ELITechGroup B.V.
P.O.Box 100
6950 AC Dieren
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands
T: +31 313 430 500
F: +31 313 427 807
info.ecsnl@elitechgroup.com
www.elitechgroup.com
Chamber of Commerce 09175642

To: Whom it May Concern

Regulatory status of parts & accessories

As mentioned on the current Declarations of Conformity of our Clinical Chemistry Analyzers also the accessories conform to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC). This applies to the parts and accessories as mentioned in the attached list.

'IVD accessory' means an article which, whilst not being an IVD medical device, is intended specifically by its manufacturer to be used together with an IVD device to enable that IVD device to be used in accordance with its intended purpose.

ELITechGroup B.V.

Adriaan P. Intveld
Manager Quality Assurance & Regulatory Affairs

Part number	Description	IVD medical device	IVD accessory	general laboratory use	spare part	supporting part
1540-001	Anti-Slip sheet					✓
2206-007	Cooling Liquid (1 L)					✓
3062-021	Sample cup (1000 pcs)		✓			
3062-033	Sample tube 6 ml (500 pcs)					✓
3062-040	Water container 10 L					✓
3062-041	Water container 5 L					✓
3066-155	Syringe 100 µl		✓			
3066-156	Syringe 1 ml		✓			
3069-040	Keyboard Dust cover					✓
3069-047	Keyboard Dust cover					✓
3070-518	Cap holder					✓
3070-538	Cap rotor Left					✓
3070-539	Cap rotor right					✓
3201-002	Dichromate 8 Abs (25ml)		✓			
3365-192	USB Stick					✓
3374-003	Mains cable (USA)					✓
3374-059	Pumpunit cable		✓			
3374-066	Mains cable					✓
3374-097	Serial Null-modem cable					✓
3374-286	USB Extension cable					✓
4804-038	Reagent identification Disc					✓
6001-826	Diluted Waste container		✓			
6001-827	Concentrated Waste container		✓			
6001-860	Water container		✓			
6001-861	Tube assy (analyser)		✓			
6001-872	Tube assy (cooling unit)		✓			
6002-102	Assorter unit				✓	
6002-386	System software on CD		✓			
6002-706	Reaction Rotor set (3 pcs)		✓			
6002-726	System Disc		✓			
6002-817	Bottle 30 ml (20 pcs)		✓			
6002-818	Bottle 15 ml (20 pcs)		✓			
6002-904	Water container 5 L		✓			
6002-910	Assorter unit				✓	
6002-913	External tubing		✓			
6003-074	System software on USB stick		✓			
6003-444	Diluted Waste Container 5 L		✓			
6003-466	Keyboard Support option					✓
6003-797	CW Waste Container 2 L		✓			
6003-808	Assorter unit				✓	

ISO 9001 -NF EN ISO 13485

ELITechGroup SEPPIM

REAGENTS

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 Scientifc equipments.

May 22nd, 2012

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

Alți reagenți înafara de Elitech Clinical Systems, nu au fost testați şi validați la echipamentele Vital Scientific şi noi nu cunoaştem compatibilitatea şi 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 Mottin
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

MEDICA

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

Products For Health Care

AUTHORIZATION LETTER

TO WHOM IT MAY CONCERN:

MEDICA CORPORATION, having facilities at 5 Oak Park Drive, Bedford, MA 01730, USA, do hereby authorize the company:

GBG-MLD SRL
Tighina str.65, office 607
MD-2001, Chisinau,
Republic of Moldova

to be our **DISTRIBUTOR** for the **EasyLyte®, EasyElectrolyte™, EasyBloodGas™** and **EasyStat®** analyzers as well as associated reagents and consumables in **Moldova.**

GBG-MLD SRL is authorized by **MEDICA CORPORATION** to enter tenders and quote for all aforementioned products.

GBG-MLD SRL is authorized by **MEDICA CORPORATION** to present offers on our behalf to tenders placed by the government and other institutions for Medica products and consumables

GBG-MLD SRL responsibilities include sales of the **EasyLyte®, EasyElectrolyte™, EasyBloodGas™** and **EasyStat®** analyzers and providing service as well as maintaining a supply of reagents and replacement parts.

GBG-MLD SRL is also authorized to provide warranty service for the Medica **EasyLyte®, EasyElectrolyte™, EasyBloodGas™** and **EasyStat®** analyzers.

This authorization is effective immediately and is valid until December 31, 2019, unless revoked earlier in writing by Medica Corporation.

Dave Anacone
Director of Sales
MEDICA CORPORATION

1/5/18
Date

MEDICA

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

Products For Health Care

Declaration of Conformity CE

Product Name:	Model/Type:
EasyStat and accessories per attachment	pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct
EasyBloodGas and accessories per attachment	pH/pCO2/pO2

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, March 30, 2017

Signature:

Name: Photios Makris, Ph.D.
Title: Director of Regulatory Affairs

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6001	EasyBloodGas Analyzer	21 07 11 01
7001	EasyStat Analyzer, Ca	21 07 11 03
7017	EasyStat Analyzer, Cl	21 07 11 03
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO2 Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO2 Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 10
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution Kit	11 01 01 27
6402	Red Test Dye Solution	11 30 01 11
6503	EasyBloodGas Capillary Tube Kit	21 07 11 01
6603	EasyBloodGas Demonstration Kit	21 07 11 01
6306	EasyBloodGas Sampler	21 07 11 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 07 11 03
6506	EasyBloodGas Sensor Module	21 07 11 01
6507	EasyStat/EasyBloodGas Valve Module	21 07 11 03
6508	Compression Plate	21 07 11 03
6518	Serial Cable, 25-pin	21 07 11 03
6537	Serial Cable, 9-pin	21 07 11 03
6520	Barcode Reader Kit	21 07 11 03
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 07 11 03
7309	Bi-Level Hematocrit Quality Control	11 50 02 90
7603	EasyStat Demonstration Kit	21 07 11 03
7303	EasyStat/EasyBloodGas Capillary Tube Kit	21 07 11 03
7306	EasyStat Sampler	21 07 11 03
7304	EasyStat Pump Tube	21 07 11 03
7506	EasyStat Sensor Module	21 07 11 03
7302	Probe Wipers	21 07 11 03

MEDICA

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

Products For Health Care

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, March 30, 2017

Signature:

Name: Photios Makris Ph D
Title: Director of 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 Maintenace 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

EasyElectrolyte Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolytes Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolytes Na/K/Li Analyzer	21 07 11 02
4102	EasyElectrolyte Reagent Module Na/K/Cl	11 04 04 02
4103	EasyElectrolyte Reagent Module Na/K/Li	11 04 04 02
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
4203	EasyElectrolyte Cl Electrode	11 04 01 03
4204	EasyElectrolyte Li Electrode	11 04 01 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte 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	Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Demonstration Kit, Na/K/Cl	21 07 11 02
4406	EasyElectrolyte Demonstration Kit, Na/K/Li	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 (5 rolls)	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	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
6518	Serial Cable, 25-pin	21 07 11 02
6537	Serial Cable, 9-pin	21 07 11 02
6520	Barcode Reader Kit	21 07 11 02

Certificate No. 2046-11-2017

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer/Distributor
MEDICA CORP.
5 OAK PARK DRIVE
BEDFORD, MA USA 01730

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from November 13, 2017 to November 12, 2019.

