø12 x 86 mm*
3778/E/TB	Provette Ø12 x 86 mm. in PMMA, con gel separatore, tappo basso	*PMMA test tubes with separating gel, Ø12 x 86 mm, low cap*
4875/E	Provette Ø13 x 75 mm. in PMMA, con granuli separatori + acceleratore	*PMMA test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/E	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/E/TB	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/ETB	Provette con granuli + acc. per 5ml di sangue, in PP,	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4876/TR/E	Provette Ø13 x 75 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 75 mm*
4878/E	Provette Ø12 x 86 mm. in PP, con granuli separatori + acceleratore, tappo azzurro	*PP test tubes with separating granules + clot accelerator, Ø12 x 86 mm, light blue cap*
4878/TR/E	Provette Ø12 x 86 mm. in PP, con granuli separatori + acceleratore, tappo rosso	*PP test tubes with separating granules + clot accelerator, Ø12 x 86 mm, light red cap*
4883/E	Provette Ø13 x 100 mm in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø13 x 100 mm*
4883/E/TN	Provette Ø13 x 100 mm in PP, con granuli separatori + acceleratore, tappo nero	*PP test tubes with separating granules + clot accelerator, Ø13 x 100 mm, black cap*
4884/E	Provette Ø16 x 100 mm. in PMMA, con granuli separatori + acceleratore	*PMMA test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4885	Provette Ø16 x 100 mm. in PS, con granuli separatori + acceleratore	*PS test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4885/E	Provette Ø16 x 100 mm. in PS, con granuli separatori + acceleratore	*PS test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4885/R	Provette Ø16 x 100 mm. in PS, con granuli separatori + acceleratore, tappo rosso	*PS test tubes with separating granules + clot accelerator, Ø16 x 100 mm, red cap*
4886/E	Provette Ø16 x 100 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4886/TR/E	Provette Ø16 x 100 mm. in PP, con granuli separatori + acceleratore	*PP test tubes with separating granules + clot accelerator, Ø16 x 100 mm*
4888/E	Provette Ø12 x 86 mm. in PMMA, con granuli separatori + acceleratore	*PMMA test tubes with separating granules + clot accelerator, Ø12 x 86 mm*
4888/EB	Provette Ø12 x 86 mm. in PMMA, con granuli separatori + acceleratore, tappo bianco	*PMMA test tubes with separating granules + clot accelerator, Ø12 x 86 mm, white cap*
5975/E	Provette Ø13 x 75 mm. in PMMA, con granuli separatori	*PMMA test tubes with separating granules, Ø13 x 75 mm*
5976/E	Provette Ø13 x 75 mm. in PP, con granuli separatori	*PP test tubes with separating granules, Ø13 x 75 mm*
5978/E	Provette Ø12 x 86 mm. in PP, con granuli separatori	*PP test tubes with separating granules, Ø12 x 86 mm*
5990	Granuli separatori in PS confezione da 1 Kg	Separating granules in PS
5993/E	Provette Ø13 x 100 mm in PP, con granuli separatori	*PP test tubes with separating granules, Ø13 x 100 mm*
5995/E	Provette Ø16 x 100 mm. in PMMA, con granuli separatori	*PMMA test tubes with separating granules, Ø16 x 100 mm*
5995/ER	Provette con granuli per 10ml di sangue, in PMMA,	*PMMA test tubes with separating granules, Ø16 x 100 mm*
5996/E	Provette Ø16 x 100 mm. in PP, con granuli separatori	*PP test tubes with separating granules, Ø16 x 100 mm*
5998/E	Provette Ø12 x 86 mm. in PMMA, con granuli separatori	*PMMA test tubes with separating granules, Ø12 x 86 mm*

Dulio BUONO
Responsabile Assicurazione Qualità

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

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der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD** **(Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /** **EG Annex III (expect point 6) of IVDD 98/79/EC** **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE** **Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 2022.12.14 General Manager

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

BOEN HEALTHCARE CO.,LTD 苏州柏恩贸易有限公司

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

BOEN HEALTHCARE CO., LTD
Unit 602, International Center, No.535, Shenxu Road,
Suzhou, 215021, Jiangsu, China

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Microscope Slide

der Klasse: /
of class: /
de la classe: /
di classe:

Common/Others IVD
(Devices of NOT Annex II and NOT self-test)

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d’évaluation de la conformité: /
Procedura di valutazione della conformità:

Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /
EG Annex III (expect point 6) of IVDD 98/79/EC
Annexe III (sauf le point 6) de l'IVDD 98/79 / CE
Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 2022.01.01

General Manager

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

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 orifizi 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, Is, 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, Is, 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*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

SSQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

DATA SHEET

LITHIUM HEPARIN

Polypropylene test tubes, with blue pressure cap, suitable for analysis in Clinical Chemistry and Immunology.

Cod.	Test Tubes	Blood
2403	Ø 12x86 mm	2.5 ml
2404	Ø 12x86 mm	5.0 ml
2407	Ø 16x100 mm	10.0 ml

cofrac
CERTIFICATION DE SYSTÈMES DE MANAGEMENT
accréditation
N° 4-0023
PORTÉE
DISPONIBLE
SUR
www.cofrac.fr

CERTIFICAT
CERTIFICATE

N° A 3001-9001

Nous certifions par la présente que le Système de Management de la société :
We hereby certify that the Management System of the company:

BIOLABO
LES HAUTES RIVES
02160 Maizy (France)

est conforme aux exigences de la norme suivante :
is in compliance with the requirements of the following standard:

ISO 9001 :2015

Le domaine d'application du Système de Management est le suivant :
The scope of the Management System is:

Conception, Fabrication et Vente de Dispositifs Médicaux de Diagnostic In Vitro. Support Technique et Service D'Assistance.

Design, Manufacturing and sale of in Vitro Diagnostic Medical Devices. Technical Support and Support Services.

