

MEDICA

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

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
65 Tighina Site
Office 607
Chisinau, MD-2001
Republic of Moldova

to be our **DISTRIBUTOR** for the **EasyLyte®**, **EasyElectrolytes™**, **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®**, **EasyElectrolytes™**, **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®**, **EasyElectrolytes™**, **EasyBloodGas™** and **EasyStat®** analyzers.

This authorization is effective immediately and is valid until December 31, 2022, unless revoked earlier in writing by Medica Corporation.


David Hagopian
VP, Sales & Marketing
MEDICA CORPORATION

2/4/2020
Date



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Declaration of Conformity

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

 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

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6001	EasyBloodGas Analyzer	21 07 11 01
7001	EasyStat Analyzer	21 07 11 03
7017	EasyStat Analyzer	21 07 11 03
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO ₂ Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO ₂ Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 50
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	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 03
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 03
6506	EasyBloodGas Sensor Module	21 07 11 01
6507	EasyBloodGas Valve Module	21 07 11 03
6508	Compression Plate	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	EasyElectrolyte/EasyStat Na Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat 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	EasyBloodGas/EasyStat 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



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Products For Health Care

EasyStat Analyzer Material Safety Data Sheet (MSDS)

December 7, 2015

Attention: Safety Officer/MSDS Requestor

In the table below is a list of chemicals/solutions required to operate and maintain the EasyStat analyzer. This list identifies which solutions require and do not require a Material Safety Data Sheet (MSDS).

According to Occupational Safety and Health Administration (OSHA) regulations, substances containing more than 1% of a hazardous material or more than 0.1% of an extremely hazardous material require the availability of a Material Safety Data Sheet (MSDS). If a Material Safety Data Sheet (MSDS) is required, it will accompany this memo.

Products in the table below that do not require a Material Safety Data Sheet (MSDS) should be handled with care and avoid contact with skin. If contact occurs, wash exposed area with plenty of water. As a reference, refer to the product labels for contents of active ingredients.

NOTE: Dispose of chemicals in accordance with local, state and federal regulations.

<u>Product Description</u>	<u>Catalog Number(s)</u>	<u>MSDS Required</u>	<u>Chemical Substance</u>
Reagent Module	7101	No	Non-hazardous material
Daily Cleaning Solution Kit	2118	Yes	Pepsin (powder)
Quality Control Kits	6303, 6304, 6305, 7309	No	Non-hazardous material
EasyStat Electrodes	6201, 6202, 6203, 6204, 7205, 7206, 7207, 7208	No	Non-hazardous material
Red Test Dye Solution	6402	No	Non-hazardous material
Troubleshooting Kit	7301	No	Non-hazardous material

On Behalf of Medica Corporation

Photios Makris
Director of Regulatory Affairs



SAFETY DATA SHEET

SECTION 1: Identification

Product Identifier: Pepsin 1:3000 Powder
Other Identity: None
Recommended Use: Food Additive/Dietary Supplement
Supplier: American Laboratories, Inc.
Supplier Address: 4410 South 102nd St. Omaha, NE 68127
Supplier Phone: 1-402-339-2494
Emergency Phone: 1-402-339-2494 Monday - Friday 8:00 a.m. to 5:00 p.m. CST

SECTION 2: Hazard Identification

Hazard Class: Skin irritant Category 2
Eye irritant Category 2A
Skin sensitizer Category 1B
Respiratory sensitizer Category 1B

Signal Word: Danger
Hazard Statements: Causes mild skin irritation
Causes eye irritation
May cause an allergic skin reaction
May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements: IF ON SKIN: In case of contact with skin, wash skin with soap and water. Remove contaminated clothing and wash.

IF IN EYES: In case of contact with eyes, flush eyes with low pressure water for at least 15 minutes. If irritation develops, seek medical attention.

IF INHALED: Avoid breathing dust. In case of inadequate ventilation wear respiratory protection. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. May cause sensitization by inhalation in hypersensitive individuals. Avoid dust generation.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Hazard Symbols:



Other Hazards: If extremely high levels of dust are generated in ambient air, material can support combustion.

SECTION 3: Composition/Information on Ingredients

Pepsin	CAS Number: 9001-75-6	% by weight: 15 – 30%
Lactose	CAS Number: 64044-51-5	% by weight: 70 – 85%

SECTION 4: First-aid Measures

First Aid Eye:	In case of contact with eyes, flush eyes with low pressure water for at least 15 minutes. If irritation develops, seek medical attention.
First Aid Skin:	In case of contact with skin, wash skin with soap and water. Remove contaminated clothing and wash.
First Aid Ingestion:	If swallowed, rinse mouth and throat thoroughly with tap water. Drink water.
First Aid Inhalation:	If inhaled remove from contaminated area to fresh air. Report situation. Seek medical attention if allergic response is exhibited.
First Aid Advice:	The allergic symptoms are such as runny nose, cough, sneeze, languor, slight attack of fever. Contact with powder causes irritation to sensitive skin and eyes. Any person who experiences any allergic or sensitive reactions to this powder should refrain from handling it again.