Certificate No. 2046-11-2017

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer/Distributor

MEDICA CORP.
5 OAK PARK DRIVE
BEDFORD, MA USA 01730

Name of Product(s)

Catalog #	
2004	EasyLyte Na/K Analyzer
2014	EasyLyte Plus Na/K/Cl Analyzer
2015	EasyLyte Lithium Na/K/Li Analyzer
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer
2021	EasyLyte Na/K/Cl/Li Analyzer
2070	EasyLyte EasySampler
2030	EasyLyte EXPAND Na/K/Cl/Ca/Li Analyzer
C2004	EasyLyte Na/K Analyzer
C2014	EasyLyte Plus Na/K/Cl Analyzer
C2015	EasyLyte Lithium Na/K/Li Analyzer
C2016	EasyLyte Calcium Na/K/Ca/pH Analyzer
L2014	EasyLyte Plus Na/K/Cl Analyzer
L2015	EasyLyte Lithium Na/K/Li Analyzer
L2016	EasyLyte Calcium Na/K/Ca/pH Analyzer
L2021	EasyLyte Na/K/Cl/Li Analyzer
2026	EasyLyte Na/K/Cl/Li Solutions Pack, 400mL
2026	EasyLyte Na/K/Cl/Li Solutions Pack, 800mL
2109	EasyLyte Na/K Solutions Pack, 400mL
2120	EasyLyte Na/K Solutions Pack, 800mL
2112	EasyLyte Na/K/Cl Solutions Pack, 400mL
2121	EasyLyte Na/K/Cl Solutions Pack, 800mL
2115	EasyLyte Na/K/Li Solutions Pack, 400mL
2122	EasyLyte Na/K/Li Solutions Pack, 800mL
2114	EasyLyte Na/K/Ca/pH Solutions Pack, 400mL
2123	EasyLyte Na/K/Ca/pH Solutions Pack, 800mL
2124	EasyLyte Na/K/Cl/Ca/Li Solutions Pack, 800mL
L2026	EasyLyte Na/K/Cl/Li Solutions Pack, 400mL
L2026	EasyLyte Na/K/Cl/Li Solutions Pack, 800mL
L2112	EasyLyte Na/K/Cl Solutions Pack, 400mL
L2121	EasyLyte Na/K/Cl Solutions Pack, 800mL
L2115	EasyLyte Na/K/Li Solutions Pack, 400mL
L2122	EasyLyte Na/K/Li Solutions Pack, 800mL
L2114	EasyLyte Na/K/Ca/pH Solutions Pack, 400mL
L2123	EasyLyte Na/K/Ca/pH Solutions Pack, 800mL
2074	Sample Cup Retainer Ring
2076	Sample Tray
2095	EasyLyte Maintenance Kit
2100	EasyLyte Calcium Tubing Kit
2101	EasyLyte K+ Electrode
2102	EasyLyte Na+ Electrode
2103	EasyLyte Reference Electrode
2104	EasyLyte Tubing Kit
2105	EasyLyte Quarterly Operating Kit
2106	EasyLyte Li+ Electrode
2107	EasyLyte Sample Probe
2108	EasyLyte Solutions Valve
2111	Urine Diluent (500mL)
2113	EasyLyte Cl- Electrode
2116	Daily Cleaning Solution Kit
2120	EasyLyte Ca++ Electrode
2119	EasyLyte pH Electrode

Certificate No. 2046-11-2017

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

2152	EasyLyte Disposable Reference Electrode
2257	EasyLyte Sample Detector
2258	EasyLyte Membrane Assembly
2292	EasyLyte Capillary Adapter Cleaning Kit
2293	Capillary Tubes
2309	Wash Solution (50mL)
2323	EasyLyte Probe Wipers (6 ct.)
2492	EasyLyte Internal Filling Solution (125mL)
2541	EasyLyte Printer Paper (3 rolls)
2544	EasyLyte C Series Printer Paper (5 rolls)
2571	Calcium Troubleshooting Kit
2572	Troubleshooting Kit
2577	Standard Urine Solution (50mL)
2578	Red Test Dye Solution (50mL)
2590	EasyLyte Capillary Adapter Kit
2595	500µL Sample Cups (500 ct.)
2596	2mL Sample Cups (500 ct.)
13745	Anti-Evaporation Caps (500 ct.)
2598	EasyLyte Daily Cleaner Cup
2814	Bi-Level Quality Control Kit
2815	Tri-Level Quality Control Kit
2843	Quality Control Sample Cups (60 ct.)
7118	Daily Rinse/Cleaning Solution Kit

----------END OF PRODUCT LIST----------

Certificate No. 2039-11-2017

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

Name of Manufacturer/Distributor
MEDICA CORP
5 OAK PARK DRIVE
BEDFORD, MA USA 01730

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from November 13, 2017 to November 12, 2019.

Certificate No. 2039-11-2017

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer/Distributor
MEDICA CORP
5 OAK PARK DRIVE
BEDFORD, MA USA 01730

Name of Product(s)

Catalog #	
6001	EasyBloodGas Analyzer
6002	EasyBloodGas Analyzer
6003	EasyBloodGas Analyzer
6011	EasyBloodGas Analyzer
6030	EasyBloodGas Analyzer
6050	EasyBloodGas Analyzer
6060	EasyBloodGas Analyzer
6990	EasyBloodGas Analyzer
6061	EasyBloodGas Analyzer
6201	EasyStat/EasyBloodGas pH Electrode
6202	EasyStat/EasyBloodGas pCO2 Electrode
6203	EasyStat/EasyBloodGas pO2 Electrode
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode
6101	EasyBloodGas Reagent Module
5301	EasyBloodGas Troubleshooting Kit
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control
2116	Daily Cleaning Solution
5402	Red Test Dye Solution
5503	EasyBloodGas Capillary Tube Kit
5603	EasyBloodGas Demonstration Kit
5306	EasyBloodGas Sample
6504	EasyBloodGas/EasyElectrolyte Pump Tube
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper
6506	EasyBloodGas Sensor Module
6507	EasyBloodGas Valve Module
6508	Compression Plate
6518	Serial Cable, 25-pin
6537	Serial Cable, 9-pin
6520	Barcode Reader Kit
7302	Probe Wipers

END OF PRODUCT LIST

BUREAU VERITAS
Certification

Certificate

Awarded to

Avantor Performance Materials Poland S.A.

ul. Sowińskiego 11, 44-101 GLIWICE
POLAND

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

STANDARD

ISO 9001:2015

SCOPE OF SUPPLY

SALES OF CHEMICAL SERVICES AND CHEMICAL PRODUCTS INCLUDING FINE CHEMICALS, ENNOBLED CHEMICALS, HIGH PURITY SOLVENTS, CHEMICAL SERVICES.

PRODUCTION AND TESTING OF CHEMICAL PRODUCTS INCLUDING FINE CHEMICALS, ENNOBLED CHEMICALS AND HIGH PURITY SOLVENTS.

Certification Cycle Start Date: **15 September 2018**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: **14 September 2021**

To check this certificate validity please call: +48 22 549 04 00
Further clarification regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

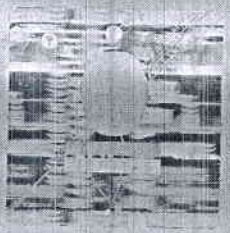
Issue Date: 29 June 2018

Certificate Number: **PL008875/P**

Piotr Popławski
Local Technical Manager

PCA
Polskie Centrum Akredytacji
Certyfikacja Systemów Zarządzania
AC 081
QMS

MIX
Paper from responsible sources
FSC® C074440



avantor

To whom is may concern

Date: January 9, 2019 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 the Republic of Moldova

The Products 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.

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.

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

avantor™

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

Anna Szuba
Quality Director

NIP 631-010-10-67
Numer w KRS: 0000010019
Sąd rejestrowy: Sąd Rejonowy w Gliwicach
X Wydział Gospodarczy KRS
Kapitał zakładowy 2 580 793,00 zł
Regon: 276593350

Product	Product number	Pack size
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
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

Product	Product number	Pack size
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
CyMet™ NR V	3486.1000PE	1 L
CyMet™ Ruby CN Free	3485.1000PE	1 L
CyMet™ ST 1600/2000 CN free	2988.5000PC	5 L
LeucoLyse	3759.5000	5 L
LeucoLyse Ruby	3475.5000PC	5 L
	2989.5000PC	5 L
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
DetectoTerge™ BS	3766	1 L
ProClean™	2970.0900PE	900 ml
	3900	5 L
	3900-00	5 L
	3768.1000	1 L micros
ProClean™ Abacus	3432.5000	5 L
ProClean™ CD	3432.1000PE	1 L
ProClean™ Extra	3902.0100PE	100 ml
	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
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
8-Parameter Control 4xN	3463/3464/3465	2.5 ml
8-Parameter Control 1xL+4xN+1xH	3747	4 x 2.5 ml
8-Parameter Control extended L/N/H	3751	6 x 2.5 ml
3-Diff Control L/N/H	3633/3634/3635	2.5 ml
	3433/3434/3435	2.5 ml
3-Diff Control extented L/N/H	3502/3503/3504	4.5 ml
CD-Diff Control L/N/H	3421/3422/3423	2.5 ml
CD-Diff Control 2xL+2xN+2xH	3452/3453/3454	3.0 ml
K-Diff Control L/N/H	3838	6 x 3.0 ml
Platelet Control- Extended value	3455/3456/3457	2.5 ml
WBC Reduced RBC L/H	3424	5 x 3.0 ml
XE-Diff Control L/N/H	3698/3699	3.0 ml
	3731/3732/3733	4.5 ml
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
UltraClear™	3905.2500PE	2.5 L
	3905.5000PE	5 L
	3905.9010PE	10 L

Product	Product number	Pack size
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
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	3059	20 L
	3059.9010PC	10 L

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

Hiroshi Shimosaka
President
ERMA INC.

