

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:

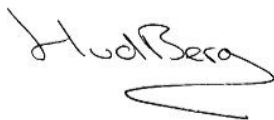
- Register, promote, offer, negotiate prices and sell our Products in Moldova;
- carry out the required product training of the medical and technical personnel who will use these products.

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

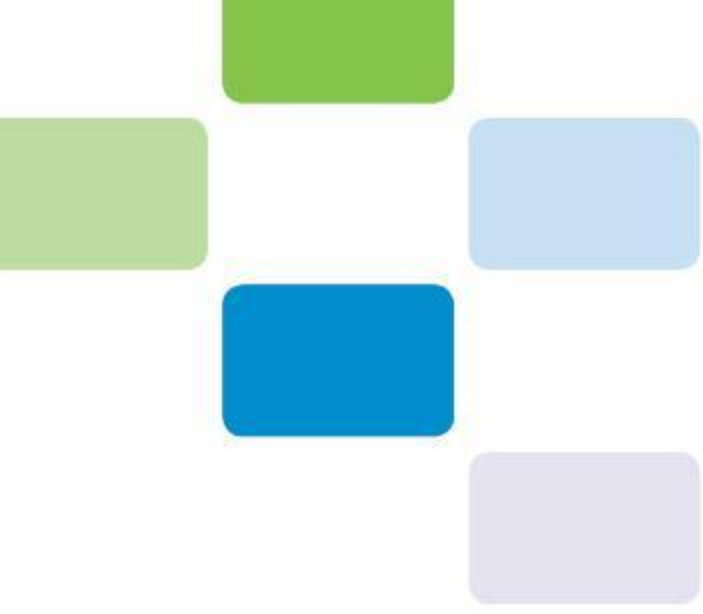
H. Shimosaka

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




DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY

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

fabbricante **VACUTEST KIMA S.r.l. - articoli per laboratori analisi**
manufacturer **disposable labware**

indirizzo **Via dell'Industria, 12**
address **35020 Arzergrande (PD) - Italia**

telefono **+39-049-9720624**
phone

fax **+39-049-9720182**
fax

posta elettronica **info@vacutestkima.it**
e-mail

identificazione dei prodotti
product identification

**Sistema di prelievo di sangue e altri liquidi biologici
mediante provette con vuoto predeterminato in plastica
"VACUTEST KIMA".**

**"VACUTEST KIMA" vacuum blood and biological liquids
collection tubes in plastic.**

nome commerciale
brand name

"VACUTEST KIMA"

classificazione dei prodotti
product classification

**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.
devices other than those mentioned in Annex II of the Directive 98/79/EC as amended**

Si dichiara

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

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

Hereby we declare

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

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

luogo e data
place and date

Arzergrande, 01/01/2015

firma
signature

**Assicuratore Qualità / Quality Manager
Giovanni Chiarin**





IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n.
CERTIFICATE No.

4265/5/A

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

MEUS S.r.l.

Unità Operative / Operative Units

Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia.

Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

Via dell'Industria 2-16 - 35020 Arzergrande (PD) - Italia

Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia.
Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.
Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

*Design and production of diagnostic kits for blood and biological liquids analysis.
Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Design and production of moulds for plastic labware.*

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.

Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

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

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,

si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

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Vincenzo Delacqua

Rappresentante Direzione / Management Representative

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it



SGQ N° 004 A



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendali.
CISQ is the Italian Federation of management system Certification Bodies.



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

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

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

ROLL S.r.l.

UNITÀ OPERATIVA / OPERATIVE UNIT

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

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

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

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

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

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
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CERTIFICATO n. **4265/5/D**
CERTIFICATE No. _____

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

VACUTEST KIMA S.r.l.

Sede / Head office

Via dell'Industria, 12 - 35020 Arzzergrande (PD) – Italia

Uffici direzionali e amministrativi

Unità Operative / Operative Units

Via dell'Industria, 12 - 35020 Arzzergrande (PD) – Italia

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine.
Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Via Leonardo Da Vinci, 22 – 35028 Piove di Sacco (PD)

Uffici commerciali e magazzino.

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

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Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.

Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

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CERTIFICATO n.
CERTIFICATE No.

4265/5/A

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

MEUS S.r.l.

Unità Operative / Operative Units

Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia.

Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

Via dell'Industria 2-16 - 35020 Arzergrande (PD) - Italia

Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia.
Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.
Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

*Design and production of diagnostic kits for blood and biological liquids analysis.
Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Design and production of moulds for plastic labware.*

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.

Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

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CERTIFICATO n. **4265/5/D**
CERTIFICATE No. _____

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Sede / Head office

Via dell'Industria, 12 - 35020 Arzzergrande (PD) - Italia

Uffici direzionali e amministrativi

Unità Operative / Operative Units

Via dell'Industria, 12 - 35020 Arzzergrande (PD) - Italia

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine.
Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Via Leonardo Da Vinci, 22 - 35028 Piove di Sacco (PD)

Uffici commerciali e magazzino.

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

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Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.

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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



MEDICA

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

Declaration of Conformity

Product Name:

EasyLyte 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

 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

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