

Avantor Performance Materials Poland Spółka Akcyjna
Sowińskiego 11
44-101 Gliwice
Tel. 48 32 2392 000

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:

Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard. This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.

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

Gliwice, Poland

January 25, 2019

A handwritten signature in blue ink that reads 'Anna Szuba'.

Anna Szuba
Quality Director

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Diluents		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
	3969-00	20 L
Diluid™ Abacus	3430.9020	20 L
	3430.9010	10 L
	3430-00	20 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
	3963.9010	10 L
	3963-00	20 L
Diluid™ Erma	3459.9020	20 L
	3459-00	20 L
Diluid™ Mindray	3439.9020PC	20 L
	3439-00	20 L
Diluid™ NR	3483.9020PC	20 L
	3483-00	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832.9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
Lyses		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22 CN Free	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823.1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3970-00	10 L
	3977	5 L
CyMet™ Abacus CN free	3431.1000	1 L
	3431-00	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN free	3511.1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416.0500	500 ml
CyMet™ H20	3853.1000	1 L
CyMet™ KX CN Free	3425-00	500 ml
	3425.0500	500 ml
CyMet™ Micro	3852.1000	1 L
CyMet™ Micro CN free	3863.1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml

J.T.Baker product list for CE marked products

Product	Product number	Pack size
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759.5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	2989.5000PC	5 L
Cleaners		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3900-00	5 L
	3768,1000	1 L micros
ProClean™ Abacus	3432,5000	5 L
	3432.1000PE	1 L
ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862,5000	5 L
	3862.9020PC	20 L
	3862-00	5 L
	3867-00	1 L micros
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
Hematology Controls		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control extended L/N/H	3421/3422/3423	2.5 ml
CD-Diff Control L/N/H	3452/3453/3454	3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838	6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457	2.5 ml
Platelet Control- Extended value	3424	5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699	3.0 ml
XE-Diff Control L/N/H	3731/3732/3733	4.5 ml
Fixatives		
Cervix Spray Fixative	3869,1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933,1000	1 L
	3933.5000PC	5 L
	3933,9010	10 L
	3933,9020	20 L
	3933.1000MB	1000 L
	3933.9020PE	20 L
	3933.9010JL	10 L
	3933.9020JL	20 L
Clearing agents		
UltraClear™	3905.2500PE	2.5 L
	3905.5000PE	5 L
	3905.9010PE	10 L

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
	3856,2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870,1000	1 L
	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555,2500PE	2,5 L
Papanicolaou 3B	3556,1000PE	1 L
	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921,0500	500 ml
	3921,0600	6 x 100 ml
	3921,9025ST	25 L
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
PBS		
PBS	3059	20 L
	3059.9010PC	10 L

Declaration of CE conformity

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

Teugseweg 20
7418 AM Deventer
the Netherlands

herewith declares the following:

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

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

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

Deventer, the Netherlands.

22 November 2011



Dr. J. Mittendorf
QA & RA Manager

J.T.Baker product list for CE marked products

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

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

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

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

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

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

22 November 2011

To whom this may concern

Date: March 01, 2021

Letter of Authorization

Avantor Performance Materials Poland S.A., reg. No. 0000010108 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histology located at:

Sowińskiego 11
44-101 Gliwice
Poland

herewith confirms that:

I.M Global Biomarketing Group Moldova S.R.L
Republic of Moldova
MD-2001, Chisinau
Tighina str. 65, 607 office
Tel (373 22) 549 120, 549 121
Fax (373 22) 547 373

is authorized to act as our distributor for our hematology/histology reagents and controls (Products) in Moldova

We declare that we will supply the Products for the needs of tenders.

We declare that we will supply the Products for tenders with warranty as per the Avantor General Conditions of Sale.

Furthermore I.M Global Biomarketing Group is duly entitled to:

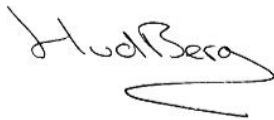
- Register, promote, offer, negotiate prices and sell our Products in Moldova;
- carry out the required product training of the medical and technical personnel who will use these products.

The product specialists of I.M Global Biomarketing Group have been duly trained and are qualified for providing all services in regards to consulting, sales, maintenance and training.

In all the above activities I.M Global Biomarketing Group is acting in its own name and on its own account.

This authorization letter is valid until about 1 year after date.

