CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

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 ed 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. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici 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. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

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

Digitally signed by Ceaicovschi Tudor
Date: 2023.03.01 11:06:41 EET
Reason: MoldSign Signature
Location: Moldova

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	2020-10-30	2023-10-29

Settore IAF 14 - 29

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

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

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 13485-2016 (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. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici 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. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

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.
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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	2020-10-30	2023-10-29

SGQ 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

Declaration of CE conformity

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

Teugseweg 20
7418 AM Deventer
The Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T.Baker® label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III. The BeneSphera™ 3 Part Diff Analyzer H32 is in compliance with IEC 61010, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self-registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

January 6, 2015

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker® product list for CE marked products

Product no.	Product	Pack size
Hematology Analyzer		
2983	BeneSphera™ 3-part Diff Hematology Analyzer H32	1 unit
Clinical Chemistry Analyzer		
2946	BeneSphera™ Clinical Chemistry Analyzer C72	1 unit
Diluents		
3961	Diluid 100 Plus	20 liter
2990.9010PC	Diluid™ 22	10 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9020	Diluid Abacus	20 liter
3430.9010	Diluid Abacus	10 liter
3996	Diluid AC 900	20 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
2901.9010PC	Diluid BS34	10 liter
3963	Diluid III Diff	20 liter
3963.9010	Diluid III Diff	10 liter
3459.9020	Diluid Erma	20 liter
3419.9020PC	Diluid M5	20 liter
3439.9020PC	Diluid Mindray	20 liter
3483.9020PC	Diluid NR	20 liter
2987.9020PC	Diluid Ruby	20 liter
3832.9020	Diluid/Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3495.9010PC	Sheath D	10 liter
3471.9020PC	Sheath Fluid 3000/3500	20 liter
Lyses		
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet 1000 CN free	5 liter
2986.0500PE	CyMet™ 22	500 ml
3469.9010PC	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3839.5000PC	CyMet 3500	5 liter
3825	CyMet 3500 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3417.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
2950.2500PE	CyMet ASA	2.5 liter
2951.0500PE	CyMet ASB	500 ml
2952.9010PC	CyMet AS CN Free	10 liter
3755	CyMet Automated	5 liter
2982.0500PE	CyMet BS3 CN free	500 ml
2902.1000PE	CyMet BS34 CN Free	1 liter
3968.0500	CyMet III Diff	500 ml
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3511.1000	CyMet III Diff CN free	1 liter
3511.5000	CyMet III Diff CN free	5 liter
3416.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3853.1000	CyMet H20	1 liter
3425.0500	CyMet KX CN Free	500 ml
2985.1000PE	CyMet LH 53	1 liter
3489.1000PE	CyMet MBA	1 liter
3418.1000PE	CyMet MD(I)	1 liter
2984.1000PE	CyMet MD(I) 53	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3497.0500PE	CyMet MH CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3863.1000	CyMet Micro CN free	1L micros
3441.0500PE	CyMet Mindray	500 ml
3440.0500PE	CyMet Mindray CN Free	500 ml
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
2988.5000PC	CyMet Ruby CN Free	5 liter
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3788	CyMet STX/STL	1 liter
3475.5000PC	LeucoLyse	5 liter
2989.5000PC	LeucoLyse Ruby	5 liter
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3513.1000PE	RBCLyse™	1 liter
3518G.1000PE	RBCLyse G	1 liter
3514.0500PE	WBCStabilise™	500 ml
Reticulocyte Reagents		
3493.1000PE	RetiClear™ MHG	1 liter
3774	RetiCount™	30 ml
2953.0210PE	RetiCount AS	210 ml
3777	RetiCount CD	15 x 3.5 ml
3494.0200PE	RetiCount G	200 ml
Cleaners		
3507.9020	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3763	DetectoTerge™	5 liter
3766	DetectoTerge	1 liter
2970.0900PE	DetectoTerge BS	900 ml
3917	HypoChlorite	5 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3432.1000PE	ProClean Abacus	1 liter
3432.5000	ProClean Abacus	5 liter
3902.0100PE	ProClean CD	100 ml
3862.9020PC	ProClean Extra	20 liter
3862.5000	ProClean Extra	5 liter
3862.1000	ProClean Extra	1 liter
3867.1000PE	ProClean Extra	1L micros
3498.1000PE	ProClean MX5	1 liter
3901	ProClean Plus	100 ml
3442.5000PE	Rinse Mindray	5 liter