Ce certificat demeurera en vigueur jusqu'à sa fin de validité à moins d'avis contraire, à condition que la mise en place et la conformité du Système du Management soient jugées satisfaisantes lors des audits de surveillance et que les conditions du contrat de AB Certification soient observées.
This certificate is valid until its expiry date unless further notice, provided that the compliance and implementation of the Management System are found to be satisfactory at follow-up audits and that AB Certification contract rules are fulfilled.

Fait à PARIS, le 13 décembre 2021
Signed in PARIS on the 13rd of December 2021

Date de fin de validité : 23 décembre 2024
Expiry date : 23rd of December 2024

Date initiale de Certification : 24 décembre 2018
Original Registration Date : 24th of December 2018

Georges ABI RACHED
Le Représentant d'AB Certification
AB Certification Representative

BIOLABO S.A.S.
Les Hautes Rives
02160 MAIZY - FRANCE
Siret 317 398 832 00038
TVA : FR 82 317 398 832

Le Représentant de l'Entreprise
The Company Representative

cofrac
CERTIFICATION DE SYSTÈMES DE MANAGEMENT
Accréditation N°4-0033
PORTÉE DISPONIBLE SUR www.cofrac.fr

AB certification

CERTIFICAT
CERTIFICATE

N° A 3001-13485

Nous certifions par la présente que le Système de Management de la société :
We hereby certify that the Management System of the company:

BIOLABO
LES HAUTES RIVES
02160 Maizy (France)

est conforme aux exigences de la norme suivante :
is in compliance with the requirements of the following standard:

ISO 13485 :2016

Le domaine d'application du Système de Management est le suivant :
The scope of the Management System is:

Conception, Fabrication et Vente de Dispositifs Médicaux de Diagnostic In Vitro. Support Technique et Service D'Assistance.

Design, Manufacturing and sale of in Vitro Diagnostic Medical Devices. Technical Support and Support Services.

Ce certificat demeurera en vigueur jusqu'à sa fin de validité à moins d'avis contraire, à condition que la mise en place et la conformité du Système du Management soient jugées satisfaisantes lors des audits de surveillance et que les conditions du contrat de AB Certification soient observées.
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Le Représentant d'AB Certification
AB Certification Representative

BIOLABO S.A.S.
Les Hautes Rives
02160 MAIZY - FRANCE
Tél. : 33 (0)3 23 25 15 50
Fax : 33 (0)3 23 25 62 56
SIRET 317 398 832 00038
TVA : FR 82 317 398 832

Le Représentant de l'Entreprise
The Company Representative

A qui de droit / *To whom it may concern*

DECLARATION DE CONFORMITE CE

DECLARATION OF EUROPEAN CONFORMITY

REACTIFS & INSTRUMENTS DE LABORATOIRE
LABORATORY REAGENTS & INSTRUMENTS

Je soussigné, Isabelle Oget, Directrice des Affaires Réglementaires de BIOLABO S.A.S., certifie par la présente que nos Réactifs Code HS 3822 00 00 et Instruments sont fabriqués par la société BIOLABO S.A.S sur le site de Maizy (F-02160) pour une distribution mondiale incluant l'Union Européenne.

I, the undersigned, Mrs Oget Isabelle, Regulatory Affairs Director of BIOLABO S.A.S, certify that our Reagents HS Code 3822 00 00 and Instruments
are manufactured by BIOLABO S.A.S in its Maizy facilities (Les Hautes Rives, F-02160, France) for a world-wide distribution including European Union (EU).

1) La procédure de déclaration de conformité suivie est conforme aux indications de l'Annexe III de la Directive Européenne DMDIV 98/79/CE.

   The conformity assessment procedure being followed is Annex III of the IVD Directive 98/79/EC

2) Les Produits désignés **(CONFORMEMENT A L' ANNEXE, 7 PAGES)** sont classés comme suit :

   Autres dispositifs (tous dispositif, sauf Annexe II et autotests)

   *These products (**ACCORDING TO ATTACHED LIST, 7 PAGES**) are classified as follows:*
   Other devices (all devices, except Annex II and self testing devices)

3) Ces produits remplissent toutes les exigences essentielles (Annexe I) de la Directive Européenne DMDIV 98/79/CE.

   These products fulfil the essential requirements (Annexe I) of European Directive IVDMD 98/79/EC.

4) Ces exigences sont documentées à l'aide de dossiers techniques incluant les informations suivantes :

   Essential requirements are reviewed by checking the technical files, including the following information:

   - Dossier de revue de conformité aux Exigences Essentielles.
     File for checking Essential Requirements of above mentioned European Directive.
   - Dossier de conception
     File for device's design
   - Dossier Performances (spécifications techniques)
     File for performance (technical specifications).
   - Description des Processus dans le Système Qualité

- *Process management (BIOLABO Standard Operating Procedures)*
- Référentiel d'étiquetage, Référentiel des notices
- *Labelling instructions and references, Package inserts instructions and references.*
- Dossiers de suivi des lots et retour d'information des utilisateurs.

  File for batches Traceability including customer's information
- Dossier d'analyse des risques, basé sur le référentiel EN ISO 14971.

  Risk Analysis, based on EN ISO 14971.

5) Le référentiel qualité de BIOLABO S.A.S. est certifié ISO 9001:2015 et ISO 13485 :2016 sous le N°A3001 par AB Certification (Organisme accrédité COFRAC).

   BIOLABO S.A.S Quality System Management is ISO 9001:2015 certified and ISO 13485:2016 certified under N°A3001, by AB Certification (Accredited Body by COFRAC).

6) Je déclare exactes et sincères les informations de la présente déclaration, certifiant que les produits désignés ci-dessus sont conformes aux exigences de la directive européenne 98/79/CE, lesquelles exigences sont intégralement remplies et documentées

   I declare that the above information is true and sincere, certifying the product mentioned above fully comply with European Directive 98/79/CE

7) Je m'engage à mettre à la disposition des autorités compétentes de la République Française tout élément d'information qui me serait demandé, y compris dans le cadre de vérifications requises par leurs homologues étrangers.

   I commit myself to provide to competent French Republic authorities any information which would be requested related to this product, whatever is the origin of such request which may come from their foreign homologues.