Avantor Performance Materials S.A.
Poland



H van den Berg,
Marketing Product Manager Diagnostics



Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

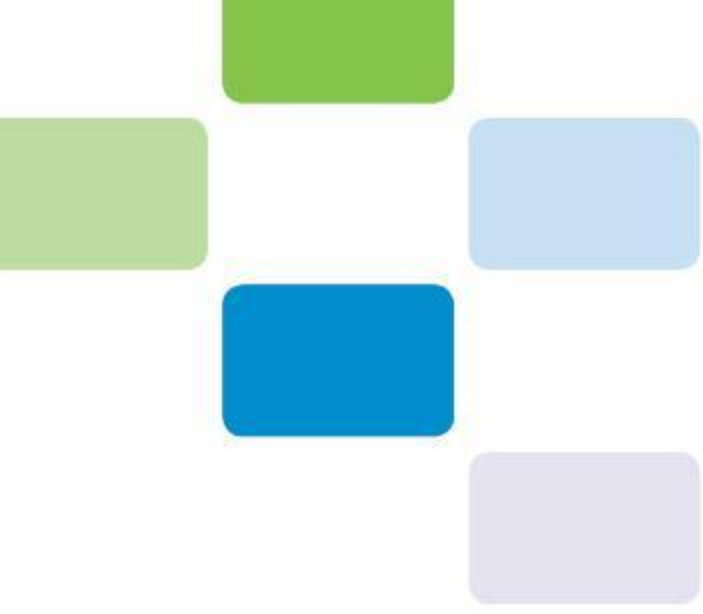
H. Shimosaka

Hiroshi Shimosaka

President

ERMA INC.





BeneSphera™
3 PART
DIFFERENTIAL
Hematology Analyzer

 **BeneSphera™ TRAINING**

Mr /-Ms Sergiu Sorocovici
Global Biomarketing Group
str. Tighina 65, of. 607
2001 Chisinau, Moldau

has attended a 2-days training on goods manufactured or distributed by us.
April 12th – April 13th, 2012

Deventer, The Netherlands
Place, Date 13.04.2012

H. J. Daas






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

For and on behalf of NQA, USA

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



MEDICA

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

Declaration of Conformity **CE**

Product Name:

EasyLyte and accessories per attachment

EasyElectrolytes and accessories per attachment

Model/Type:

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

EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

 Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

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

Means of Conformity

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

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:



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

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenance Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02



Declaration of Conformity



We: ELITechGroup B.V.
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

Declare under sole responsibility that the product indicated below (including all spares and accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE marking.

Product : **Clinical chemistry analyzer**
Product No. : **6003-400**
Model : **Selectra ProM**
GMDN code : **56678**

Product classification

As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure

In accordance with Annex III of the IVDD

The product (including all spares and accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL)
- All other member states of the European Union (EU)
- All other states that are part of the European Economic Area (EEA), including Switzerland

Spankeren, March 2015

A. Altink
Managing Director



Declaration of Conformity



List of applied (harmonized) standards

	Standard version	Description	Certification by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
	IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	DEKRA
	IEC 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.	DEKRA
	EN ISO 13485:2012	Medical devices—Quality management systems— Requirements for regulatory purposes.	
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems— Requirements for regulatory purposes.	

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 (6 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 2026).

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons les électrodes conformes à la Directive 2011/65/UE du parlement européen et du conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques incluant la DIRECTIVE DÉLÉGUÉE (UE) 2015/863 DE LA COMMISSION du 31 mars 2015 modifiant l'annexe II de la Directive 2011/65/UE du Parlement européen et du Conseil en ce qui concerne la liste des substances soumises à limitations.

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 (6 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, 2026).

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify electrodes; conform to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, including Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

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 (6 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 2026).

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos los electrodos conformes con la Directiva 2011/65/UE del parlamento europeo y del consejo del 8 de junio de 2011 sobre restricciones a la utilización de algunas sustancias peligrosas en aparatos eléctricos y electrónicos incluyendo la Directiva delegada (UE) 2015/863 de la comisión del 31 de marzo de 2015 por la que se modifica el anexo II de la Directiva 2011/65/UE del Parlamento Europeo y del Consejo en cuanto a la lista de sustancias restringidas.