Product no.	Product	Pack size
Reagent Packs		
2910	Reagent Pack BS34	1 pack
Hematology Controls and Calibrators		
3427/3428/3429	8-Parameter Control L/N/H	2.5 ml
3463/3464/3465	8-Parameter Control L/N/H	2.5 ml
3701/3702/3703	8-Parameter Control L/N/H	4.5 ml
3746	8-Parameter Control L+N+H	3 x 2.5 ml
3747	8-Parameter Control 4xN	4 x 2.5 ml
3751	8-Parameter Control 1xL+4xN+1xH	6 x 2.5 ml
3633/3634/3635	8-Parameter Control ext L/N/H	2.5 ml
3433/3434/3435	3-Diff Control L/N/H	2.5 ml
3502/3503/3504	3-Diff Control L/N/H	4.5 ml
3466	3-Diff Control 4xL	4 x 2.5 ml
3467	3-Diff Control 4xN	4 x 2.5 ml
3468	3-Diff Control 4xH	4 x 2.5 ml
3421/3422/3423	3-Diff Control ext L/N/H	2.5 ml
3681/3682/3683	5D Control L/N/H	5.0 ml
3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3613/3614/3615	BC-Diff 5 Control L/N/H	4.5 ml
3940	Cal Set 1	2 x 2.5 ml
3452/3453/3454	CD-Diff Control L/N/H	3.0 ml
3838	CD-Diff Control 2xL+2xN+2xH	6 x 3.0 ml
3455/3456/3457	K-Diff Control L/N/H	2.5 ml
3424	Platelet Control Ext. value	5 x 3 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3652/3653/3654	XE-RET Control L/N/H	3.0 ml

Product no.	Product	Pack size
Stains and Dyes		
3800.1000PE	Eosin-Y Alcoholic	1 liter
3800.2500PE	Eosin-Y Alcoholic	2.5 liter
3800.9200	Eosin-Y Alcoholic	200 liter
3446.1000PE	Eosin Y 0.5% Aqueous	1 liter
3446.9200	Eosin Y 0.5% Aqueous	200 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3856.9180ST	Giemsa	180 liter
3870.1000	Hematoxyline (Mayer)	1 liter
3870.2500	Hematoxyline (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3873.9200	Hematoxyline (Harris, Gill II)	200 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	500 ml
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
Clearing agent		
3905.2500PE	UltraClear™	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
Mounting media		
3921.0500	UltraKitt™	500 ml
3921.0600	UltraKitt	6 x 100 ml
3921.9025ST	UltraKit	25 liter
3882.0500	Mounting Medium High	500 ml
3883.0500	Mounting Medium Low	500 ml
Fixatives		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010PE	10% v/v Buffered Formaldehyde	10 liter
3933.9020	10% v/v Buffered Formaldehyde	20 liter
3933.9200	10% v/v Buffered Formaldehyde	200 liter
3880.1000	Bouin's Fixative	1 liter
3869.1200	Cervix Fixative	12 x 125 ml
3884.9010PC	Cytology Fixative LBCM	10 liter
3409.9010	Immuno PBS 20x concentrated	10 liter
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

CERTIFICATE

This is to certify that

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope:
Sales and supply of branded and private label chemicals, consumables, laboratory equipment, furniture, and medical devices from global leading developers and manufacturers of those products to customers in biopharma, healthcare, advanced technology and applied materials, education and government; manufacture of private label products, primarily laboratory and production chemicals including custom manufacturing solutions used in biopharmaceutical and industrial applications and production processes; provide value-added service offerings such as client outsourced activities: including sourcing and procurement, logistics, chemical and equipment tracking, lab and production services, scientific services and sample management; technical services in-house and at customer sites including installation, maintenance, qualification, calibration and repair of laboratory equipment

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	530840 QM15
Valid from	2021-08-04
Valid until	2024-06-28
Date of certification	2021-08-04