La présente déclaration est établie à Maizy, France, le 12 février 2021 et pour valoir ce que de droit

This Declaration is issued at Maizy, France, on 12 February 2021.

BIOLABO S.A.S.
Les Hautes Rives
02160 MAIZY - FRANCE
Phone : 33 (0)3 23 25 15 50
Fax : 33 (0)3 23 25 62 56
Siret 317 398 832 00038
TVA : FR 82 317 398 832

I. OGET

DIRECTION DES AFFAIRES REGLEMENTAIRES
REGULATORY AFFAIRS DIRECTOR

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs de Biochimie poudre polyvalents / Versatile Biochemistry powder reagents	
80351	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
80001	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
87601	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
99029	ALCOOL Ethanol	ALCOHOL Ethanol
99059	ALCOOL Ethanol	ALCOHOL Ethanol
80027	ALT / TGP (IFCC) Monoréactif	ALT / GPT (IFCC) Single vial
80127	ALT / TGP (IFCC) Monoréactif	ALT / GPT (IFCC) Single vial
80227	ALT / TGP (IFCC) Monoréactif	ALT / GPT (IFCC) Single vial
80327	ALT / TGP (IFCC) Monoréactif	ALT / GPT (IFCC) Single vial
92027	ALT / TGP Méthode Colorimétrique	ALT / GPT Colorimetric Method
99261	AMMONIAC Méthode Enzymatique	AMMONIA Enzymatic Method
99523	AMYLASE CNPG3	AMYLASE CNPG3
99123	AMYLASE CNPG3	AMYLASE CNPG3
99223	AMYLASE CNPG3	AMYLASE CNPG3
80025	AST / TGO (IFCC) Monoréactif	AST / GOT (IFCC) Single vial
80125	AST / TGO (IFCC) Monoréactif	AST / GOT (IFCC) Single vial
80225	AST / TGO (IFCC) Monoréactif	AST / GOT (IFCC) Single vial
80325	AST / TGO (IFCC) Monoréactif	AST / GOT (IFCC) Single vial
92025	AST / TGO Méthode Colorimétrique	AST / GOT Colorimetric Method
99832	BICARBONATE Méthode Enzymatique	BICARBONATE Enzymatic Method
99852	BICARBONATE Méthode Enzymatique	BICARBONATE Enzymatic Method
80553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
97553	BILIRUBINE DIRECTE Méthode DCA	DIRECT BILIRUBIN DCA Method
97443	BILIRUBINE TOTALE Méthode DCA	TOTAL BILIRUBIN DCA Method
97408	C.L.F. Capacité Latente de Fixation du Fer	U.I.B.C Unsaturated Iron Binding Capacity
92308	C.T.F. Capacité Totale de Fixation du Fer	T.I.B.C. Total Iron Binding Capacity
80106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
87656	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
87356	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
88656	CHOLESTEROL Non estérifié CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP
99656	CHOLESTEROL Non estérifié CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP
86536	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Precipitant
86516	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Precipitant
82526	CHOLINESTERASE Butyrylthiocholine	CHOLINESTERASE Butyrylthiocholine
92207	CK-NAC IFCC Monoréactif	CK-NAC IFCC Single Vial
92307	CK-NAC IFCC Monoréactif	CK-NAC IFCC Single Vial
80008	FER (SFBC) Bathophénanthroline	IRON (SFBC) Bathophenanthrolin
97099	G6-PDH lyophilisée Méthode cinétique U.V.	Lyophilised G6-PDH U.V. Kinetic Method
97089	G6-PDH Méthode cinétique U.V.	G6-PDH U.V. Kinetic Method
97199	G6-PDH Méthode Automatisée	G6-PDH Automated Method
81110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
81210	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
81310	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
80009	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
87109	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
87409	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
16GL8	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
82250	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
97217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
97317	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
92011	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
92111	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
92511	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
99881	LIPASE Méthode cinétique	LIPASE Kinetic Method
99891	LIPASE Méthode cinétique	LIPASE Kinetic Method
87212	MAGNESIUM Calmagite	MAGNESIUM Calmagite