Sées, le 12 octobre 2023

Valérie LAMBERT,

Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglamentarios



ELITech Clinical Systems SAS

Zone Industrielle
61500 SEES - France

Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51

SIRET 318 365 228 00036

Cécile GOUBAULT,

Directeur Général-Délégué
Managing Director
Directora General



Annex

REF	PRODUCT NAME	GMDN Code
3918-004	Sodium Electrode (Na+)	52896
3918-005	Potassium Electrode (K+)	52892
3918-006	Chloride Electrode (Cl-)	52876
3918-003	Carbon Dioxide Electrode (CO2)	60773
3918-002	Reference Electrode (REF)	59241
ALBU-0250	ALBUMIN	53597
ALBU-5220	ALBUMIN	53597
ALBU-0600	ALBUMIN p. 5, 6	53597
ALBU-5600	ALBUMIN	53597
ALBU-0700	ALBUMIN	53597
ALBU-5700	ALBUMIN	53597
ALBU-M830	ALBUMIN	53597
ALBU-5M30	ALBUMIN	53597
ALPI-0230	ALP IFCC	52928
ALPI-5100	ALP IFCC	52928
ALPI-6050	ALP IFCC	52928
ALSL-0250	ALT/GPT 4+1 SL	52923
ALSL-5220	ALT/GPT 4+1 SL	52923
ALSL-6050	ALT/GPT 4+1 SL	52923
ALSL-0410	ALT/GPT 4+1 SL	52923
ALSL-5415	ALT/GPT 4+1 SL	52923
ALSL-6255	ALT/GPT 4+1 SL	52923
ALSL-0430	ALT/GPT 4+1 SL	52923
ALSL-0455	ALT/GPT 4+1 SL	52923
ALSL-0510	ALT/GPT 4+1 SL p. 1-4	52923
ALSL-5515	ALT/GPT 4+1 SL	52923
ALSL-6615	ALT/GPT 4+1 SL	52923
ALSL-M490	ALT/GPT	52923
ALSL-5M90	ALT/GPT	52923
ALSL-6M30	ALT/GPT	52923
AMSL-0230	AMYLASE SL	52940
AMSL-5220	AMYLASE SL	52940
AMSL-0390	AMYLASE SL	52940
AMSL-5405	AMYLASE SL	52940
AMSL-0400	AMYLASE SL p. 9-12	52940
AMSL-M430	AMYLASE	52940
AMSL-5M30	AMYLASE	52940
ASLO-0250	ANTI-STREPTOLYSIN O	59055
ASLO-5025	ANTI-STREPTOLYSIN O	59055
ASLO-6006	ANTI-STREPTOLYSIN O	59055
ASLO-4001	ANTI-STREPTOLYSIN O	51744
ASSL-0250	AST/GOT 4+1 SL	52954
ASSL-5220	AST/GOT 4+1 SL	52954
ASSL-6050	AST/GOT 4+1 SL	52954
ASSL-0410	AST/GOT 4+1 SL	52954
ASSL-5415	AST/GOT 4+1 SL	52954
ASSL-6255	AST/GOT 4+1 SL	52954
ASSL-0430	AST/GOT 4+1 SL	52954
ASSL-0455	AST/GOT 4+1 SL	52954
ASSL-0510	AST/GOT 4+1 SL p. 15-18	52954
ASSL-5515	AST/GOT 4+1 SL	52954
ASSL-6615	AST/GOT 4+1 SL	52954
ASSL-M490	AST/GOT	52954
ASSL-5M90	AST/GOT	52954
ASSL-6M30	AST/GOT	52954
AUML-0250	URIC ACID MONO SL	53583
AUML-5220	URIC ACID MONO SL	53583
AUML-0420	URIC ACID MONO SL	53583
AUML-5405	URIC ACID MONO SL	53583
AUML-0427	URIC ACID MONO SL	53583
AUML-0497	URIC ACID MONO SL	53583
AUML-5505	URIC ACID MONO SL	53583
AUML-0500	URIC ACID MONO SL	53583
AUML-0507	URIC ACID MONO SL p. 80, 81	53583
AUML-0707	URIC ACID MONO SL	53583
AUML-5710	URIC ACID MONO SL	53583
AUML-M830	URIC ACID	53583
AUML-5M30	URIC ACID	53583
AUSL-0250	URIC ACID SL	53583
AUSL-5220	URIC ACID SL	53583
AUSL-6050	URIC ACID SL	53583
BIDI-0250	BILIRUBIN DIRECT 4+1	53233
BIDI-5220	BILIRUBIN DIRECT 4+1	53233
BIDI-6050	BILIRUBIN DIRECT 4+1	53233
BIDI-0500	BILIRUBIN DIRECT p. 19, 20, 23, 24	53233
BIDI-5600	BILIRUBIN DIRECT	53233
BITD-6250	BILIRUBIN DIRECT	53233