DAkkS Deutsche Akkreditierungsstelle D-ZM-16074-01-00

DQS GmbH

Markus Bleher
Managing Director

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530842 **VWR International GmbH** **Graumanngasse 7** **1150 Wien** **Austria**	Sales and supply; Lab and Production Services
530843 **VWR International GmbH** **Zimbagasse 5** **1210 Wien** **Austria**	Distribution; Technical Services
530841 **VWR International bv** **Researchpark Haasrode 2020** **Geldenaaksebaan 464** **3001 Leuven** **Belgium**	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531223 **VWR International GmbH** **Rue de Rive 18** **1260 Nyon** **Switzerland**	Sales and supply
531224 **VWR International GmbH** **Grabenstraße 1** **8952 Schlieren** **Switzerland**	Sales and supply; Distribution; Lab and Production Services; Technical services
531221 **VWR International GmbH** **Lerzenstraße 16 / 18** **8953 Dietikon** **Switzerland**	Sales and supply

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530844 **VWR International s.r.o.** **Praská 442** **281 67 Stribrná Skalice** **Czech Republic**	Sales and supply; Distribution; Kitting Services; Technical services
530847 **VWR International s.r.o.** **Pivovarská 30** **75661 Rožnov prod Radhoštêm** **Czech Republic**	Sales and supply
530868 **VWR International GmbH** **Großenhainer Straße 99** **01127 Dresden** **Germany**	Sales and supply
530869 **VWR International GmbH** **Wöhlerstraße 42** **30163 Hannover** **Germany**	Sales and supply
530867 **VWR International GmbH** **Hilpertstraße 20A** **64295 Darmstadt** **Germany**	Sales and supply; Lab and Production Services; Technical services
539946 **VWR International GmbH** **Heinrich-Blanc-Straße 40** **76646 Bruchsal** **Germany**	Distribution

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530865 **VWR International GmbH** **John-Deere-Straße 5** **76646 Bruchsal** **Germany**	Sales and supply; Distribution
530866 **VWR International GmbH** **Vichystraße 2** **76646 Bruchsal** **Germany**	Distribution
530870 **VWR International GmbH** **Fraunhoferstr.11** **85737 Ismaning** **Germany**	Sales and supply
530871 **VWR International GmbH** **James-Franck-Ring 9** **89081 Ulm** **Germany**	Sales and supply
530859 **VWR International A/S** **Tobaksvejen 21** **2860 Søborg** **Denmark**	Sales and supply; Distribution; Lab and Production Services; Technical services
531213 **VWR International Eurolab, S.L.** **C/ De la Technología, 5-17A7 - Llinars Park** **08450 Llinars Del Vallès Barcelona** **Spain**	Sales and supply; Distribution; Lab and Production Services; Technical services

Annex to certificate
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VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530860 **VWR International Oy** **Valimotie 9** **00380 Helsinki** **Finland**	Sales and supply; Distribution; Lab and Production Services; Technical services
530863 **VWR International S.A.S.** **Europarc** **26 Avenue Leonard de Vinci** **33608 Pessac Cedex** **France**	Sales and supply
530861 **VWR International S.A.S** **Chemin de la Croix Saint-Marc** **Z.I. de Vaugereeau** **45250 Briare-le-Canal** **France**	Distribution; Manufacture
530862 **VWR International S.A.S** **Immeuble Estréo,** **1-3 Rue d'Aurion** **93110 Rosny-sous-Bois** **France**	Sales and supply; Lab and Production Services; Technical services
531226 **VWR International Ltd** **VWR House** **Warren Court** **Feldspar Close** **Enderby** **LE19 4SD** **Leicester** **United Kingdom**	Sales and supply

Annex to certificate
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VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
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Location	Scope
531228 **LAB3 Service** **1 Dragon Court** **Crofts End Road** **St George** **Bristol** **BS5 7XX** **United Kingdom**	Lab and Production Services; Technical services
531225 **VWR International Ltd.** **Customer Service Centre** **Hunter Boulevard** **Magna Park** **Lutterworth, Leicestershire** **LE17 4 XN** **United Kingdom**	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531227 **VWR International Ltd.** **14 Media Village** **Liscombe Park** **Soulbury** **Leighton Buzzard** **LU7 0GA** **United Kingdom**	Sales and supply
540366 **VWR International** **Medical Equipment Supplies and Management** **The Solutions Buckshaw Village, Chorley** **Chorley** **PR7 7EL** **United Kingdom**	Sales and supply; Distribution; Technical Services