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs de Biochimie poudre polyvalents / Versatile Biochemistry powder reagents	
82560	PHOSPHATASE ACIDE Méthode Cinétique	ACID PHOSPHATASE Kinetic Method
3300060	PHOSPHATASE ACIDE Méthode Point Final (PNPP)	ACID PHOSPHATASE End Point Method (PNPP)
92214	PHOSPHATASE ALCALINE (DEA)	ALKALINE PHOSPHATASE DEA Method
92314	PHOSPHATASE ALCALINE (DEA)	ALKALINE PHOSPHATASE DEA Method
99105	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDS Colorimetric enzymatic Method
99110	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDS Colorimetric enzymatic Method
80016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
92026	Solution Soude 0,4 N	NaOH Solution 0.4 N
80019	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
87319	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
80221	UREE Méthode colorimétrique	UREA Colorimetric Method
80321	UREE Méthode colorimétrique	UREA Colorimetric Method
92032	UREE U.V. Méthode Cinétique	UREA U.V. Kinetic Method
92132	UREE U.V. Méthode Cinétique	UREA U.V. Kinetic Method
99032	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
99132	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
92315	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method
92330	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method
	Réactifs de Biochimie liquide prêt à l'emploi polyvalents / Versatile Biochemistry ready-to-use liquid reagents	
LP80501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
LP80601	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
80002	ALBUMINE Méthode BCG	ALBUMIN BCG Method
80107	CREATININE Méthode cinétique	CREATININE Kinetic method
90107	CREATININE Méthode Enzymatique	CREATININE Enzymatic method
80005	CHLORURES Méthode Colorimétrique	CHLORIDE Colorimetric Method
80015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHORUS U.V. Method
3502200	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
LP80507	ALT TGP (IFCC)	ALT GPT (IFCC)
LP80607	ALT TGP (IFCC)	ALT GPT (IFCC)
LP99553	AMYLASE CNPG3	AMYLASE CNPG3
LP80505	AST TGO (IFCC)	AST GOT (IFCC)
LP80605	AST TGO (IFCC)	AST GOT (IFCC)
92108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
80403	BILIRUBINE TOTALE ET DIRECTE Méthode Acide Sulfanilique	TOTAL AND DIRECT BILIRUBIN Sulfanilic Acid Method
80443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
90004	CALCIUM Méthode Arsenazo III	CALCIUM Arsenazo III Method
80004	CALCIUM Méthode CPC	CALCIUM CPC Method
LP80106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
90206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90406	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90426	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
90816	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
LP80209	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
LP87809	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
98212	MAGNESIUM CALMAGITE Haute Stabilité - Haute Linéarité	MAGNESIUM CALMAGITE High Stability – High Linearity
LP87016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
97016	PROTEINES U.S. Méthode Rouge de Pyrogallol	U.S. PROTEIN Pyrogallol Red Method
LP80519	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
LP80619	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
LP99532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
LP99632	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs dédiés pour KENZA One / Dedicated reagents for KENZA One	
K1501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
K1002	ALBUMINE Méthode BCG	ALBUMIN BCG Method
K1507	ALT / TGP (IFCC)	ALT / GPT (IFCC)
K1523	AMYLASE CNPG3	AMYLASE CNPG3
K1ASO	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
K1505	AST / TGO (IFCC)	AST / GOT (IFCC)
K1553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
K1443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
K1004	CALCIUM Méthode Arsenazo III	CALCIUM Arsenazo III Method
K1005	CHLORURES Méthode Colorimétrique	CHLORIDE Colorimetric Method
K1106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
K1206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
K1416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
K1207	CK-NAC IFCC	CK-NAC IFCC
K1107	CREATININE Méthode cinétique	CREATININE Kinetic method
K1117	CREATININE Méthode Enzymatique	CREATININE Enzymatic method
K150E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
K1210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
K1RF1	FACTEURS RHUMATOIDES (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
K1108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
K1508	FERRITIN	FERRITIN
K1110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
K1209	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
K1010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
K1217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
K1011	L.D.H. (LDH-P) Méthode DGKC	L.D.H. (LDH-P) DGKC Method
K1212	MAGNESIUM CALMAGITE	MAGNESIUM CALMAGITE
K1214	PHOSPHATASE ALCALINE Méthode DEA	ALKALINE PHOSPHATASE DEA Method
K1015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHORUS U.V. Method
K1084	POTASSIUM Enzymatique	POTASSIUM Enzymatic
K1016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEINS Biuret Method
K1085	SODIUM Enzymatique	SODIUM Enzymatic
K1208	TRANSFERRIN	TRANSFERRIN
K1519	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
K1532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
K1701	VITAMIN D	VITAMIN D
K1901	ZINC	ZINC
	Réactifs dédiés pour KENZA 240 et KENZA 450 TX/ISE / Dedicated reagents for KENZA 240 and KENZA 450 TX/ISE	
K2501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
K4501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
K2002	ALBUMINE Méthode BCG	ALBUMIN BCG Method
K2507	ALT / TGP (IFCC)	ALT / GPT (IFCC)
K4507	ALT / TGP (IFCC)	ALT / GPT (IFCC)
K2523	AMYLASE CNPG3	AMYLASE CNPG3
K4523	AMYLASE CNPG3	AMYLASE CNPG3
K2ASO	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
K4ASO	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
K2505	AST / TGO (IFCC)	AST / GOT (IFCC)
K4505	AST / TGO (IFCC)	AST / GOT (IFCC)
K2553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
K4553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
K2443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
K4443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
K2004	CALCIUM Méthode Arsenazo III	CALCIUM Arsenazo III Method
K2005	CHLORURES Méthode Colorimétrique	CHLORIDE Colorimetric Method
K2106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
K2206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
K4206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
K2416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
K4416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs dédiés pour KENZA 240 et KENZA 450 TX/ISE / Dedicated reagents for KENZA 240 and KENZA 450 TX/ISE	
K2207	CK-NAC IFCC	CK-NAC IFCC
K4207	CK-NAC IFCC	CK-NAC IFCC
K2107	CREATININE Méthode cinétique	CREATININE Kinetic method
K2117	CREATININE Méthode Enzymatique	CREATININE Enzymatic method
K4117	CREATININE Méthode Enzymatique	CREATININE Enzymatic method
K250E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
K2210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
K4210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
K2RF1	FACTEURS RHUMATOIDES (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
K4RF1	FACTEURS RHUMATOIDES (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
K2108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
K4108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
K2508	FERRITIN	FERRITIN
K4508	FERRITIN	FERRITIN
K2110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
K4110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
K2209	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
K2010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
K4010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
K2217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
K4217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
K2011	L.D.H. (LDH-P) Méthode DGKC	L.D.H. (LDH-P) DGKC Method
K4011	L.D.H. (LDH-P) Méthode DGKC	L.D.H. (LDH-P) DGKC Method
K2212	MAGNESIUM CALMAGITE	MAGNESIUM CALMAGITE
K2214	PHOSPHATASE ALCALINE Méthode DEA	ALKALINE PHOSPHATASE DEA Method
K4214	PHOSPHATASE ALCALINE Méthode DEA	ALKALINE PHOSPHATASE DEA Method
K2015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHORUS U.V. Method
K2084	POTASSIUM Enzymatique	POTASSIUM Enzymatic
K2016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEINS Biuret Method
K2017	PROTEINES U.S. Méthode Rouge de Pyrogallol	U.S. PROTEIN Pyrogallol Red Method
K2085	SODIUM Enzymatique	SODIUM Enzymatic
K2208	TRANSFERRIN	TRANSFERRIN
K4208	TRANSFERRIN	TRANSFERRIN
K2519	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
K2532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
K4532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
K2701	VITAMIN D	VITAMIN D
K4701	VITAMIN D	VITAMIN D
K2901	ZINC	ZINC
K4901	ZINC	ZINC
	Calibrants et contrôles de biochimie / Biochemistry calibrators and controls	
95010	EXATROL-N Taux 1	EXATROL-N Level 1
95110	EXATROL-N Taux 1	EXATROL-N Level 1
95011	EXATROL-P Taux 2	EXATROL-P Level 2
95111	EXATROL-P Taux 2	EXATROL-P Level 2
95015	MULTICALIBRATOR Calibrateur Multiparamétrique	MULTICALIBRATOR Multiparametric calibrator
95115	MULTICALIBRATOR Calibrateur Multiparamétrique	MULTICALIBRATOR Multiparametric calibrator
95801	Calibrant LIPASE	LIPASE Calibrator
95406	CALIBRATEUR CHOLESTEROL-HDL	HDL-CHOLESTEROL CALIBRATOR
95806	CALIBRATEUR CHOLESTEROL-LDL	LDL-CHOLESTEROL CALIBRATOR
95506	CALIBRATEUR HDL LDL CK-MB	HDL LDL CK-MB CALIBRATOR
95013	Contrôle Normal AMMONIAC ALCOOL BICARBONATE	Normal Control AMMONIA ALCOHOL BICARBONATE
95023	Contrôle Pathologique AMMONIAC ALCOOL BICARBONATE	Pathological Control AMMONIA ALCOHOL BICARBONATE
95012	Contrôle urinaire Taux 1 et Taux 2	Urinary Control Level 1 and Level 2
95289	G6-PDH Contrôle Déficient (hémolysat humain lyophilisé)	G6-PDH Deficient control (Lyophilised human hemolysed blood)
95089	G6-PDH Contrôle normal (hémolysat humain lyophilisé)	G6-PDH Normal control (Lyophilised human hemolysed blood)
97599	G6-PDH Control Set	G6-PDH Control Set
95315	KIT CALCULS URINAIRES Contrôles Positifs et Négatifs	STONE ANALYSIS SET Positive and Negative Controls
95516	Sérum de contrôle HDL LDL CK-MB Lipides Taux 1	Control serum HDL LDL CK-MB Lipids Level 1
95526	Sérum de contrôle HDL LDL CK-MB Lipides Taux 2	Control serum HDL LDL CK-MB Lipids Level 2