Annex

REF	PRODUCT NAME	GMDN Code
BIDI-M430	DIRECT BILIRUBIN	53233
BIDI-5M30	DIRECT BILIRUBIN	53233
BIDI-6M10	DIRECT BILIRUBIN	53233
BIDV-0850	DIRECT BILIRUBIN ENVOY	53233
BITO-0250	BILIRUBIN TOTAL 4+1	53229
BITO-5220	BILIRUBIN TOTAL 4+1	53229
BITO-6050	BILIRUBIN TOTAL 4+1	53229
BITO-0600	BILIRUBIN TOTAL 4+1 p. 27,28,30,31	53229
BITO-5600	BILIRUBIN TOTAL 4+1	53229
BITD-6400	BILIRUBIN TOTAL 4+1	53229
BITO-M430	TOTAL BILIRUBIN	53229
BITO-5M30	TOTAL BILIRUBIN	53229
BITO-6M10	TOTAL BILIRUBIN	53229
BITV-0850	TOTAL BILIRUBIN ENVOY	53229
CALA-0250	CALCIUM ARSENAZO	45789
CALA-5220	CALCIUM ARSENAZO	45789
CALA-0600	CALCIUM ARSENAZO p. 33,34	45789
CALA-5600	CALCIUM ARSENAZO	45789
CALA-M430	CALCIUM ARSENAZO	45789
CALA-5M30	CALCIUM ARSENAZO	45789
CALI-0550	ELICAL 2	47868
CALI-1550	ELICAL 2	47868
CHDL-0250	HDL CHOLESTEROL	53391
CHDL-5021	HDL CHOLESTEROL	53391
CHDL-6014	HDL CHOLESTEROL	53391
CHDL-0600	HDL CHOLESTEROL p. 86,87	53391
CHDL-5090	HDL CHOLESTEROL	53391
CHDL-6060	HDL CHOLESTEROL	53391
CHDL-M330	HDL CHOLESTEROL	53391
CHDL-5M30	HDL CHOLESTEROL	53391
CHDL-6M30	HDL CHOLESTEROL	53391
CHEB-0250	CHOLINESTERASE	52971
CHEB-5008	CHOLINESTERASE	52971
CHEB-6005	CHOLINESTERASE	52971
CHSL-0250	CHOLESTEROL SL	53359
CHSL-5220	CHOLESTEROL SL	53359
CHSL-0455	CHOLESTEROL SL	53359
CHSL-0497	CHOLESTEROL SL	53359
CHSL-5505	CHOLESTEROL SL	53359
CHSL-0500	CHOLESTEROL SL	53359
CHSL-0507	CHOLESTEROL SL p. 39,40	53359
CHSL-0700	CHOLESTEROL SL	53359
CHSL-5710	CHOLESTEROL SL	53359
CHSL-0707	CHOLESTEROL SL p. 41,42	53359
CHSL-M690	CHOLESTEROL	53359
CHSL-5M90	CHOLESTEROL	53359
CKMB-0900	CK-MB CONTROL	44693
CKMB-1030	CK-MB CONTROL	44693
CKSL-0230	CK NAC SL	53003
CKSL-5220	CK NAC SL	53003
CKSL-6050	CK NAC SL	53003
CKSL-0410	CK NAC SL p. 88,89	53003
CKSL-5405	CK NAC SL	53003
CKSL-6255	CK NAC SL	53003
CKSL-0430	CK NAC SL	53003
CKSL-M230	CK NAC	53003
CKSL-5M30	CK NAC	53003
CKSL-6M10	CK NAC	53003
CLDL-0250	LDL CHOLESTEROL p. 84,85	53395
CLDL-5021	LDL CHOLESTEROL	53395
CLDL-6014	LDL CHOLESTEROL	53395
CLDL-M330	LDL CHOLESTEROL	53395
CLDL-5M30	LDL CHOLESTEROL	53395
CLDL-6M30	LDL CHOLESTEROL	53395
CMSL-0230	CK-MB	52994
CMSL-5220	CK-MB	52994
CMSL-6220	CK-MB	52994
CMSL-WR	CK-MB	52994
CMSL-0410	CK-MB SL p. 90,91	52994
CMSL-5405	CK-MB SL	52994
CMSL-6255	CK-MB SL	52994
CONT-0060	ELITROL I p. 96	47869
CONT-1060	ELITROL I	47869
CONT-0160	ELITROL II p. 97	47869
CONT-1160	ELITROL II	47869
CRCO-0600	CREATININE JAFFE	53251
CRCO-5600	CREATININE JAFFE	53251
CRCO-6600	CREATININE JAFFE	53251
CRCO-0700	CREATININE JAFFE	53251