AVANTOR™
PERFORMANCE MATERIALS

CyMet* Erma III Diff

Intended use
CyMet* Erma III Diff is a specially filtered, non-sterile blood lysing reagent fluid for use in cell counting and sizing.
The reagent is designed for automated instrumentation, capable to monitor a three-part WBC differential, based on the aperture impedance principle. CyMet* Erma III Diff is also used to analyse Hemoglobin by optical measurement. CyMet* Erma III Diff should be used in combination with Diluid* ERMA.

Summary and principle
The reagent is used prior to counting and sizing of WBC. The reagent stromatolysis RBC to release Hemoglobin prior to analyse it by optical measurement and modifies WBC for counting and sizing.

Content: CyMet* Erma III Diff is water based and contains:
Quaternary ammonium compounds and KCN (<0.1%).

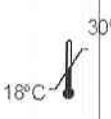
Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

Storage and stability: CyMet* Erma III Diff is stable for two years at 18-30°C.

Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
CyMet* Erma III Diff should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual.
Reagent may be used with Proclean* And Hypochlorite 0.5% as a cleaning agent.
Furthermore reagent may be used with Diluid* ERMA.

Pack size
REF 3460.0500 CyMet* Erma III Diff 500 ml HDPE bottle
* Trademark of Avantor™ Performance Materials - Deventer – The Netherlands



Avantor™ Performance Materials
Teugseweg 20 – 7418 AM Deventer – The Netherlands
Tel: +31 (0)570 687500
The devices as mentioned in this sheet comply with the In Vitro Diagnostic Medical Device Directive 98/79/EG

VERSION: 2011-08-12

AVANTOR™
PERFORMANCE MATERIALS

ProClean*

Intended use
ProClean* is a specially filtered, non-sterile cleaning fluid for use in cleaning of cell counters.
The product is designed for semi-automated and automated instrumentation, capable to clean blood diluting parts of the instrument.

Summary and principle
The reagent is used to clean blood diluting parts prior to remove cell fragments from the instrument.

Content
ProClean* is water based and contains:
Proteolytic enzym, poly-oxy-ethylene-alkyl-alcohol, NaCl, Na_2SO_4 and preservatives in an inorganic buffer compound. ProClean Contains a purple inert dye.

Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

Storage and stability
ProClean* is stable for two years at 18-30°C.

Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
ProClean* should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual.
Reagent may be used with all kinds of Diluids* and CyMet's*.

Pack size
REF 3900	ProClean*	5 litres cubitainer

* Trademark of Avantor™ Performance Materials - Deventer – The Netherlands

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VERSION: 2011-08-12

AVANTOR
PERFORMANCE MATERIALS

Diluid* Erma

Intended use
Diluid* Erma is a specially filtered, non-sterile blood diluting fluid for use in cell counting and sizing.
The reagent is designed for automated instrumentation, capable to monitor a three-part WBC differential, based on the aperture impedance principle and electronically adjusted to operate at an osmolality of 330 ± 20 mOsm/kg. Diluid* Erma should be used in combination with CyMet* ERMA III Diff and Lyzerglobin* PCE.

Summary and principle
The reagent is used to dilute whole blood prior to counting and sizing of RBC, PLT and WBC. Content of the reagent maintains stability of RBC, PLT and WBC during counting.

Content: Diluid* Erma is water based and contains:
NaCl, Na_2SO_4, procaine HCl and preservatives in an inorganic buffer compound.

Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

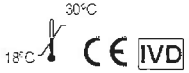
Storage and stability: Diluid* Erma is stable for three years at 18-30°C.

Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
Diluid* Erma should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual. Reagent may be used with Hypochlorite 0.5% or Proclean* as a cleaning agent. Furthermore reagent may be used with next lysing reagents: with CyMet* ERMA III Diff and Lyzerglobin* PCE.

Pack size
REF 3459.9020	Diluid* Erma	20 litres cubitainer

* Trademark of Avantor™ Performance Materials - Deventer – The Netherlands



Avantor™ Performance Materials
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VERSION: 2011-08-12

AVANTOR™
PERFORMANCE MATERIALS

Hypochlorite 0.5%

Intended use
Hypochlorite 0.5% is a specially filtered, non-sterile cleaning fluid for use in cleaning of cell counters.
The reagent is designed for semi-automated and automated instrumentation, capable to clean blood diluting parts of the instrument.

Summary and principle
The reagent is used to clean blood diluting parts prior to remove cell fragments from the instrument.

Content
Hypochlorite 0.5% is water based and contains:
Sodium hypochlorite (0.5% active chlorine) and poly-oxy-ethylene-alkyl-alcohol.

Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

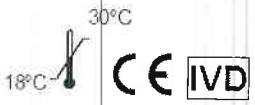
Storage and stability
Hypochlorite 0.5 % is stable for one year at 18-30°C.

Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
Hypochlorite 0.5% should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual.
Reagent may be used with all kinds of Diluids* and CyMet's*.

Pack size
REF 3917.1000 Hypochlorite 0.5% 1 liter bottle
REF 3917.5000 Hypochlorite 0.5% 5 liter bottle

* Trademark of Avantor™ Performance Materials - Deventer – The Netherlands



Avantor™ Performance Materials
Teugseweg 20 – 7418 AM Deventer – The Netherlands
Tel +31 (0)570 687500
The devices as mentioned in this sheet comply with the In Vitro Diagnostic Medical Device Directive 98/79/EG

VERSION: 2011-08-12

МиниМед®
поставщик лабораторий

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

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

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

Регистрационное удостоверение № ФСР 2011/11306 от 07.12.2015 г.

Паспорт

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

Серия	20-18	Дата изготовления	11.2018 г.	Использовать до	11.2019 г.

1. Назначение

Предназначен для окрашивания форменных элементов крови.

2. Технические требования

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

3. Транспортирование и хранение

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

4. Гарантии изготовителя

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

Начальник ПТО **Бабич В.А.**

Общество с ограниченной ответственностью · Начальник ПТО · г. Брянск · Бабич В.А. · МиниМед

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

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

ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4265/4**

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

GRUPPO VACUTEST KIMA

Sede / *Head Office*
Via dell'Industria,12 – 35020 Arzergrande (PD) - Italia
Unità Operative / *Operative Units*
MEUS S.r.l. - Via Leonardo da Vinci, 24B – 26 – 28 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
MEUS S.r.l. - Via dell'Industria, 2 - 16 – 35020 Arzergrande (PD) - Italia
ROLL S.R.L. - Via Leonardo Da Vinci, 24A – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
KIMA S.R.L. - Via Leonardo da Vinci, 22 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
VACUTEST KIMA S.r.l. - Via dell'Industria,12 – 35020 Arzergrande (PD) – Italia
VACUTEST KIMA S.r.l. via L. Da vInci, 22 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*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. 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. 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. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

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. Design and production of Holders for vacuum sampling. 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. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. 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.