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531229 **Basan - the cleanroom division of VWR** **Units 2 & 3 Newton Court** **Basingstoke** **RG24 8GF** **United Kingdom**	Sales and supply; Distribution; Manufacture
546015 **Hichrom Ltd** **1-3 The Markham Centre, Station Road,** **Theale,** **Reading, Berkshire** **RG7 4AB** **United Kingdom**	Manufacture of UHPLC and HPLC columns with lot traceability. Procurement and distributor for UHPLC and HPLC columns and associated solvents, packing materials and accessories with lot traceability
531198 **VWR International Kft.** **Simon László utca 4** **4034 Debrecen** **Hungary**	Sales and supply; Distribution; Lab and Production Services; Technical services
531199 **VWR International Ltd** **Orion Business Campus** **Northwest Business Park** **Ballycoolin, Blanchardstown** **Dublin 15** **Ireland**	Sales and supply; Distribution; Lab and Production Services; Technical services
531200 **VWR International (Northern Ireland) Ltd** **19 Clarendon Street** **Derry BT4 87EP** **Ireland**	Sales and supply

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VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531201 **VWR International s.r.l.** **Via San Giusto 85** **20153 Milano** **Italy**	Sales and supply; Lab and Production Services; Technical Services; Manufacture
531203 **VWR International B.V.** **Orlyplein 85** **1043 AP Amsterdam** **Netherlands**	Sales and supply; Lab and Production Services; Technical services
531205 **VWR International AS** **Brynsalleen 4** **0667 Oslo** **Norway**	Sales and supply; Lab and Production Services; Technical services
531206 **VWR International AS** **Kokstadtflaten 35** **5152 Bønes (Bergen)** **Norway**	Sales and supply
531207 **VWR International AS** **Leirfossvegen 27** **7038 Trondheim** **Norway**	Sales and supply
531211 **VWR International Sp. z. o.o.** **Limbowa 5** **80-175 Gdańsk** **Poland**	Sales and supply; Lab and Production Services; Technical services

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

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Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531212 **VWR International Sp. z. o.o.** **Aleja Niepodległości 606/610** **81-879 Sopot** **Poland**	Distribution
531208 **VWR International** **Material De Laboratorio, LDA** **Centro Empresarial de Alfragide** **Rua da Industria, nº 6** **2610-088 Alfragide** **Portugal**	Sales and supply; Distribution; Lab and Production Services; Technical services
531217 **VWR International AB** **Fagerstagatan 18A** **163 94 Stockholm** **Sweden**	Sales and supply; Lab and Production Services; Technical services
531220 **VWR International AB** **Skiffervägen 12** **224 78 Lund** **Sweden**	Sales and supply
531218 **VWR International AB** **Varbergsgatan 2** **412 65 Göteborg** **Sweden**	Sales and supply
531219 **VWR International AB** **Nordiskt Centrallager** **Gjuterigatan 3 (Bofors Industriområde)** **691 50 Karlskoga** **Sweden**	Distribution

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

The design, engineering, manufacturing and distribution of Single Use Systems and supporting hardware, including installation-, service- and maintenance activities for the pharmaceutical and biotech industry.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

Certificate Number:	16880
EAC Code:	34
Certified Since:	March 22, 2012
Valid Until:	March 19, 2024
Reissued:	March 20, 2021
Cycle Issued:	March 20, 2021

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

РАЗРЕШЕНИЕ
на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключающей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

1535

MINISTERUL SĂNĂTĂȚII AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РЕСПУБЛИКИ МОЛДОВА
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, mun. Chișinău, str. Gheorghe. Asachi, 67 a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
e-mail: office@ansp.gov.md

DOCUMENTAȚIE MEDICALĂ/ Медицинская документация
FORMULAR/ Форма Nr. 303-2/c
APROBAT DE MS al RM / Утверждена МЗ РМ Nr. 828 от 31.10.11
Centrul de încercări de laborator acreditat de către Centrul Național de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LÎ-044 din 17.02.2018 valabil până la 16.02.2026

AVIZ SANITAR
PENTRU PRODUSELE ALIMENTARE ȘI NEALIMENTARE Nr. P-14162/2022

Санитарное заключение для пищевых и непищевых продуктов

din/от **30 mai 2022**

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea și desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается что производство, ввоз, использование и реализация продукции / оборудования
Pachete (saci) pentru colectarea deșeurilor biologice: 350*490*30(V-7,5 L), 400*490*30(V-15 L), 460*600*40(V-20 L), 600*700*30(V-30 L), 600*900*40(V-50 L), 750*1100*50(V-120 L)

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* (se va indica denumirea completă a Regulamentului (lor) sanitar (e) */указать полное наименование санитарного (ых) регламента (ов)*)
HG 308/2011, HG 278/2013

Organizația-producătoare/importatoare, țara de origine / *организация произв./импортер, страна происхождения*
Sanintrade S.R.L., Republica Moldova

Destinatarul avizului sanitar / *получатель санитарного заключения*
BELNIS S.R.L. , Republica Moldova, mun. Chișinău, sec. Riscani, str-la 2 Petricani, 19, bloc. 1, ap./of.