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
	Réactifs d'hémostase / Haemostasis reagents	
13560	BIO-CK TCA Kaolin	BIO-CK APTT Kaolin
13570	BIO-CK TCA Kaolin	BIO-CK APTT Kaolin
13450	BIO-FIBRI Dosage Chronométrique du Fibrinogène	BIO-FIBRI Chronometric determination of Fibrinogen
13451	BIO-FIBRI Dosage Chronométrique du Fibrinogène	BIO-FIBRI Chronometric determination of Fibrinogen
13660	BIO-SIL TCA Silice	BIO-SIL APTT Silica
13670	BIO-SIL TCA Silice	BIO-SIL APTT Silica
13702	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13704	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13712	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13880	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13885	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13881	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13980	BIO-TT Temps de Thrombine	BIO-TT Thrombin Time
13565	CHLORURE DE CALCIUM 0,025M	CALCIUM CHLORIDE 0.025M
13302	FACTOR II Plasma Déficient	FACTOR II Deficient plasma
13309	FACTOR IX Plasma Déficient	FACTOR IX Deficient plasma
13305	FACTOR V Plasma Déficient	FACTOR V Deficient plasma
13307	FACTOR VII Plasma Déficient	FACTOR VII Deficient plasma
13308	FACTOR VIII Plasma Déficient	FACTOR VIII Deficient plasma
13310	FACTOR X Plasma Déficient	FACTOR X Deficient plasma
13311	FACTOR XI Plasma Déficient	FACTOR XI Deficient plasma
13312	FACTOR XII Plasma Déficient	FACTOR XII Deficient plasma
13883	TAMPON OWREN KOLLER	OWREN KOLLER BUFFER
	Calibrants et contrôles d'hémostase / Haemostasis calibrators and controls	
13965	TP-CALSET Set de Plasmas de Référence	TP-CALSET Standard Set
13970	BIO-CAL Plasma de référence	BIO-CAL Reference Plasma
13961	PLASMA CONTRÔLE Taux 1	CONTROL PLASMA Level 1
13962	PLASMA CONTRÔLE Taux 2	CONTROL PLASMA Level 2
13963	PLASMA CONTRÔLE Taux 3	CONTROL PLASMA Level 3
13210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
13211	D-DIMER Control 1	D-DIMER Control 1
13212	D-DIMER Control 2	D-DIMER Control 2
13971	COATROL 1 Taux 1	COATROL 1 Level 1
13972	COATROL 2 Taux 2	COATROL 2 Level 2