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

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ
www.cisq.com

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

08SGCM_02_IT

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ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4**

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

GRUPPO VACUTEST KIMA

Sede / *Head Office*
Via dell'Industria,12 – 35020 Arzergrande (PD) - Italia
Unità Operative / *Operative Units*
MEUS S.r.l. - Via Leonardo da Vinci, 24B – 26 – 28 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
MEUS S.r.l. - Via dell'Industria, 2 - 16 – 35020 Arzergrande (PD) - Italia
ROLL S.R.L. - Via Leonardo Da Vinci, 24A – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
KIMA S.R.L. - Via Leonardo da Vinci, 22 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
VACUTEST KIMA S.r.l. - Via dell'Industria,12 – 35020 Arzergrande (PD) – Italia
VACUTEST KIMA S.r.l. via L. Da vInci, 22 Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

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

UNI EN ISO 9001:2015

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. 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. 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. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

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. Design and production of Holders for vacuum sampling. 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. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

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

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

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

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

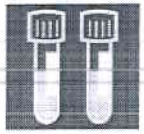
FEDERAZIONE CISQ
www.cisq.com

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

0449CM_03_IT

VACUTEST kima

Search ... Search



CLOT ACTIVATOR TUBES

CODE	SIZE	DESCRIPTION	DRAWING	COLOUR	SHELF-LIFE	PACKAGING	LABEL
11006	13 x 75 mm IN	Clot activator	2 ml	Red	18 months	100 / 1000	Paper
112490	13 x 75 mm	Clot activator	2 ml	Fuchsia	18 months	100 / 1000	Paper
11005	13 x 75 mm	Clot activator	3 ml	Red	18 months	100 / 1000	Paper

CODE	SIZE	DESCRIPTION	DRAWING	COLOUR	SHELF-LIFE	PACKAGING	LABEL
11238	13 x 75 mm	Clot activator	4 ml	Rusty	18 months	100 / 1000	Paper
11250	13 x 75 mm	Clot activator	4 ml	Fuchsia	18 months	100 / 1000	Paper
111258	13 x 75 mm	Clot activator	4 ml	Green	18 months	100 / 1000	Paper
611010	13 x 75 mm	Clot activator	4 ml	Red	18 months	100 / 1000	Transparent
11020	13 x 100 mm	Clot activator	6 ml	Red	18 months	100 / 1000	Paper
11118	13 x 100 mm	Clot activator	6 ml	Yellow	18 months	100 / 1000	Paper
11073	13 x 100 mm	Clot activator	6 ml	Beige	18 months	100 / 1000	Paper
11141	13 x 100 mm	Clot activator	6 ml	Electric blue	18 months	100 / 1000	Paper
111095	13 x 100 mm	Clot activator	6 ml	Orange	18 months	100 / 1000	Paper
11083	13 x 100 mm	Clot activator	6 ml	White	18	100 / 1000	Paper

VACUTEST kima

Search ...

EDTA TUBES

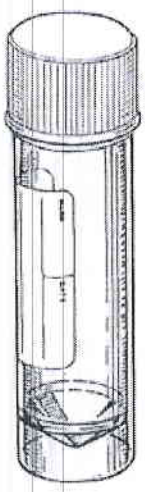
CODE	SIZE	DESCRIPTION	DRAWING	COLOUR	SHELF-LIFE	PACKAGING	LABEL
13501	13 x 75 mm	K2 EDTA	1 ml	Lavender	18 months	100 / 1000	Paper
13505	13 x 75 mm	K2 EDTA	2 ml	Lavender	18 months	100 / 1000	Paper
13520	13 x 75 mm	K2 EDTA	2 ml	Translucent lavender	18 months	100 / 1000	Paper

VACUTEST kima

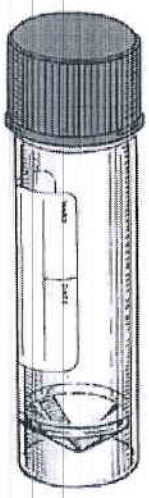
Search ...

Search

CONTAINERS FOR URINE AND BIOLOGICAL SAMPLES



184620
NON STERILE
Ø 26x92mm
Vol. 30 ml
Polypropylene container with label and screw cap.



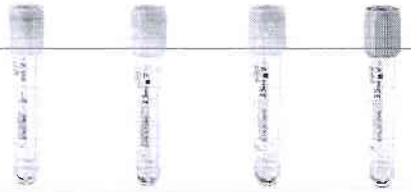
184720
STERILE
Ø 26x92mm
Vol. 30 ml
Sterile polypropylene container with label and screw cap.

184730
STERILE
Individually wrapped.

VACUTEST kima

Search ... Search

BUFFERED SODIUM CITRATE TUBES



STERILE R

CODE	SIZE	DESCRIPTION	DRAWING	VOLUME	COLOUR	SHELF-LIFE	PACKAGING	LABEL
14074	13 x 75 mm IN	Sodium citrate 3.2%	1.8 ml	2ml	Translucent light blue	12 months	100 / 1000	Plastic
140740	13 x 75 mm IN	Sodium citrate 3.2%	1.8 ml	2ml	Light blue	12 months	100 / 1000	Plstic
14010	13 x 75 mm IN	Sodium citrate 3.8%	1.8 ml	2ml	Translucent light blue	12 months	100 / 1000	Plastic
140100	13 x 75 mm IN	Sodium citrate 3.8%	1.8 ml	2ml	Light blue	12	100 / 1000	Plastic

CODE	SIZE	DESCRIPTION	DRAWING	VOLUME	COLOUR	SHELF-LIFE	PACKAGING	LABEL
14084	13 x 75 mm IN	Sodium citrate 3.2%	2.25 ml	2.5 ml	Translucent light blue	12 months	100 / 1000	Plastic
140840	13 x 75 mm IN	Sodium citrate 3.2%	2.25 ml	2.5 ml	Light blue	12 months	100 / 1000	Plastic
14020	13 x 75 mm IN	Sodium citrate 3.8%	2.25 ml	2.5 ml	Translucent light blue	12 months	100 / 1000	Plastic
140200	13 x 75 mm IN	Sodium citrate 3.8%	2.25 ml	2.5 ml	Light blue	12 months	100 / 1000	Plastic
14365	13 x 75 mm GR	Sodium citrate 3.2%	3.15 ml	3.5 ml	Translucent light blue	9 months	100 / 1000	Plastic
143650	13 x 75 mm GR	Sodium citrate 3.2%	3.15 ml	3.5 ml	Light blue	9 months	100 / 1000	Plastic
143656	13 x 75 mm GR	Sodium citrate 3.2%	3.15 ml	3.5 ml	Electric blue	9 months	100 / 1000	Plastic
14315	13 x 75 mm GR	Sodium citrate 3.8%	3.15 ml	3.5 ml	Translucent light blue	9 months	100 / 1000	Plastic
143150	13 x 75 mm GR	Sodium citrate 3.8%	3.15 ml	3.5 ml	Light blue	9 months	100 / 1000	Plastic

VACUTEST kima

Search ... Search

HEPARIN TUBES

CODE	SIZE	DESCRIPTION	DRAWING	COLOUR	SHELF-LIFE	PACKAGING	LABEL
12057	13 x 75 mm	Lithium Heparin	2 ml	Dark green	18 months	100 / 1000	Paper
12005	13 x 75 mm	Lithium Heparin	2 ml	Green	18 months	100 / 1000	Paper
12010	13 x 75 mm	Lithium Heparin	4 ml	Green	18 months	100 / 1000	Paper
12087	13 x 100 mm	Lithium Heparin	6 ml	Red	18 months	100 / 1000	Paper
12093	13 x 100 mm	Lithium Heparin	6 ml	Yellow	18 months	100 / 1000	Paper
12030	16 x 100 mm	Lithium Heparin	9 ml	Green	18 months	100 / 1000	Paper
123100	13 x 75 mm	Sodium Heparin	4 ml	Green	18 months	100 / 1000	Paper
123300	13 x 100 mm	Sodium Heparin	6 ml	Green	18 months	100 / 1000	Paper
12330	13 x 100 mm	Sodium Heparin	6 ml	Dark Blue	18 months	100 / 1000	Paper
12340	16 x 100 mm	Sodium Heparin	9 ml	Green	18 months	100 / 1000	Paper

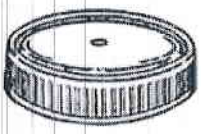
Recommended use

Mixing indications: immediately after blood collection, gently invert the sample 6-8 times
Minimum time before centrifugation: none
Maximum time before centrifugation: 2 hrs after collection
Centrifugation speed: at 1300 g for 10 minutes at 20 - 25 °C
Sample preservation: for plasma separated from blood cells see following table

Storage temperatures			< -20°C
Maximum preservation time	8 hours	< 24 hours	> 48 hours

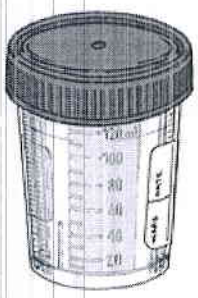
18129

STERILE
Ø 30x58mm
Vol. 35 ml
Sterile polystyrene feces container with spoon, label and press-on cap.



