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ORDIN DE PLATA NR.: 429                                TIP.DOC. 1 :
                                DATA EMITERII:11 noiembrie 2019 :
=====:
PLATITI: 240-00                                LEI: Doua Sute Patruzeci lei 00 ban :
i                                                                                                     :
=====:
PLATITOR: (R) "BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L.                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
                                                                                                     :
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R) Institutul                                CONTUL DE PLATI/CODUL IBAN :
Mamei si Copilului IMSP                                MD91ML000000000225152859 :
                                CODUL FISCAL :1003600151643 / :
                                                                                                     :
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PRESTATORUL BENEFICIAR                                CODUL BANCII:
BC"Moldindconbank"S.A.                                :MOLDMD2X :
=====:
DESTINATIA PLATII:Garantia pentru oferta: TIPUL TRANSFERULUI :
la procedura de achizitie publica nr. o: NORMAL/URGENT :N:
cds-b3wdp1-MD-1571723608598 din 12.11.20: :
19 : :
: : L.S. :
=====:
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DATA PRIMIRII:11/11/2019 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
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                                (semnatura electronica) :
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L.S.                                (semnatura electronica) :
CONducator: :
                                (semnatura manuala) :
CONTABIL-SEF: :
                                (semnatura manuala) :
SEMnatura PRESTATORUL                                L.S. :
-----:
MOTIVUL REFUZULUI                                : L.S. :
-----:

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BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

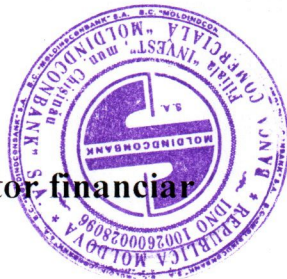
Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent
in moneda nationala al “BIOSISTEM MLD” S.R.L. (c/f 1010600028048), cu
IBAN MD95ML000000002251429243.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

Hereby DECLARES

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

Directive on in Vitro Diagnostic Medical Devices (98/79/EC)

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6th, 2012




Dr. Antonio Elduque
Managing director
BioSystems S.A.



• Certified Management System
• EN ISO 9001
• EN ISO 13485



CLINICAL CHEMISTRY – BIOCHEMISTRY:

| | |
|---------------------------------------|------------------------------------|
| a-Amylase-Direct | Creatine Kinase (CK) |
| a-Amylase-EPS | Creatine Kinase-MB (CK-MB) |
| a-Amylase-Pancreatic | Creatinine |
| Acid Phosphatase (ACP) | Fructosamine |
| Alanine Aminotransferase (ALT/GPT) | Fructose |
| Albumin | g-Glutamyltransferase (g-GT) |
| Alkaline Phosphatase (ALP)-AMP | Glucose |
| Alkaline Phosphatase (ALP)-DEA | Iron – Chromazurol |
| AspartateAminotranferase (AST/GOT) | Iron – Ferrozine |
| Bilirubin (direct) | Iron Binding Capacity |
| Bilirubin (total and direct) | Lactate Dehydrogenase (LDH) |
| Bilirubin (total) | Lactate Dehydrogenase (LDH) – IFCC |
| Calcium – Arsenazo | Lipase |
| Calcium – MTB | Magnesium |
| Cholesterol | Phosphorus |
| Cholesterol HDL | Protein (total) |
| Cholesterol HDL direct | Protein (urine) |
| Cholesterol HDL Precipitating reagent | Pyridoxal Phosphate |
| Cholesterol LDL direct | Triglycerides |
| Cholesterol LDL Precipitating reagent | Urea/BUN-Color |
| Cholinesterase (CHE) | Urea/BUN-UV |
| Citrate | Uric Acid |

CLINICAL CHEMISTRY – TURBIDIMETRY:

| | |
|------------------------------|--------------------------------|
| a1-acid Glycoprotein | C-Reactive Protein (CRP) |
| Albumin (Microalbuminuria) | C-Reactive Protein-hs (CRP-hs) |
| Anti-Streptolysin O (ASO) | Ferritin |
| Antithrombin III | Immunoglobulin A (IgA) |
| Apolipoprotein A-I (Apo A-I) | Immunoglobulin G (IgG) |
| Apolipoprotein B (Apo B) | Immunoglobulin M (IgM) |
| b2-Microglobulin | Prealbumin |
| Complement Component C3 | Rheumatoid Factors (RF) |
| Complement Component C4 | Transferrin |

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

| | |
|--|--------------------|
| 17-Hydroxycorticosteroids | Hemoglobin A1C |
| 17-Ketosteroids | Hemoglobin A2 |
| 5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG) | Metanephrines |
| 5-Hydroxyindoleacetic acid (5-HIAA) | Vanilmandelic Acid |