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
Réactifs calibrants et contrôles d'Immunoturbidimétrie / Turbidimetric Immunoassay reagents, calibrators and controls		
RF050E	Facteurs Rhumatoides (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
RF520E	Facteurs Rhumatoides (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
RF CALSET51	BIOLABO FR Kit de Calibration	BIOLABO RF Standard Set
RF CALSH1	BIOLABO FR Calibrant Super Haut	BIOLABO RF Standard Super High
RF CONT1	BIOLABO FR Contrôle	BIOLABO RF Control
RF CONT5	BIOLABO FR Contrôle	BIOLABO RF Control
CRP050E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP620E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP CALSET51	BIOLABO CRP Kit de Calibration	BIOLABO CRP Standard Set
CRP CALSH1	BIOLABO CRP Calibrant Super Haut	BIOLABO CRP Standard Super High
CRP CONTL1	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP CONTL5	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP CONTH1	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
CRP CONTH5	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
ASLO050E	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO620E	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO CALH1	BIOLABO ASLO Calibrant Haut	BIOLABO ASLO Standard High
ASLO CALSH1	BIOLABO ASLO Calibrant Super Haut	BIOLABO ASLO Standard Super High
ASLO CALSET41	BIOLABO ASLO Kit de Calibration	BIOLABO ASLO Standard Set
ASLO CONT1	BIOLABO ASLO Contrôle	BIOLABO ASLO Control
ASLO CONT5	BIOLABO ASLO Contrôle	BIOLABO ASLO Control
23010	MICROALBUMINE Test Immunoturbidimétrique	MICROALBUMIN Turbidimetric Immunoassay
23011	MICROALBUMINE Test Immunoturbidimétrique	MICROALBUMIN Turbidimetric Immunoassay
23012	MICROALBUMINE Calibrant Super Haut	MICROALBUMIN Standard Super High
23013	MICROALBUMINE Kit de calibration	MICROALBUMIN Standard Set
23014	MICROALBUMINE Contrôle	MICROALBUMIN Control
22050	HbA1c ENZYM	HbA1c ENZYM
22052	HbA1c ENZYM Kit de calibration	HbA1c ENZYM Standard Set
22010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
22011	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
22012	HbA1c Kit de calibration	HbA1c Standard Set
22013	HbA1c Kit de contrôle	HbA1c Control Set
Tests sur lame / Slide tests		
9905TH	S. Typhi H (d.H)	S. Typhi H (d.H)
9905TO	S. Typhi O (9,12-O)	S. Typhi O (9,12-O)
9905AH	S. Paratyphi AH (a-H)	S. Paratyphi AH (a-H)
9905AO	S. Paratyphi AO (1,2,12-O)	S. Paratyphi AO (1,2,12-O)
9905BH	S. Paratyphi BH (b-H)	S. Paratyphi BH (b-H)
9905BO	S. Paratyphi BO (1,4,5-O)	S. Paratyphi BO (1,4,5-O)
9905CH	S. Paratyphi CH (c-H)	S. Paratyphi CH (c-H)
9905CO	S. Paratyphi CO (6,7-O)	S. Paratyphi CO (6,7-O)
9905BA	Brucella abortus	Brucella Abortus
9905PK	Proteus OXK	Proteus OXK
9905P19	Proteus OX19	Proteus OX19
9905P2	Proteus OX2	Proteus OX2
9905BM	Brucella Melitensis	Brucella Melitensis
9905RB	Rose Bengal (B. Abortus)	Rose Bengal (B. Abortus)
9901PC	Contrôle Positif Polyvalent	Positive Polyvalent Control
9901NC	Contrôle Négatif Polyvalent	Negative Polyvalent Control
99058	ANTIGENES FEBRILES Pour Tests de Widal Félix	STAINED FEBRILE ANTIGENS For Widal Felix Tests
081050	ASLO-LATEX	ASLO-LATEX
097100	CRP-LATEX	CRP-LATEX
098100	FR-LATEX	FR-LATEX
3800100	RPR-CHARBON	RPR-CHARBON
3800150	RPR-CHARBON	RPR-CHARBON
4500100	TPHA	TPHA
4500200	TPHA	TPHA
085100	HCG-LATEX	HCG-LATEX

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
Analyseurs / Analysers		
KENZA MAX	KENZA MAX BioChemisTry PHOTOMETRE	KENZA MAX BioChemisTry PHOTOMETER
KENZA ONE	KENZA ONE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA ONE - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240TX	KENZA 240TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 240TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240ISE	KENZA 240ISE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE avec module ISE	KENZA 240ISE - AUTOMATIC BIOCHEMISTRY ANALYSER with ISE Module
KENZA 450TX	KENZA 450TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 450TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 450ISE	KENZA 450ISE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 450ISE - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 120TX	KENZA 120TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 120TX - AUTOMATIC BIOCHEMISTRY ANALYSER
BIOSOLEA 2	BIO SOLEA 2 - COAGULOMETRE 2 CANAUX	BIO SOLEA 2 - COAGULOMETER 2 CHANNELS
BIOSOLEA 4	BIO SOLEA 4 - COAGULOMETRE 4 CANAUX	BIO SOLEA 4 - COAGULOMETER 4 CHANNELS
SOLEA 100	SOLEA 100 - ANALYSEUR AUTOMATIQUE D'HEMOSTASE	SOLEA 100 - FULL AUTOMATED COAGULATION ANALYSER
Consommables et solutions de nettoyage / Consumables and cleaning solutions		
SCUP120	Serum Cup K120TX	Serum Cup K120TX
CO0080	SERUM CUPS	SERUM CUPS
CO4015	EXTRA Cleaning	EXTRA Cleaning
CO4020	IPO Cleaning	IPO Cleaning
CO0058	SERUM CUPS K450	SERUM CUPS K450
K450CS	Cleaning Solution K450	Cleaning Solution K450
RP240ISE	Pack Réactifs - ISE	Reagent Pack - ISE
G2058/A	Cleaning Solution - ISE	Cleaning Solution - ISE
5202	Electrode K - ISE	Electrode K - ISE
5205	Electrode Li - ISE	Electrode Li - ISE
5207	Electrode Cl - ISE	Electrode Cl - ISE
5201	Electrode Na - ISE	Electrode Na - ISE
5204	Electrode de référence	Reference Electrode
S100CS	CLEANING SOLUTION SOLEA 100	CLEANING SOLUTION SOLEA 100

Certificate of Registration

This certificate has been awarded to

AO Vector-Best

3, Pasechnaya str., Novosibirsk, 630117, Russian Federation

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Design, Development, and Production of In Vitro Diagnostic Medical Devices (ELISA, PCR)

Certificate Number **209535/A/0003/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
05 October 2022	1	04 October 2025	1
Revision Date	**Revision Number**	**Original Certificate Issue Date**	**Scheme Number**
06 October 2022	1	05 October 2022	n/a

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

On behalf of the Schemes Manager

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:
9362-8

Initial Certification Date:
March 28, 2012

Date of Certification Decision:
March 24, 2021

Issuing Date:
March 27, 2021

Valid Until:
March 27, 2024

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

BOEN HEALTHCARE CO., LTD.