231173

NON STERILE
Vol. 150 ml
Polypropylene container with separated cap.
Graduated to 120 ml.
Writing surface 28x48 mm.



231178

STERILE
Vol. 150 ml
Sterile polypropylene container with label and screw cap.
Graduated to 120 ml.
Writing surface 28x48 mm.

URINE TEST TUBES 12ML

18159
NON STERILE
Vol. 12 ml
Polystyrene urine test
tube with conical bottom.

18159
NON STERILE
Vol. 12 ml
Polystyrene urine test
tube with sediment bulb.

18261
STERILE

18260
NON STERILE
Yellow tip for automatic
pipette Gilson type.
Vol. 0:200 ul

18171
STERILE

18170
NON STERILE
Yellow tip for automatic
pipette Eppendorf-Brand-Socorex type.
Vol. 0:200 ul

18173
STERILE

18172
NON STERILE
Light blue tip for automatic
pipette Eppendorf-Gilson-
Brand-Socorex type.
Vol. 200:1000 ul

18175
STERILE

18174
NON STERILE
White tip for automatic pipette MLA type.
Vol. 0:200 ul

iHealth
Bluetooth glucose monitor - see page 3

GLUCOSE MONITORS FOR DAILY DIABETES TESTING

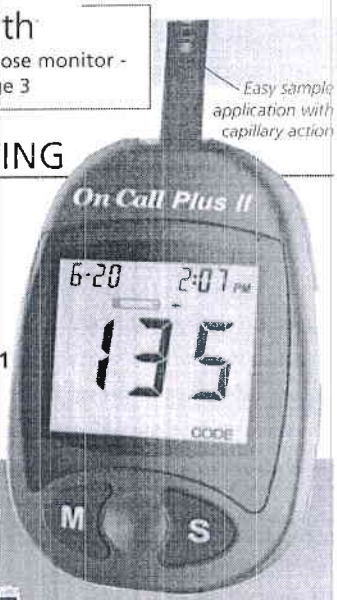
Advanced technology glucose monitors. Available as unit only or complete kit.
Kit includes 10 strips, code chip, control solution, 10 sterile lancets, lancet device, clear cap (for testing on forearm or palm), carrying case, user manual.

CE 0123

Main features:
- accurate result in just 5 seconds
- only 0.5 µl sample size
- automatic calibration with code chip
- plasma calibration results
- advanced data management with 7, 14, 30 days average
- affordable for frequent monitoring
- flexibility to test on the forearm, palm or fingertip
- certified ISO 15197:2013

- BIOSENSOR TECHNOLOGY
- 5 SECOND TEST TIME
- ONLY 0.5 µL BLOOD SAMPLE

Easy sample application with capillary action



23891

Easy calibration with chip PLASMA calibration results

TECHNICAL SPECIFICATIONS

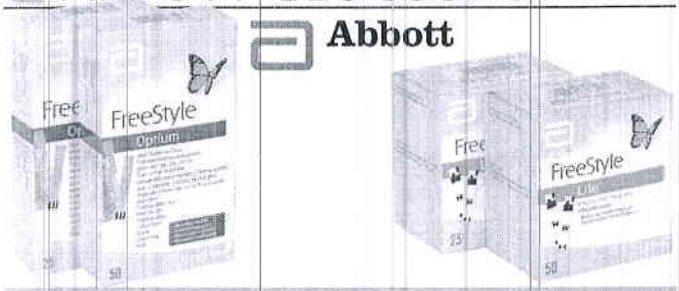
Measurement Range	20 to 600 mg/dL or 1.1 to 33.3 mmol/L
Sample Sites - Size	Finger tips, Forearm or palm - 0.5 µL
Test Time	Approximately 5 seconds
Power Source	One 2032 or equivalent 3.0 V coin cell battery
Battery Life	12 months or approximately 1,000 tests
Memory	Up to 300 records with time and date

mg/dL			mmol/L	ON CALL® PLUS II GLUCOSE MONITOR
Italian Greek	English French	Spanish Portuguese	English French	
23890	23891	23892	23881	Glucose monitor Plus-meter only
23895	23896	23897	23886	Glucose monitor Plus-kit

GIMA code	Accessories and consumables for GLUCOSE MONITOR ON CALL® PLUS AND ON CALL® PLUS II
23910	Glucose Strips - box of 25 strips
23912	Glucose Strips - box of 50 strips
23913	Glucose Strips - box of 100 strips
23914	Control Solution
23919	Auto lancet device
23917	Lancets 28G for 23919 - sterile - box of 25 pcs
23916	Lancets 28G for 23919 - sterile - box of 100 pcs

23896

ABBOTT GLUCOSE STRIPS



ABBOTT FREESTYLE OPTIUM BLOOD GLUCOSE TEST STRIPS

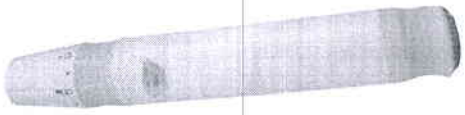
GIMA code	Compatibility	Minimum order
23942	FreeStyle Optium Neo, FreeStyle Libre, FreeStyle Optium, Optium Xceed, Optium, Optium Easy, Boots	box of 25
23943		box of 50

ABBOTT FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS

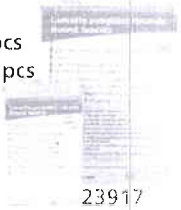
23944	FreeStyle Lite, FreeStyle Freedom Lite, FreeStyle InsuLinx, FreeStyle Navigator II	box of 25
23945		box of 50

LANCETS AND LANCET DEVICE

• **23919 AUTO LANCET DEVICE**
Reusable auto lancet plastic device, adjustable tip, allows precise configuration of lancet penetration.



23916



23917

• **23917 GIMA LANCETS - 28G - sterile - box of 25 pcs**
• **23916 GIMA LANCETS - 28G - sterile - box of 100 pcs**
Lancets are fine needles that can be used with code 23919 and most of lancet devices in the market to draw a blood sample for glucose testing. Multilanguage box: GB, FR, IT, DE, ES, PT, GR, PL, Arabic.

23916-17

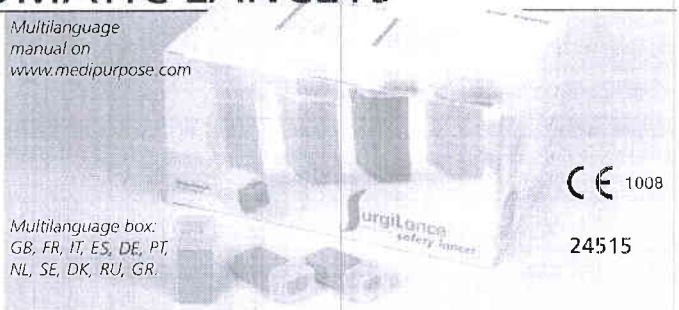
SURGILANCE SAFETY AUTOMATIC LANCETS

SURGILANCE SAFETY AUTOMATIC LANCETS - NEEDLES
Multi purpose capillary blood sampling devices for all testing requirements.
The one-step safety lancet is easier to use, no arming is required, and safer, once lancet is used it is rendered inoperable.
High-speed delivery and penetration method minimizes patient pain and operator error.
Latex-free, hypo-allergenic, disposable, sterile.