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Annex

REF	PRODUCT NAME	GMDN Code
CRSL-0250	CREATININE PAP SL	53250
CRSL-5221	CREATININE PAP SL	53250
CRSL-6070	CREATININE PAP SL	53250
CRSL-0630	CREATININE PAP SL	53250
CRSL-5505	CREATININE PAP SL	53250
CRSL-6470	CREATININE PAP SL	53250
CRSL-M490	CREATININE PAP	53250
CRSL-5M90	CREATININE PAP	53250
CRSL-6M30	CREATININE PAP	53250
FEFE-0230	IRON FERENE	54758
FEFE-5140	IRON FERENE	54758
FEFE-6040	IRON FERENE	54758
FEFE-0600	IRON FERENE p. 57, 58, 59	54758
FEFE-5600	IRON FERENE	54758
FEFE-6400	IRON FERENE	54758
FEFE-0850	IRON ENVOY	54758
FEFE-M230	IRON FERENE	54758
FEFE-5M30	IRON FERENE	54758
FEFE-6M10	IRON FERENE	54758
GHSL-0250	GLUCOSE HK SL	53301
GHSL-5220	GLUCOSE HK SL	53301
GHSL-6050	GLUCOSE HK SL	53301
GHSL-0600	GLUCOSE HK SL p. 49-52	53301
GHSL-5505	GLUCOSE HK SL	53301
GHSL-6605	GLUCOSE HK SL	53301
GHSL-M490	GLUCOSE HK	53301
GHSL-5M90	GLUCOSE HK	53301
GHSL-6M30	GLUCOSE HK	53301
GISL-0250	GAMMA-GT PLUS SL	53027
GISL-5220	GAMMA-GT PLUS SL	53027
GISL-6050	GAMMA-GT PLUS SL	53027
GISL-0400	GAMMA-GT PLUS SL	53027
GISL-0420	GAMMA-GT PLUS SL p. 47, 48	53027
GISL-5405	GAMMA-GT PLUS SL	53027
GISL-6255	GAMMA-GT PLUS SL	53027
GISL-M230	GAMMA-GT	53027
GISL-5M30	GAMMA-GT	53027
GISL-6M10	GAMMA-GT	53027
GPSL-0250	GLUCOSE PAP SL	53301
GPSL-5220	GLUCOSE PAP SL	53301
GPSL-0455	GLUCOSE PAP SL	53301
GPSL-0497	GLUCOSE PAP SL	53301
GPSL-5505	GLUCOSE PAP SL	53301
GPSL-0500	GLUCOSE PAP SL	53301
GPSL-0507	GLUCOSE PAP SL p. 53, 54	53301
GPSL-0700	GLUCOSE PAP SL	53301
GPSL-5710	GLUCOSE PAP SL	53301
GPSL-0707	GLUCOSE PAP SL p. 55, 56	53301
GPSL-M690	GLUCOSE PAP	53301
GPSL-5M90	GLUCOSE PAP	53301
HBAC-0043	HbA1c CALIBRATOR SET p. 82, 83	53315
HBAC-4301	HbA1c CALIBRATOR SET	53315
HBAC-4302	HbA1c CALIBRATOR SET	53315
HBAC-4303	HbA1c CALIBRATOR SET	53315
HBAC-4304	HbA1c CALIBRATOR SET	53315
HBAC-0049	HbA1c CONTROL L + H p. 82, 83	44435
HBAC-4605	HbA1c CONTROL L + H	44435
HBAC-4705	HbA1c CONTROL L + H	44435
HBAC-0240	HbA1c p. 82, 83	59090
HBAC-5224	HbA1c	59090
HBAC-6076	HbA1c	59090
HBAC-6004	HbA1c	59090
HBAC-7225	HbA1c	59090
HBAE-0043	HbA1c Enzymatic Calibrator Set	53315
HBAE-4301	HbA1c Enzymatic Calibrator Set	53315
HBAE-4303	HbA1c Enzymatic Calibrator Set	53315
HBAE-M130	HbA1c Enzymatic	63151
HBAE-5M30	HbA1c Enzymatic	63151
HBAE-6M30	HbA1c Enzymatic	63151
HBAE-7050	HbA1c Enzymatic	63151
HDLL-0011	CHOLESTEROL HDL 2G CALIBRATOR	44696
HDLL-0041	CHOLESTEROL HDL 2G CALIBRATOR	44696
HDLL-0230	CHOLESTEROL HDL SL 2G	53391
HDLL-0380	CHOLESTEROL HDL SL 2G	53391
HDLL-0390	CHOLESTEROL HDL SL 2G	53391
HLCA-0041	HDL LDL CALIBRATOR p. 84-87	47868
HLCA-4001	HDL LDL CALIBRATOR	47868
ICRP-0043	CRP IP CALIBRATOR SET	41838