SECTION 5: Fire-Fighting Measures

Fire Fighting Extinguishing Media:	Water, foam, dry chemical, carbon dioxide
Fire Fighting Chemical Hazards:	May cause allergic respiratory reaction
Fire Fighting Protective Actions:	Not available

SECTION 6: Accidental Release Measures

For non-emergency personnel:	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see section 8).
For emergency personnel:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
Environmental precautions:	Avoid dispersal of spilled material.
Containment:	If a spill occurs: Spilled product should be removed immediately to avoid formation of dust. Vacuum or gently moisten with water and collect into a sealable container for disposal. Flush spill area with plenty of water (low pressure) into approved sewer. Avoid formation of aerosols and dusts. Ensure sufficient ventilation. Wash contaminated clothing.
Clean up:	Not available
Other issues:	Not available

SECTION 7: Handling and Storage

Handling advice:	Never handle powder without appropriate personal protective equipment in accordance with Section 8. Avoid formation of dust. Avoid splashing and high pressure washing. Ensure good ventilation of the room when handling this product.
Hygiene:	Maintain good conditions of industrial hygiene
Storage:	Store in tightly closed poly-liners within a sealed container in an odor-free environment, where normal temperatures do not exceed 30°C and normal relative humidity is not more than 70%.
Conditions to avoid:	Not available
Control:	Not available
Maintain:	Not available
Other advice:	Not available

SECTION 8: Exposure Controls/Personal Protection

Occupational exposure limits:	Not available
Biological limit values:	Not available
Control banding:	Not available
Appropriate engineering controls:	Adequate ventilation required for dusty conditions.
Eye/face protective equipment:	Protective glasses or eye shield recommended.
Skin protection:	Impermeable gloves recommended.
Respiratory protection:	None required under usual condition of use. However, if breathable dusts are present, a suitable dust mask is recommended (refer to NIOSH Criteria Guides to determine appropriate unit).
Thermal protection:	Not available
Special requirements:	Not available

SECTION 9: Physical and Chemical Properties

Appearance:	Off-White to Light Yellow Powder
Odor:	Characteristic enzyme odor
Odor Threshold:	Not available
pH:	3.0 – 4.5
Melting point/freezing point:	Not available
Initial boiling point and boiling range:	Not available
Flash point:	Not available
Evaporation rate:	Not available
Flammability (solid, gas):	Not available
Upper/lower flammability or explosive limits:	Not available
Vapor pressure:	Not available
Vapor density:	Not available
Relative density:	Not available
Solubility:	Soluble
Partition coefficient: n-octanol/water:	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity:	Not available

SECTION 10: Stability and Reactivity

Reactivity:	Not available
Stability:	Stable
Hazardous reactions:	Not available
Conditions to avoid:	Not available
Incompatible materials:	Not available
Hazardous decomposition products:	Not available

SECTION 11: Toxicological Information

Acute toxicity:	Not available
Skin corrosion/irritation:	Skin irritant Category 2
Serious eye damage/irritation:	Eye irritant Category 2A
Respiratory or skin sensitization:	Respiratory sensitizer Category 1B, Skin sensitizer Category 1B
Germ cell mutagenicity:	Not available
Carcinogenicity:	Not classified as a carcinogen by IARC, OSHA, or NTP
Reproductive toxicity:	Not available
STOT-single exposure:	Not available
STOT-repeated exposure:	Not available
Aspiration hazard	Not available

SECTION 12: Ecological Information

Toxicity:	Not available
Persistence and degradability:	Product is readily biodegradable.
Bioaccumulative potential:	Not available
Mobility in soil:	Not available
Other adverse effects:	Not available

SECTION 13: Disposal Considerations

Disposal Methods: No special disposal method required, except that in accordance with current local authority regulations

SECTION 14: Transport Information

UN Number:	Not classified
UN Proper Shipping Name:	Not classified
Transportation Hazard Class:	Not classified
Packing Group:	Not classified
Transport Environmental Hazard:	Not classified
Transport Special Precautions:	Not classified
MARPOL:	Not classified

SECTION 15: Regulatory Information

The active ingredient and all components of the enzyme preparation are listed on the TSCA Inventory.

SECTION 16: Other Information

ALTHOUGH THE INFORMATION AND RECOMMENDATIONS SET FORTH IN THIS SHEET ARE BELIEVED TO BE CORRECT AS OF THE DATE HEREOF, AMERICAN LABORATORIES, INC. MAKES NO REPRESENTATION AS TO THE COMPLETENESS OR ACCURACY OF SUCH INFORMATION AND RECOMMENDATIONS. AMERICAN LABORATORIES, INC. SHALL IN NO EVENT BE RESPONSIBLE FOR DAMAGES OF WHATSOEVER NATURE DIRECTLY OR INDIRECTLY RESULTING FROM THE PUBLICATION OR USE OF OR RELIANCE UPON SUCH INFORMATION AND RECOMMENDATIONS. YOU ARE ENCOURAGED TO ADVISE ANYONE WORKING WITH OR EXPOSED TO SUCH PRODUCTS OF THE INFORMATION CONTAINED HEREIN.

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EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Sorocovici Sergiu

Of Global Biomarketing Group

*has completed training for the operation and service of the
EasyLyte, EasyBloodGas, and EasyStat analyzers.*

November 25, 2004

Date



MEDICA

Randall Rollins

*Signed: Randall Rollins
Technical Service Manager*