SURGILANCE® SAFETY LANCETS - NEEDLES

GIMA code	Colour	Depth of penetration	Entire needle Gauge	Needle tip Gauge	Blood Flow	Finger Stick	Glucose	Hematocrit	Minimum order
24513	Yellow	1.0 mm	G21	G26	5-10 µl	•	•		box of 100
24514	Grey	1.8 mm	G21	G23	10-20 µl	•	•		box of 100
24515	Orange	2.2 mm	G21	G22	20-40 µl	•	•	•	box of 100
24517	Pink	2.8 mm	G21	G21	40-60 µl	•	•	•	box of 100

Multilanguage manual on www.medipurpose.com



CE 1008

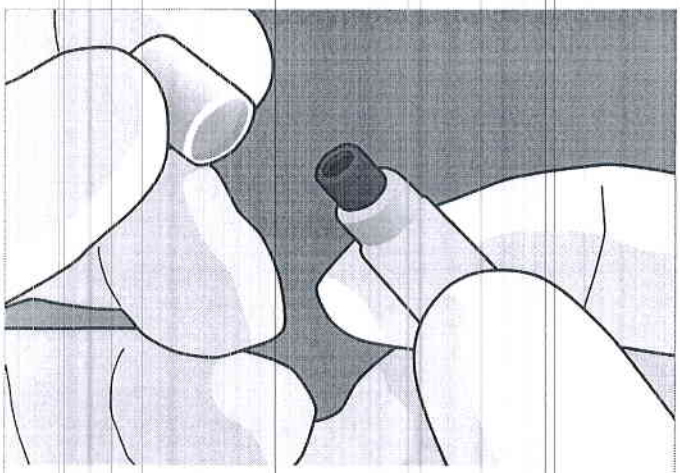
Multilanguage box: GB, FR, IT, ES, DE, PT, NL, SE, DK, RU, GR.

24515

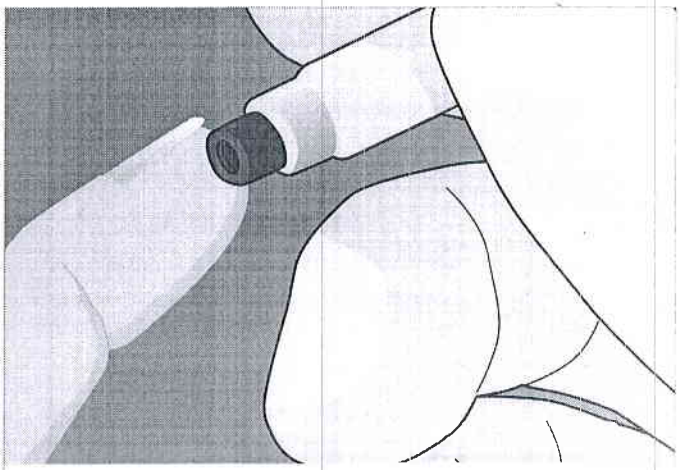
INSULINE PEN NEEDLES SEE PAGE 52

SurgiLance™ safety lancet Instructions for Use

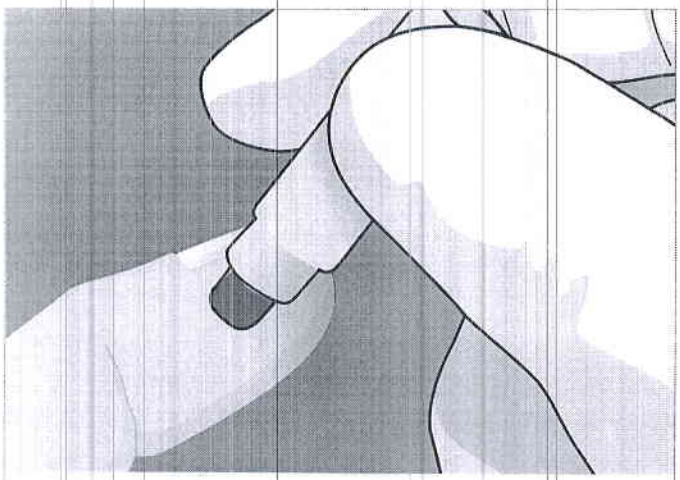
SurgiLance™ Life safety lancet



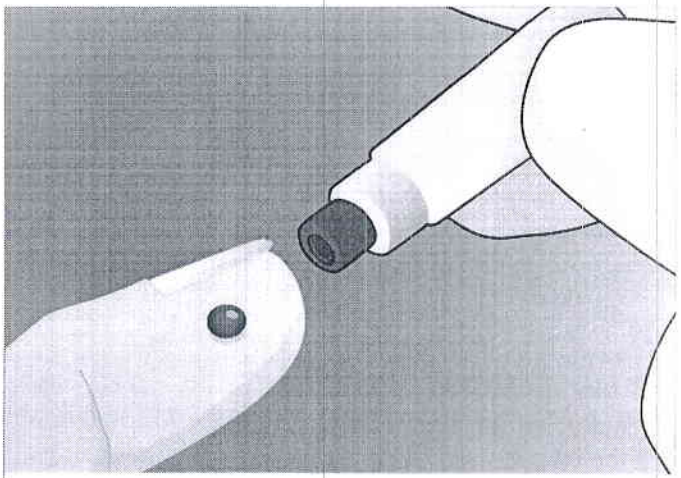
1 Clean test site with isopropyl alcohol and air dry. Remove protective cap from safety lancet.



2 Place red end of safety lancet on the test site.



3 Push the safety lancet down against test site to activate lancet mechanism.



4 Once used, simply discard lancet into a sharps container.

medipurpose.com/surgilance/ifu

MediPurpose™

Artwork Ref: MPP-QMS-ART-xxx Rev x

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

has established and applies a quality management system for medical devices for the following scope:

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

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-10-16
Certificate Registration No.:	SX 60133221 0001
An audit was performed. Report No.:	21234760 009
This Certificate is valid until:	2021-10-15

Certification Body

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

TÜVRheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Date 2018-10-12

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

EC Certificate

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

Registration No.: HD 60105393 0001

Report No.: 21234760 001

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

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

Replaces Approval, Registration No.: HD 60034211 0001

Expiry Date: 2020-10-15

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

Effective Date: 2015-10-16

Date: 2015-10-16

Notified Body
Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: HD 60105393 0001
Report No.: 21234760 001

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products included:

- Cannulas for blood collection

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

- MBU Capillaries

Date: 2015-10-16

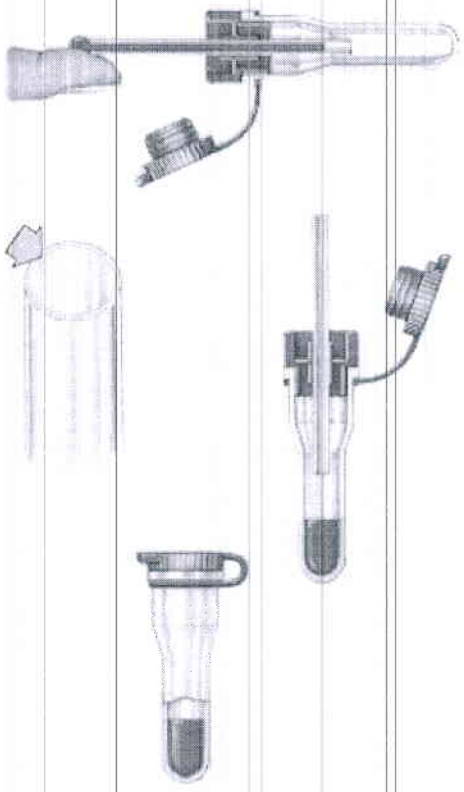
Notified Body
Dipl.-Ing. I. Munkler

Capillary blood collection system
Capillary blood collection GK

Capillary blood collection GK
It consists of a prepared test vessel and a prepared plastic end-to-end collection capillary with stopper.
- Easy handling
- Plastic capillary* with exact filling volume; complete inner surface prepared, unbreakable
- Collection vessel serves as centrifugal vessel; prepared for all common tests
- Light protected, tinted vessels for bilirubin analyses

* with conformity certificate in accordance with the Weights and Measurement Regulations
Fill the capillary with capillary blood from a horizontal position.
After filling let the blood flow into the vessel from a vertical position (shake out remaining blood).
Remove the capillary, press on the attached stopper and mix or centrifuge.