Annex

REF	PRODUCT NAME	GMDN Code
ICRP-4311	CRP IP CALIBRATOR SET	41838
ICRP-4312	CRP IP CALIBRATOR SET	41838
ICRP-4313	CRP IP CALIBRATOR SET	41838
ICRP-4314	CRP IP CALIBRATOR SET	41838
ICRP-4315	CRP IP CALIBRATOR SET	41838
ICRP-0046	CRP IP CONTROL I	41839
ICRP-4610	CRP IP CONTROL I	41839
ICRP-0047	CRP IP CONTROL II	41839
ICRP-4710	CRP IP CONTROL II	41839
ICRP-0400	CRP IP	53705
ICRP-6125	CRP IP	53705
ICRP-5025	CRP IP	53705
ICRP-M230	CRP IP	53705
ICRP-6M30	CRP IP	53705
ICRP-5M30	CRP IP	53705
IFRT-0042	FERRITIN CALIBRATOR	41927
IFRT-4230	FERRITIN CALIBRATOR	41927
IFRT-0230	FERRITIN	53718
IFRT-5020	FERRITIN	53718
IFRT-6005	FERRITIN	53718
IHAP-0400	HAPTOGLOBIN IP	53737
IHAP-6125	HAPTOGLOBIN IP	53737
IHAP-5025	HAPTOGLOBIN IP	53737
IIGA-0400	IgA IP	53760
IIGA-6125	IgA IP	53760
IIGA-5025	IgA IP	53760
IIGG-0400	IgG IP	53787
IIGG-6125	IgG IP	53787
IIGG-5025	IgG IP	53787
IIGM-0400	IgM IP	53795
IIGM-6125	IgM IP	53795
IIGM-5025	IgM IP	53795
IMAL-0043	μALBUMIN IP CALIBRATOR SET	53477
IMAL-4311	μALBUMIN IP CALIBRATOR SET	53477
IMAL-4312	μALBUMIN IP CALIBRATOR SET	53477
IMAL-4313	μALBUMIN IP CALIBRATOR SET	53477
IMAL-4314	μALBUMIN IP CALIBRATOR SET	53477
IMAL-4315	μALBUMIN IP CALIBRATOR SET	53477
IMAL-0046	μALBUMIN IP CONTROL I	53478
IMAL-4610	μALBUMIN IP CONTROL I	53478
IMAL-0047	μALBUMIN IP CONTROL II	53478
IMAL-4710	μALBUMIN IP CONTROL II	53478
IMAL-0400	μALBUMIN IP	53475
IMAL-6125	μALBUMIN IP	53475
IMAL-5025	μALBUMIN IP	53475
IMAL-M230	MICROALBUMIN IP	53475
IMAL-6M30	MICROALBUMIN IP	53475
IMAL-5M30	MICROALBUMIN IP	53475
IORO-0400	OROSOMUCOID IP	53606
IORO-6125	OROSOMUCOID IP	53606
IORO-5025	OROSOMUCOID IP	53606
IPAL-0400	PREALBUMIN IP	53957
IPAL-6125	PREALBUMIN IP	53957
IPAL-5025	PREALBUMIN IP	53957
IPRO-0043	PROTEIN IP CALIBRATOR SET	53593
IPRO-4311	PROTEIN IP CALIBRATOR SET	53593
IPRO-4312	PROTEIN IP CALIBRATOR SET	53593
IPRO-4313	PROTEIN IP CALIBRATOR SET	53593
IPRO-4314	PROTEIN IP CALIBRATOR SET	53593
IPRO-4315	PROTEIN IP CALIBRATOR SET	53593
IRCT-0046	RHEUMATOLOGY CONTROL I	47869
IRCT-4610	RHEUMATOLOGY CONTROL I	47869
IRCT-0047	RHEUMATOLOGY CONTROL II	47869
IRCT-4710	RHEUMATOLOGY CONTROL II	47869
IRFA-0042	RF CALIBRATOR	42230
IRFA-4220	RF CALIBRATOR	42230
IRFA-0230	RHEUMATOID FACTOR	55111
IRFA-5020	RHEUMATOID FACTOR	55111
IRFA-6005	RHEUMATOID FACTOR	55111
ISCA-0250	ISE CALIBRATORS	52867
ISCA-4221	ISE CALIBRATORS	52867
ISCA-4222	ISE CALIBRATORS	52867
ITRF-0400	TRANSFERRIN IP	59041
LACI-0250	LACTATE	53342
LACI-5008	LACTATE	53342
LACI-6005	LACTATE	53342
LDLL-0011	CHOLESTEROL LDL 2G CALIBRATOR	41728
LDLL-0041	CHOLESTEROL LDL 2G CALIBRATOR	41728