Temei pentru recunoașterea conformității produselor Regulamentului (lor) sanitar (e) menționat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило
Demers, contract nr.796-01 din 08.05.2020, facturi, certificate de calitate, aviz sanitar nr.4837 din 02.12.2021
(a enumera documentele de însoțire, buletinele de analiză */ перечислить сопроводительные док., протоколы исслед.)*

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*

Parametrii (factorii) / *показатели (факторы)*	**Normativul sanitar** / *санитарный норматив*
Pachetele sunt confecționate din materiale plastice admise pentru colectarea deșeurilor biologice	

Domeniu de utilizare / *Область применения:*
colectarea deșeurilor biologice

Condițiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*
plasarea pe piață în condițiile respectării legislației în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное заключение действительно до:* 31.05.2023

DIRECTORUL AGENȚIEI NAȚIONALE PENTRU SĂNĂTATE PUBLICĂ

Digitally signed by Jelamschi Nicolae
Date: 2022.05.30 15:48:53 EEST
Reason: MoldSign Signature
Location: Moldova

Nicolae Jelamschi
(numele, prenumele/ Ф.И.О.)

(semnătura / подпись)

L.Ș.

ANSP/HAO3

SP **10-XVI-09** 0001564 **O3**

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2029595-1
Organization:	General Life Biotechnology Co., Ltd. 6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist., New Taipei City 242 Taiwan
Scope:	Design and Development, Manufacture and Distribution of in vitro diagnostic clinical chemical medical devices used in monitoring of blood glucose and blood analytes, including self-testing and near patient/point of care

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.:	238520647-040
Effective date:	2022-03-09
Expiry date:	2024-04-06
Issue date:	2022-03-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2029595-1

Organization: General Life Biotechnology
Co., Ltd.
6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist.,
New Taipei City 242
Taiwan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o General Life Biotechnology Co., Ltd. 5F, No. 240, Shinshu Road Shin Juang Dist., New Taipei City 242 Taiwan	Design and Development, Manufacture and Distribution of in vitro diagnostic clinical chemical medical devices used in monitoring of blood glucose and blood analytes, including self-testing and near patient/point of care

Report No.: 238520647-040
Effective date: 2022-03-09
Expiry date: 2024-04-06
Issue date: 2022-03-09

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2029595-1

Manufacturer: General Life Biotechnology
Co., Ltd.
6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist.,
New Taipei City 242
Taiwan

Products:
- Blood Glucose, Uric Acid, and Total Cholesterol Multi-Monitoring Systems
- Blood Glucose and Uric Acid Dual-Monitoring Systems
- Blood Glucose and Total Cholesterol Dual-Monitoring Systems
- Uric Acid and Total Cholesterol Dual-Monitoring Systems
- Blood Glucose Monitoring Systems
- Uric Acid Monitoring Systems
- Total Cholesterol Monitoring Systems
- Hb Hemoglobin Test Systems
- Blood Glucose, Uric Acid, Total Cholesterol Meters
- Blood Glucose and Uric Acid Dual Meters
- Blood Glucose and Total Cholesterol Dual Meters
- Uric Acid and Total Cholesterol Dual Meters
- Blood Glucose Meters
- Uric Acid Meters
- Total Cholesterol Meters

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC 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 IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 238520647-050

Effective date: 2022-03-09

Expiry date: 2024-05-26

Issue date: 2022-03-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2029595-1

Manufacturer:
General Life Biotechnology
Co., Ltd.
6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist.,
New Taipei City 242
Taiwan