077003 EDTA 100 µl
Packing unit:
100 pcs in bag,
4.000 pcs in box
Ø 11/8 x 39 mm



ITALCERT

CERTIFICATO N° 505SGQ03

CERTIFICATE N° 505SGQ03

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

NUOVA APTACA S.r.l.

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.
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. 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

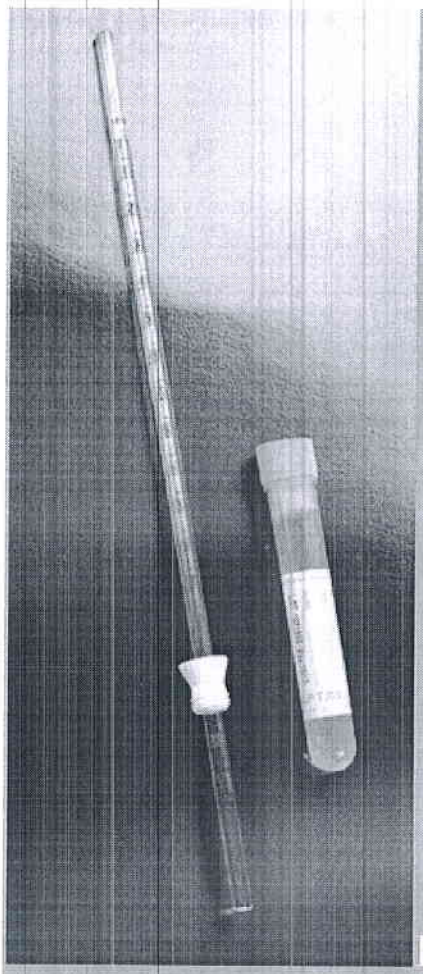
Dr. Ing. Roberto Cusolito

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	2017-10-30	2020-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 023A PRD N° 122B
SGA N° 020D ISP N° 075E
PRS N° 097C
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



E.S.R. GRADUATED PIPETTE AND Ø 13 X 75 MM TEST TUBE

E.S.R. graduated pipettes + Ø 13 x 75 mm test tubes with 0.2 ml of Na Citrate for 0.8 ml of blood, labelled, with pink cap.

Cod.
10110/75

HOLTSCH
Medizinprodukte GmbH

Herstellung und Vertrieb von
Arzneimitteln, Medizinprodukten,
Sonderanfertigungen und Promotion

In den Faltern 13 - 65232 Taunusstein

Telefon +49 (6128) 91717-7
Telefax +49 (6128) 91717-9
Telefax +49 (6128) 4 47 42
e-mail: info@holtsch-med.com

Ust.-Ident.Nr. (VAT) DE811962816

Declaration of Conformity

Product category: Pre-injection cleansing swab

Product (Name, Type)	Size	Reference
Swab dispenser Quickpad saturated with Isopropyl alcohol, sterilized	150 pads	N10000K

We herewith declare under our sole responsibility that the above mentioned product meet all the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, which apply to it, as stated in Annex VII.

Dr. Michael Gluschke
Head of Regulatory Affairs

Dispenser QUICKPAD Salfeta cu alcool®

Practic si eficient

Dispenser QUICKPAD Salfeta cu alcool ®, steril şi fiziologic, verificat ca fiind inofensiv; este ideal pentru curăţarea şi dezinfectarea pielii. Agentul activ 2-propanol actioneaza in mod eficient, ca un agent de dezinfectare "piele moale". Sistemul patentat "tampon de rupere-off" permite utilizarea unică a tamponului. Acest lucru face ca QUICKPAD® sa fie nu numai economic, ci, de asemenea, eficient în utilizarea acestuia.

Calitate si rezistenta

Capacul dispenser-ului QUICKPAD® bine etanşat, menţine tampoanele imbibate cu alcool medicinal umed şi steril. Ca urmare, distribuitorul tampon are un termen de valabilitate deosebit de lungă de 24 de luni.

Vă rugăm să reţineţi că pentru aplicatiile farmaceutice/medicale dispenser-ul QUICKPAD®, se aplică instrucţiunile de siguranţă corespunzătoare.

~~Caracteristice~~

- ~~sistemul de rupere-unica a tamponului, permite o utilizare eficientă şi economic~~.
- Controlul nivelului, datorita recipientului transparent.
- Păstrează umiditatea şi sterilitate

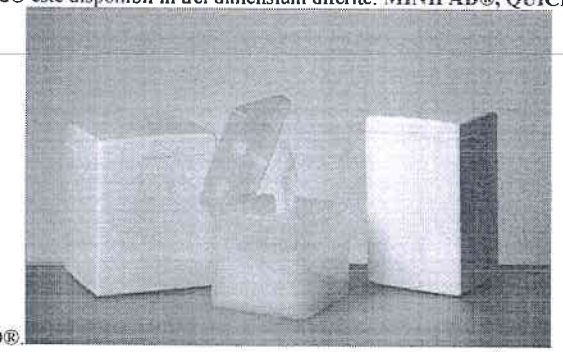
- Tampon fiziologic noninofensiv.
- Disponibil în trei dimensiuni practice (numai ca produse cosmetice).
- ~~Potrivit pentru auto-aplicare de către pacient.~~
- Gata de utilizare.
- Made in Germany Quality, CE Label

Domeniul de aplicare

QUICKPAD® este livrat gata de utilizare şi cu funcţionare sa simplă; poate fi folosit de către specialişti precum şi pacienţi pentru dezinfectarea pielii. Un produs ideal pentru diabetici şi alţi utilizatori de seringi auto-injectare subcutanată.

Gamă de produse

Quickpad® este disponibil in trei dimensiuni diferite: **MINIPAD®, QUICKPAD®** und **BIGPAD®**.

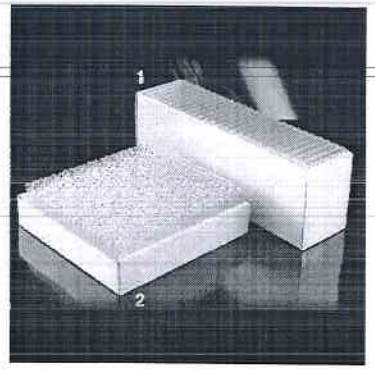


	MINIPAD®	QUICKPAD®	BIGPAD®
Dim. dispenser (L x W x H in mm)	50 x 50 x 50	50 x 50 x 80	62 x 62 x 75
Num. salfete/dispenser	50	150	100
Dim. Salfete (L x l in mm)	44 x 44	44 x 44	58 x 58

+34 936 99 50 00
deltalab@deltalab.es

Plz. Verneda 1, Pol Ind La Llana
08191 Rubí Barcelona SPAIN

EN
Tel. 936 99 50 00 deltalab@deltalab.es
Plz. Verneda 1, Pol Ind La Llana 08191
Rubí Barcelona SPAIN



Round bottom glass tubes

Made of borosilicate or soda glass.
The high quality of those tubes is reflected in the uniformity of their wall thickness and of their diameter and height dimensions.
Supplied in small quantities per case for a more convenient use in laboratory.

121°C

code	description	total capacity	int. diameter	ext. diameter	height	thickness	case qty.	case weight (Kg)	case vol. (m3)
801075	Soda glass	4 ml	8,2 mm	9,75 mm	75 mm	0.6	4×250	3,60	0,010
801275	Soda glass	6 ml	10,2 mm	11,6 mm	75 mm	0.6	4×250	4,50	0,013
813100	Soda glass	10 ml	11,1 mm	12,7 mm	100 mm	0.6	4×250	6,59	0,022
816100	Soda glass	15 ml	13,95 mm	15,75 mm	100 mm	0.6	4×250	9010	0,034
816150	Soda glass	22 m						13,60	0,049
816160	Soda glass	27 m						5,50	0,018

OK

Certificado ES10/81672

The management system of

DELTALAB, S.L.