Annex

REF	PRODUCT NAME	GMDN Code
LDLL-0230	CHOLESTEROL LDL SL 2G	53395
LDLL-0380	CHOLESTEROL LDL SL 2G	53395
LDLL-0390	CHOLESTEROL LDL SL 2G	53395
LLSL-0230	LDH-L SL	53072
LLSL-5220	LDH-L SL	53072
LLSL-6050	LDH-L SL	53072
LLSL-0400	LDH-L SL	53072
LLSL-5400	LDH-L SL	53072
LLSL-6250	LDH-L SL	53072
LLSL-0420	LDH-L SL	53072
LLSL-M230	LDH IFCC	53072
LLSL-5M30	LDH IFCC	53072
LLSL-6M10	LDH IFCC	53072
LPSL-0230	LIPASE SL	53108
LPSL-0250	LIPASE	53108
LPSL-5088	LIPASE	53108
LPSL-6061	LIPASE	53108
LPSL-0850	LIPASE ENVOY	53108
LXCR-0112	CRP LATEX	53707
MAGX-0230	MAGNESIUM XYLIDYL	46795
MAGX-0600	MAGNESIUM XYLIDYL	46795
MAGX-0850	MAGNESIUM ENVOY	46795
MGXB-0250	MAGNESIUM XB	46795
MGXB-5220	MAGNESIUM XB	46795
MGXB-0600	MAGNESIUM XB p. 64, 65	46795
MGXB-5600	MAGNESIUM XB	46795
MGXB-M430	MAGNESIUM XB	46795
MGXB-5M30	MAGNESIUM XB	46795
PASL-0230	ALP (DEA) SL	52928
PASL-5220	ALP (DEA) SL	52928
PASL-6050	ALP (DEA) SL	52928
PASL-0400	ALP (DEA) SL	52928
PASL-5405	ALP (DEA) SL	52928
PASL-6255	ALP (DEA) SL	52928
PASL-0420	ALP (DEA) SL p. 36, 37	52928
PHOS-0230	PHOSPHORUS	59123
PHOS-5220	PHOSPHORUS	59123
PHOS-0600	PHOSPHORUS	59123
PHOS-5600	PHOSPHORUS	59123
PHOS-M430	PHOSPHORUS	59123
PHOS-5M30	PHOSPHORUS	59123
PIVD-0850	ALP ENVOY	52928
PROB-0250	TOTAL PROTEIN PLUS	53985
PROB-5220	TOTAL PROTEIN PLUS	53985
PROB-0600	TOTAL PROTEIN PLUS	53985
PROB-5600	TOTAL PROTEIN PLUS	53985
PROB-0700	TOTAL PROTEIN PLUS	53985
PROB-5700	TOTAL PROTEIN PLUS	53985
PROB-M830	TOTAL PROTEIN	53985
PROB-5M30	TOTAL PROTEIN	53985
PRTU-0022	MICROPROTEIN PLUS Standard 100 mg/dL	53482
PRTU-0250	MICROPROTEIN PLUS	53481
PRTU-0600	MICROPROTEIN PLUS	53481
PRTU-5600	MICROPROTEIN PLUS	53481
PRTU-M230	URINE PROTEIN	53481
PRTU-5M30	URINE PROTEIN	53481
RHFA-M130	RHEUMATOID FACTOR	55111
RHFA-5M30	RHEUMATOID FACTOR	55111
RHFA-6M30	RHEUMATOID FACTOR	55111
RHFA-4220	RHEUMATOID FACTOR	42230
TGML-0250	TRIGLYCERIDES SL	53460
TGML-5220	TRIGLYCERIDES SL	53460
TGML-0425	TRIGLYCERIDES MONO SL NEW	53460
TGML-5415	TRIGLYCERIDES MONO SL NEW	53460
TGML-0427	TRIGLYCERIDES MONO SL NEW	53460
TGML-0455	TRIGLYCERIDES SL	53460
TGML-0497	TRIGLYCERIDES MONO SL NEW	53460
TGML-5515	TRIGLYCERIDES MONO SL NEW	53460
TGML-0515	TRIGLYCERIDES MONO SL NEW	53460
TGML-0517	TRIGLYCERIDES MONO SL NEW p. 70, 71	53460
TGML-0700	TRIGLYCERIDES MONO SL NEW	53460
TGML-5710	TRIGLYCERIDES MONO SL NEW	53460
TGML-0707	TRIGLYCERIDES MONO SL NEW p. 72, 73	53460
TGML-M690	TRIGLYCERIDES	53460
TGML-5M90	TRIGLYCERIDES	53460
TIBC-0250	Direct TIBC	53904
TIBC-5025	Direct TIBC	53904
TIBC-6007	Direct TIBC	53904
TIBC-M130	Direct TIBC	53904

Annex

REF	PRODUCT NAME	GMDN Code
TIBC-5M30	Direct TIBC	53904
TIBC-6M30	Direct TIBC	53904
TRF2-M230	TRANSFERRIN	59041
TRF2-5M30	TRANSFERRIN	59041
TRF2-6M10	TRANSFERRIN	59041
URSL-0250	UREA UV SL	53587
URSL-5220	UREA UV SL	53587
URSL-6050	UREA UV SL	53587
URSL-0420	UREA UV SL	53587
URSL-5405	UREA UV SL	53587
URSL-6255	UREA UV SL	53587
URSL-0427	UREA UV SL	53587
URSL-0455	UREA UV SL	53587
URSL-0500	UREA UV SL	53587
URSL-5505	UREA UV SL	53587
URSL-6605	UREA UV SL	53587
URSL-0507	UREA UV SL 0.77-79	53587
URSL-M830	UREA	53587
URSL-5M30	UREA	53587
URSL-6M10	UREA	53587
VITD-0043	VITAMIN D CALIBRATOR SET	54474
VITD-4311	VITAMIN D CALIBRATOR SET	54474
VITD-4312	VITAMIN D CALIBRATOR SET	54474
VITD-4313	VITAMIN D CALIBRATOR SET	54474
VITD-4314	VITAMIN D CALIBRATOR SET	54474
VITD-4315	VITAMIN D CALIBRATOR SET	54474
VITD-0049	VITAMIN D CONTROL SET	54475
VITD-4630	VITAMIN D CONTROL SET	54475
VITD-4730	VITAMIN D CONTROL SET	54475
VITD-0250	VITAMIN D	54476
VITD-5021	VITAMIN D	54476
VITD-6005	VITAMIN D	54476

vlo
CE

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

ELITECH CLINICAL SYSTEMS SAS
Zone Industrielle
61500 SEES FRANCE

pour les activités
for the activities

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

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

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

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

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

NF EN ISO 13485 : 2016

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

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

Etabli le / Issued on : July 25th, 2023

cofrac

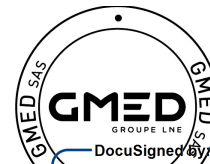


CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 10462-8

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

Renouvelle le certificat 10462-7



On behalf of the President
Marjorie PERRIMON
Certification Director



ISO 9001 -NF EN ISO 13485



R E A G E N T S

Zone Industrielle – 61500 SEES – France
Tél. : + 33 (0)2 33 81 21 00 / Fax : + 33 (0)2 33 28 77 51

TO WHOM TO BE CONCERNED

We, Seppim S.A.S., manufacturers of Elitech Clinical Systems reagents, having our factory at Zone Industrielle, 61500 Sées - France, confirm that our clinical reagents have been validated on Vital Scientific equipment. As such available Elitech Clinical Systems reagent applications for Vital Scientific instruments are CE-IVD compliant.