- Hb Hemoglobin Meters
- Glucose Test Strips
- Uric Acid Test Strips
- Total Cholesterol Test Strips
- Hb Hemoglobin Test Strips
- Glucose Control Solutions
- Uric Acid Control Solutions
- Total Cholesterol Control Solutions
- Hb Hemoglobin Control Solutions
- ß-Ketone Monitoring System
- Blood Glucose and ß-Ketone Dual-Monitoring System
- ß-Ketone Meter
- Blood Glucose and ß-Ketone Dual Meter
- ß-Ketone Test Strip
- ß-Ketone Control Solution

Report No.: 238520647-050

Effective date: 2022-03-09

Expiry date: 2024-05-26

Issue date: 2022-03-09

TÜV Rheinland LGA Products GmbH
Zertifizierstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2029595-1

Manufacturer: General Life Biotechnology
Co., Ltd.
6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist.,
New Taipei City 242
Taiwan

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	General Life Biotechnology Co., Ltd. 5F, No. 240, Shinshu Road Shin Juang Dist., New Taipei City 242 Taiwan	Blood Glucose, Uric Acid, and Total Cholesterol Multi-Monitoring Systems; Blood Glucose and Uric Acid Dual-Monitoring Systems; Blood Glucose and Total Cholesterol Dual-Monitoring Systems; Uric Acid and Total Cholesterol Dual-Monitoring Systems; Blood Glucose Monitoring Systems; Uric Acid Monitoring Systems; Total Cholesterol Monitoring Systems; Hb Hemoglobin Test Systems; Blood Glucose, Uric Acid, Total Cholesterol Meters; Blood Glucose and Uric Acid Dual Meters; Blood Glucose and Total Cholesterol Dual Meters; Uric Acid and Total Cholesterol Dual Meters; Blood Glucose Meters; Uric Acid Meters; Total Cholesterol Meters;

Report No.: 238520647-050

Effective date: 2022-03-09

Expiry date: 2024-05-26

Issue date: 2022-03-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2029595-1

Manufacturer: General Life Biotechnology
Co., Ltd.
6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist.,
New Taipei City 242
Taiwan

The scope of certification includes the following manufacturing sites:

Hb Hemoglobin Meters; Glucose Test Strips; Uric Acid Test Strips; Total Cholesterol Test Strips; Hb Hemoglobin Test Strips; Glucose Control Solutions; Uric Acid Control Solutions; Total Cholesterol Control Solutions; Hb Hemoglobin Control Solutions; ß-Ketone Monitoring System; Blood Glucose and ß-Ketone Dual-Monitoring System; ß-Ketone Meter; Blood Glucose and ß-Ketone Dual Meter; ß-Ketone Test Strip; ß-Ketone Control Solution

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

AB certification

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

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

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

CERTIFICAT
CERTIFICATE

Accréditation N°4-0023 PORTÉE DISPONIBLE SUR www.cofrac.fr

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
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

Le Représentant de l'Entreprise
The Company Representative

BOEN HEALTHCARE CO., LTD

CERTIFICATE OF ANALYSIS

Report No.: GM01-BN21

Product Name: Glass tube	Lot. No.: 20200301
MFG. Date: 2021-03	EXP. Date: 2024-02
Raw Material: Borosilicate glass	Specification: 12x75mm, cylindracal bottom, 5ml
Standard: Enterprise Standard	
Package: 250pcs/box, 2000pcs/ctn	
Quantity: 10000pcs	Report Date: 2021.04.15

Test Items	Technical Requirement	Inspection Level	Sample	AQL		Defect Qty	Result
Dimension	Length: 75±1mm Diameter: 11.75±0.25mm Thickness: 0.8-1.0mm	5pcs/lot	5pcs	0		0	Pass
				Ac	Re		
				0	1		
Appearance	The mouth and the bottom should be perpendicular to the axis	GB/T 2828.1-2003 Normal test level II	500pcs	1.5		0	Pass
				Ac	Re		
				14	15		
Function	Inner stress: the heated part should be fuchsia, other light color is allowed	10pcs/lot	10pcs	0		0	Pass
				Ac	Re		
				0	1		
Package	Label and marking should be clear, correct and the label should be on correct loction.	1 outer box/lot	1 outer box	0		0	Pass
				Ac	Re		
				0	1		
Conclusion	The product meets all the requirement by our test.						

Inspected by: Leo Sun

Checked by: Irene Qiao

BOEN HEALTHCARE CO., LTD 苏州柏恩贸易有限公司 3205011038530

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:	**Vacuum Blood Collection Tube**
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