Pol. Ind. La Llana, Plaza De La Verneda, 1
08191 Rubí (Barcelona)

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopía y coloración. Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales.

in/ from the following sites

Pol. Ind. La Llana, Plaza De La Verneda 1 - 08191 Rubí (Barcelona)

This certificate is valid from
29 November 2017 until 11 October 2019.
Issue 7. Certified since October 2010.

Este certificado es válido desde
29 de noviembre de 2017 hasta 11 de octubre de 2019.
Edición 7. Certificado desde octubre de 2010..

Authorized by

Dirección de Certificación

SGS ICS Ibérica, S.A. (Unipersonal)
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

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

TO WHOM IT MAY CONCERN

LETTER OF AUTHORIZATION

We, NUOVA APTACA s.r.l., hereby authorize Messrs. :

"GBG-MLD" S.R.L.
Tighina str.65, office 607
MD-2001,Chisinau,
Republic of Moldova

to promote, market and sell our production of plastic disposable items for laboratory in the territory of MOLDOVA as our Distributor. They are also entitled to submit bids, negotiate and sign the Contracts for all projects, accessories and other products delivered by us.

The present letter of authorization is valid from 01/01/2019 UNTIL 31/12/2019.

At the maturity will be renewed with a new one.

Yours faithfully.

NUOVA APTACA S.R.L.

Ms. Veronica Ferrari
APTACA Export Manager
export@aptaca.com
mob. +39 393 91.61.141
office +39 0141 835075
fax +390141835292
www.aptaca.com

CANELLI 08/01/2019

Certificate ES10/81671

The management system of

DELTALAB, S.L.

Polígono Industrial La Llana, Plaza De La Verneda 1,
08191 Rubí, Barcelona. Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture and sale of sterile and non sterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.

Diseño, fabricación y comercialización de productos sanitarios estériles y no estériles para la toma, transporte y conservación de muestras biológicas para análisis clínicos y de IVD.

This certificate is valid from 18 September 2017 until 11 October 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 September 2019
Issue 7. Certified since 12 October 2010

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485 2016 0417

Nuova Aptaca Srl Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

COD. 8030

Modello di utilizzo corrente per i servizi a forte produzione di rifiuti (ospedali, centri di cura, cliniche, ecc.)
Item designed for frequent use (Hospitals, Healthcare Centres, Clinics, etc.)

DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
167 x 167 x 225 mm H (coperchio montato / *Li dassembled*)	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
A base quadra / *Square base*	
PESO	WEIGHT
286 gr.	
CARICO MASSIMO	MAXIMUM LOAD
1,7 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
3 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
3,17 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
2,54 Lt.	

COD. 8040

Modello di utilizzo corrente per i servizi a forte produzione di rifiuti (ospedali, centri di cura, cliniche, ecc.)
Item designed for frequent use (Hospitals, Healthcare Centres, Clinics, etc.)

DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
167 x 167 x 285 mm H (coperchio montato / *Li dassembled*)	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
A base quadra / *Square base*	
PESO	WEIGHT
350 gr.	
CARICO MASSIMO	MAXIMUM LOAD
2,25 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
4 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
4,25 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
3,4 Lt.	

Abbott Products Romania S.R.L.
Green Court Bucharest
Gara Herastrau 4C
Corp B, etaj 2, sector 2
Bucuresti, Romania

C.U.I. RO 15910608
R.C.: J40/15462/18.11.2003
Capital Social: 595002 lei
Banca: Citibank
IBAN: RO22CITI000000724585043

Tel: +40-21-529 30 00
Fax: +40-21-529 30 01

AUTORIZATIE

Catre: Spitalul Raional Hincesti

Noi, ABBOTT PRODUCTS ROMANIA SRL, reprezentant autorizat in Romania (Strada Gara Herastrau, numarul 4C, sector 2, Bucuresti, inreg. la MEC sub nr. 1069/22) al companiei Abbott Laboratories, producator de instrumente de de hematotogie CD Emerald si CD Ruby precum si de reactivi, controale, calibratori si consumabile pentru acestea, avand capacitatile de productie in SUA, Abbott Park 60064, Illinois,Santa Clara California, Germania –Wiesbaden, Marea Britanie-Dartford, autorizam prin prezenta pe furnizorul **S.C. Global Biomarketing Group – Moldova SRL**,sa livreze produsele mai sus mentionate, la Spitalul Raional Hincesti. Prin prezenta, garantam calitatea si performantele produselor oferite si autorizam pe **S.C. Global Biomarketing Group – Moldova SRL** sa asigure, pentru produsele respective, indeplinirea obligatiilor care decurg din contractul de furnizare.

Data completarii:
26.07.2018

Producator:
ABBOTT PRODUCTS ROMANIA
Camelia Manolescu

Abbott

Abbott

Declaration of Conformity

Certificate Identification: SC-09H46

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

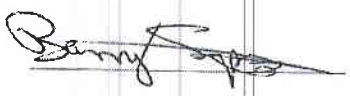
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H46-02	58236	CELL-DYN Emerald CLEANER	Self-declared
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	Self-declared
09H48-02	58237	CELL-DYN Emerald DILUENT	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	02-Dec-2015	Date of Approval:	01 DEC 2015
Date Issued:	DEC 02 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 July 6, 2015	Effective (Date or Lot Number):	DEC 03 2015

Abbott

Declaration of Conformity

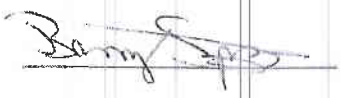
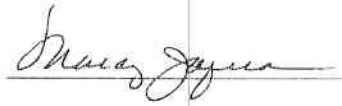
Certificate Identification:	SC-09H70
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H70-01	55865	CELL-DYN 18 Plus Calibrator	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	18 June 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V3 February 26, 2015	Effective (Date or Lot Number):	JUL 06 2015

Abbott

Declaration of Conformity

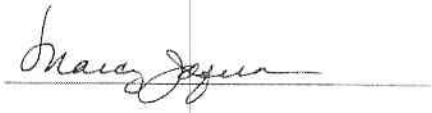
Certificate Identification:	SC-01H73
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
01H73-01	58237	CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/SHEATH	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	29 Jun 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V2 January 10, 2014	Effective (Date or Lot Number):	JUL 06 2015

Section 201

CELL-DYN 3200 / CELL-DYN Ruby Reagents

Declaration of Conformity

ABBOTT

Declaration of Conformity

Certificate Identification:	S3047-SC
Legal Manufacturer's Name:	Abbott Laboratories
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
03H78-01	N/A	CELL-DYN WBC Lyse Reagent	Self-declared
03H79-01	41955	CELL-DYN Diluent/Sheath Reagent	Self-declared
03H80-02	N/A	CELL-DYN CN-Free HGB/NOC Lyse Reagent	Self-declared
08H52-01	N/A	CELL-DYN WBC Lyse Reagent	Self-declared

Authorized European Representative (name and address)	ABBOTT Max-Planck-Ring 2 65205 Wiesbaden Germany
Storage site of technical documentation (name and address)	Abbott Laboratories 5440 Patrick Henry Drive Santa Clara, CA 95054 USA
Harmonized Standards	Refer to the product Essential Requirements Checklist

I, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Michelle Roeding	Date Issued:	07/02/2012
Full Name:	Michelle Roeding	Place Issued:	Abbott Santa Clara
Position:	Section Manager, Regulatory Affairs	Supersedes:	11/23/2009
Date of Approval:	07/02/2012	Effective (Date or Lot Number):	07/16/2012

Abbott

Declaration of Conformity

Certificate Identification:	SC-03H80
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
03H80-02	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems CN-FREE HGB/NOC LYSE	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	29 Jun. 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V2 January 10, 2014	Effective (Date or Lot Number):	JUL 06 2015

Abbott

Declaration of Conformity

Certificate Identification:	SC-99644
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
99644-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	**Self-declared**
93641-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	**Self-declared**

Authorized European Representative (name and address)	ABBOTT Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Quality Manager	Position:	Regulatory Affairs , Director
Date of Approval:	04 Sept 2015	Date of Approval:	04 Sep 2015
Date Issued:	SEP 04 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V4, January 10, 2014	Effective (Date or Lot Number):	SEP 11 2015