Reagents, other than Elitech Clinical Systems reagents, are not validated on Vital Scientific equipments, and we also can't know the impact of other reagents on Vital Scientific equipments.

May 22nd, 2012

Noi, subsemnații Seppim S.A.S., compania producătoare a reagenților Elitech Clinical Systems, având fabrica de producere în Zone Industrielle, 61500, Franța, confirmăm, că reagenții au fost testați și validați pe echipamentele Vital Scientific. Pentru acești reagenți există și protocoale specializate pentru analizatoarele produse de Vital Scientific. Atât reagenții cât și echipamentele sunt certificate CE-IVD.

Alți reagenți înafara de Elitech Clinical Systems, nu au fost testați și validați la echipamentele Vital Scientific și noi nu cunoaștem compatibilitatea și impactul lor asupra analizatoarelor Vital Scientific.

22 mai 2012

Signed on behalf of the manufacturer
Valérie GOURDON
Regulatory Affairs Manager
COMPANY SEPPIM S.A.S

SEPPIM S.A.S

4 rue Auguste Mattin
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

Société par actions simplifiée au Capital de 1 219 592.14 €
SIRET 318 365 228 00036 APE 2059Z
RC ALENCON 318 365 228

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

Page: 1 of 2



003

...making excellence a habit.™

Certificate No: **MD 69326**

Location

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

Registered Activities

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

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

Page: 2 of 2

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

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

Declaration of Conformity

helena
Biosciences Europe

HL-7-0260DC DOI 2015/08 (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
5509	D-Dimer Control H/L	47347

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: 07 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

helena
Biosciences Europe

HL-7-0674DC 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
5552	Auto Blue D-Dimer 400	47346

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: 11 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

Instrument Training

Vital Scientific BV hereby declares that the participant has attended a four days seminar for service engineers and the participant is now a certified engineer for the declared instruments.

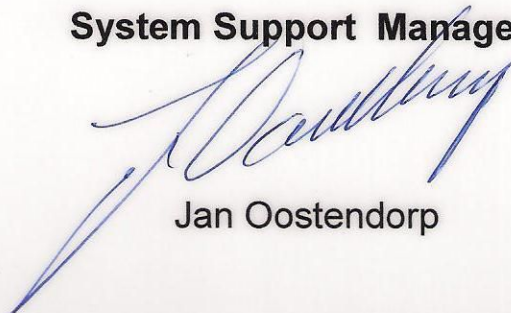
Participant: Mr. A. Legun

Company: Global Biomarketing Group-Moldova SRL
Moldova

Instrument: Vitalab: XL Series
E Series
Junior Series
Dry ISE
Micro Series
ProXS

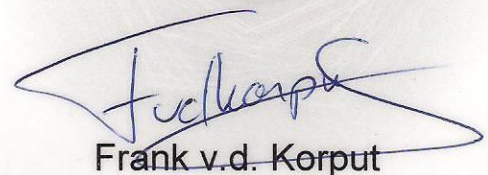
Date of training: April 20th – April 23rd, 2010

System Support Manager:



Jan Oostendorp

System Support Engineer:



Frank v.d. Kerput

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Medica Corporation

(FIN F002402)

Main Site: 5 Oak Park Drive, Bedford, Massachusetts, 01730, United States

Additional Site: 3 Oak Park Drive, Bedford, Massachusetts, 01730, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

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

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

Design, Development, Manufacture, Service, Installation and Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:

0089217-01

Initial Certification Date:

2019-04-19

Date of Certification Decision:

2022-03-24

Certification Effective Date:

2022-04-18

Certification Expiry Date:

2025-04-18



intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851



EasyBloodGas™ analyzer
EasyLyte® analyzer

EasyElectrolytes® analyzer
EasyStat® analyzer

Training Certificate

This is to certify that

Mr. Sergiu Sorocovici

Of GBG-MLD S.R.L.

has completed training for the operation and service of the

EasyBloodGas™ analyzer, EasyElectrolytes® analyzer, EasyLyte® analyzer and EasyStat® analyzer

04/22/2016
DATE



Medica Corporation

David Hagopian
Director of Technical Support



Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

H6-20N

March 24, 2005

H. Shimosaka

Hiroshi Shimosaka

President

ERMA INC.