Certificate of Analysis

Report No.: GM03-BN23

Product Name	Blood Lancet	Specification	28G
Lot. No.	230401	Mfg. Date	2023-04
Exp. Date	2028-03	Order Quantity	20000pcs
Sampling Quantity	100pcs	Inspection Date	2023.05.15
Inspection Standard	Factory Standard	Report Date	2023.05.15

Item	Technical Requirement	Result	Conclusion
Appearance	The lancet shall be clean, no foreign impurities.	Comply	Qualified
	The lancet shall be no injection defects such as burr, fly edges, bubble, etc.	Comply	Qualified
Lancet	The needle should be smooth, no defects.	Comply	Qualified
	The needle is sharp.	Comply	Qualified
Firmness	The needle is firmly connected with the base.	Comply	Qualified
Sterile	The lancet shall be sterile.	Comply	Qualified
Conclusion	Meet the requirement		

Inspector: Tom Li
Date: 2023.05.15

Checker: Leo Sun
Date: 2023.05.15

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1614112-1

Organization: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

Scope: Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1092786-40
Effective date: 2021-10-25
Expiry date: 2024-10-15
Issue date: 2021-10-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dipl.-Ing. F. Schwingen
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1614112-1

Organization: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Germany	Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices
/02	c/o KABE-Labortechnik GmbH Werner-von-Siemens-Str. 1 51674 Wiehl Germany	Warehouse

Report No.: 1092786-40
Effective date: 2021-10-25
Expiry date: 2024-10-15
Issue date: 2021-10-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dipl.-Ing. F. Schwingen
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60150763 0001

Report No.: 21234760 013

Manufacturer:
KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products:
- Cannulas for blood collection
- MBU Capillaries
(see attachment for details)

Replaces certificate, Registration No.: HD 60105393 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2020-10-07

Date: 2020-10-07

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60150763 0001
Report No.: 21234760 013

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products included:

- Cannulas for blood collection

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- MBU Capillaries

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2020-10-07

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM Opto Semiconductors GmbH

Leibnizstraße 4
93055 Regensburg
Germany

has established and applies
a Quality Management System for

Design and manufacturing of
opto semiconductor wafer,
opto electronic components and displays
(with Product Design as per Chapter 8.3).

An audit was performed and has furnished proof
that the requirements according to

IATF 16949

First Edition 2016-10-01

are fulfilled.

Issue date: **2021-08-10**

Expiry date: **2024-08-09**

Certificate Registration No.: **12 111 46091/05 TMS**

IATF Certificate No.: **0416349**

Part of the certificate is an appendix.

Head of Certification Body
Munich, 2021-08-12

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

Appendix of Certificate Registration No.: 12 111 46091/05 TMS
IATF Certificate No.: 0416349

OSRAM Opto Semiconductors GmbH
Leibnizstraße 4
93055 Regensburg
Germany

The site is supported by the following remote locations:

Address	Supporting functions
OSRAM Opto Semiconductors, Inc. Kifer Road 1150 Sunnyvale, California, CA 94086 USA	Customer service, Logistics
OSRAM GmbH Marcel-Breuer-Straße 6 80807 München Germany	Policy making, Quality system management, Sales

Head of Certification Body
Munich, 2021-08-12

MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
01 сентября 2021 – 31 августа 2024

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация, 196240

была признана соответствующей стандарту:

ISO 9001:2015

Настоящий сертификат действителен для следующей области:

ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.

Место и дата:
Espoo, 18 июня 2021

От выпускающего офиса:
DNV - Business Assurance
Keilaranta 1, 02150 Espoo, Finland

Kimmo Haarala
Представитель руководства

Невыполнение условий Договора на сертификацию делает данный Сертификат недействительным.

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com
IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n.
CERTIFICATE No. **4265/5/B**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ROLL S.r.l.

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Leonardo Da Vinci, 24A - Zona Industriale Tognana - 35028 Piove di Sacco (PD) Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Injection moulding of thermoplastic materials for medical devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0860CM_03_IT

produzione articoli per laboratorio analisi
disposable labware

DICHIARAZIONE DI CONFORMITÁ CE

EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CEE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***ROLL S.r.l.***

produzione articoli per laboratori analisi / disposable labware

indirizzo / *address*: ***Via L. da Vinci, 24/A***
35028 Piove di Sacco (PD) - Italia

telefono / *phone* ***++39-049-9703144*** fax / *fax* ***++39-049-9719542*** posta elettronica / *e-mail* ***roll@tecnomeus.it***

identificazione dei prodotti / *product identification*

Produzione in plastica monouso di provette, tappi, puntali, tazzine e articoli per strumentazione, contenitori, piastre di petri, pipette pasteur, camere di conteggio in plastica (vetrini per sedimenti urinari) anse sterili, siringhe per dispensatori e provette con tappo a doppia posizione, sonde di prelievo urine, contenitori con dispositivo di prelievo urine, KIT per urine (provette + contenitori o sonde)

Production of disposable plastic tubes, stoppers, tips, cups and products for instruments, containers, petri dishes, Pasteur pipettes, plastic counting chambers (slides for urinary sediments) sterile loops, syringes for automatic dispensers and test tubes with two-position closure cup, urine transfer straws, containers with urine device, urine KIT (test tubes + containers or transfer straws).

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CEE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CEE e s.m.i."*Dispositivi Medico–Diagnostici In Vitro"*.

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/CE as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III of the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Piove di Sacco, 27/10/2021**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
GIOVANNI CHIARIN

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ФСР 2009/05681

от **15 сентября 2009 года** Срок действия: **не ограничен.**

Настоящее удостоверение выдано

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

и подтверждает, что изделие медицинского назначения
(изделие медицинской техники)

Дозаторы пипеточные, одно- и многоканальные, "Блэк"
по ТУ 9443-008-33189998-2009

производства

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

класс потенциального риска **2а** ОКП **94 4370**

соответствующее комплекту регистрационной документации

КРД № 33014 от 09.07.2009

приказом Росздравнадзора **от 15 сентября 2009 года № 7252-Пр/09**

разрешено к производству, продаже и применению на территории Российской Федерации

Руководитель Федеральной службы
по надзору в сфере здравоохранения
и социального развития **Н.В. Юргель**

006376

Бланк изготовлен ЗАО «ОПЦИОН» (лицензия № 05-05-09/003 ФНС РФ, уровень В), договор РД № 08/63, тел. (495) 648 6068, 608 7617, г. Москва, 2008 г.

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Microscope Cover Glass**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	

CE

Suzhou, 201.05.26

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data	Name und Funktion / Name and function / Nom et fonction / Nome e funzione

МиниМед
поставщик лабораторий

241520, г. Брянск, Супонево, ул. Шоссейная, 17 А
Тел. (4832) 92-97-97, 92-24-53, -55, -56, -57, -58, -60, -62
Факс (4832) 92-24-54, 92-24-59, 92-24-61
www.minimed.ru e-mail: info@minimed.ru
Р/с 40702810308000100320 Брянское ОСБ № 8605 г. Брянск
К/с 30101810400000000601 ИНН 3234007127 БИК 041501601
КПП 320701001 ОКПО 29508133

Код ОКП 54 3920

Паспорт
Бумага фильтровальная лабораторная Гост 12026-76

Изготовитель: ОАО «Лальская бумажная фабрика»_____
Расфасована в ООО «МиниМед»_____

1. Назначение

Предназначена для лабораторных работ.

2. Основные технические характеристики

1. Марка «Ф» - средней фильтрации (для общелабораторных работ).
2. Бумага имеет равномерный просвет.
3. Фильтровальная бумага не имеет складок, загрязненных пятен, разрывов кромки бумаги и дырчатости.

№ п/п	Наименование показателей	Норма для марки «Ф»	Фактические данные
1	Масса бумаги площадью 1м², г…….	75±3	74,5
2	Сопротивление продавливанию во влажном состоянии, кПа, не менее……..	5	5,88
3	Фильтрующая способность, с, не более ……..	45	34
4	Разделительная способность (задерживает осадок)……..	сернокислого свинца холод. осажд.	задерживает
5	Массовая доля золы, %, не более……..	0,20	0,14
6	Массовая доля железа, %, не более……..	0,0040	0,0021
7	Число соринок на 1м² площадью ед. 0,1 до 0,5 мм², не более……..	150	100
	площадью св. 0,5 мм²	не допускается	
8	Влажность, проц……	6±2	6,1
9	Белизна, %, не менее……	80	80

4. Размер 21*21см ± 0,5 см; вес 1 кг.
5. Размер 84*84 см ± 0,5 см; вес 5 кг.

3. Маркировка, упаковка, транспортирование и хранение

Маркировка, упаковка, транспортирование и хранение бумаги фильтровальной – по ГОСТ 1641.

Бумага фильтровальная марки «Ф» соответствует ГОСТ 12026-76.

Начальник ОТК А. Н. Захаров

МИНИМЕД ДОКУМЕНТЫ Брянск

КОПИЯ ВЕРНА

ООО "МиниМед", 241520, Российская Федерация, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, 17 А

Тел. (4832) 92-97-97, 92-24-52, -53, -55, -56, -57, -58, -60, -61, -62
Многоканальный номер - 8-800-100-48-32
Факс (4832) 92-24-54, 92-24-59, 92-24-61

ИНН 3234007127 www.minimed.ru e-mail: info@minimed.ru

Регистрационное удостоверение № РЗН 2016/4740 от 29.05.2017

Паспорт

Посуда мерная лабораторная для клинических исследований стеклянная по ТУ 9464-013-52876351-2014

Цилиндры мерные с носиком на стеклянном основании

1. Назначение

Предназначены для отмеривания определенного объема нелетучих жидкостей.

2. Основные технические характеристики

Наименование	Вместимость, $см^3$	Допустимая погрешность, $см^3$	Цена деления, $см^3$	Высота не более, мм
Цилиндр 1-10-2	10	± 0,2	0,2	140
Цилиндр 1-25-2	25	± 0,5	0,5	170
Цилиндр 1-50-2	50	± 1,0	1,0	200
Цилиндр 1-100-2	100	± 1,0	1,0	260
Цилиндр 1-250-2	250	± 2,0	2,0	335
Цилиндр 1-500-2	500	± 5,0	5,0	390
Цилиндр 1-1000-2	1000	± 10,0	10,0	470
Цилиндр 1-2000-2	2000	± 20,0	20,0	570

1. Цилиндры изготовлены по ТУ 9464-013-52876351-2014 в соответствии с техническими требованиями ГОСТ 1770-74.
2. Изготовлены из стекла ХС1 по ГОСТ 21400-75.
3. Исполнение 1 – с носиком, класс точности 2.
4. Буква «Н» в маркировке, обозначает наливной, вымеряемый «по наполнению».

3. Упаковывание, транспортирование и хранение

Упаковка изделий обеспечивает их сохранность при транспортировке. Транспортная упаковка имеет надпись: «Осторожно, стекло». Условия транспортирования изделий - по ГОСТ 15150-69 в крытом транспорте любого вида. Условия хранения - по ГОСТ 15150-69.

4. Требования безопасности

При эксплуатации необходимо соблюдать правила безопасности при работе со стеклянными изделиями. Изделия не должны подвергаться резким ударам в процессе эксплуатации.

5. Сведения об утилизации

Изделия не представляют опасности для окружающей среды, жизни и здоровья людей после окончания срока службы. Порядок утилизации изделий определяется Потребителем.

6. Гарантии изготовителя

Изготовитель: ООО «МиниМедПром», 242600, Россия, Брянская область, г. Дятьково, ул. Ленина, д. 182, корп. 5.

Изготовитель гарантирует соответствие цилиндров мерных с носиком на стеклянном основании требованиям ТУ 9464-013-52876351-2014 и ГОСТ 1770-74 при соблюдении потребителем условий транспортирования, хранения и эксплуатации. Гарантийный срок эксплуатации — 12 месяцев со дня ввода в эксплуатацию.

7. Свидетельство о приемке

Изделия изготовлены в соответствии с действующей технической документацией и признаны годными для эксплуатации.

Начальник ОТК **Грузинцев С.А.**