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

| | |
|-------------------------------------|---|
| a-1-acid Glycoprotein Standard | Biochemistry Calibrator (Human) |
| Adenosine Deaminase (ADA) Standard | Cholesterol HDL/LDL Calibrator |
| Albumin (Microalbuminuria) Standard | CRP/CRP-hs Standard |
| Anti-Streptolysin O (ASO) Standard | Ferritin Standard |
| Antithrombin III Standard | Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard |
| Apolipoprotein A-I Standard | Prealbumin Standard |
| Apolipoprotein B Standard | Protein Calibrators |
| b2-Microglobulin Standard | Protein (urine) Standard |
| Bilirubin Standard | Rheumatoid Factors (RF) Standard |
| Biochemistry Calibrator | |

CLINICAL CHEMISTRY – INSTRUMENTS:

| | |
|-----|---------|
| A15 | BA400 |
| A25 | BTS-350 |

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

| | |
|--------------------------------------|------------------------------|
| a-Amylase-Direct | Creatine Kinase (CK) |
| a-Amylase-Pancreatic | Creatine Kinase-MB (CK-MB) |
| Adenosine Deaminase (ADA) | Creatinine |
| Alanine Aminotransferase (ALT/GPT) | g-Glutamyltransferase (g-GT) |
| Albumin | Glucose |
| Alkaline Phosphatase (ALP)-AMP | Iron Ferrozine |
| Alkaline Phosphatase (ALP)-DEA | Lactate dehydrogenase (LDH) |
| Aspartate Aminotransferase (AST/GOT) | Lipase |
| Bilirubin (direct) | Magnesium |
| Bilirubin (total) | Phosphorus |
| Calcium-Arsenazo | Protein (total) |
| Cholesterol | Protein (urine) |
| Cholesterol HDL direct | Triglycerides |
| Cholesterol LDL direct | Urea/BUN UV |
| | Uric acid |



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

| | |
|--------------------------------|------------------------------------|
| Albumin (Microalbuminuria) | Ferritin |
| Anti-Streptolysin O (ASO) | Hemoglobin A1C-Turbi (HbA1C-Turbi) |
| Antithrombin III | Immunoglobulin A (IgA) |
| Complement Component C3 | Immunoglobulin G (IgG) |
| Complement Component C4 | Immunoglobulin M (IgM) |
| C-Reactive Protein (CRP) | Rheumatoid Factors (RF) |
| C-Reactive Protein-hs (CRP-hs) | Transferrin |

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

| | |
|---------------------------------------|---------------------------------|
| ADA Controls | Hemoglobin A1C Control (Normal) |
| Biochemistry Control Serum (Human) I | Hemoglobin A2 Control |
| Biochemistry Control Serum (Human) II | Lipid Control Serum I |
| Biochemistry Control Serum I | Lipid Control Serum II |
| Biochemistry Control Serum II | Protein Control Serum I |
| CK-MB Control Serum | Protein Control Serum II |
| Control Urine | Rheumatoid Control Serum I |
| Fertility Biochemistry Control | Rheumatoid Control Serum II |
| Hemoglobin A1C Control (Elevated) | |

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

| | |
|---|--|
| Anti-Adrenal Cortex Antibodies (AACA) | Anti-Thyroid Antibodies (ATA) |
| Anti-Endomysium Antibodies (AEA) | Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML) |
| Anti-Islet Cell Antibodies (AICA) | Autoantibodies MsK/MsS (AA-MsK/MsS) |
| Anti-Keratin Antibodies (AKA) | Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS) |
| Anti-Mitochondrial Antibodies (AMA) | Autoantibodies RK/RS (AA-RK/RS) |
| Anti-nDNA antibodies (nDNA) | Autoantibodies RL/RK/RS (AA-RL/RK/RS) |
| Anti-Neutrophil Cytoplasmic Antibodies (ANCA) | Autoantibodies RL/RKm/RS (AA-RL/RKm/RS) |
| Anti-Nuclear Antibodies HEp-2 (ANA HEp-2) | Glomerular Basement Membrane Antibodies (GBMA) |
| Anti-Nuclear Antibodies RL (ANA-RL) | |
| Anti-Skin Antibodies (ASA) | |
| Anti-Smooth Muscle Antibodies (ASMA) | |
| Anti-Striated Muscle Antibodies (AStMA) | |



AUTOIMMUNITY – ELISA:

ANA Screening
Anti-Annexin V IgG/IgM (ANX)
Anti-b2-Glycoprotein 1 IgG/IgM
(b2GP1)
Anti-Cardiolipin Antibodies (ACA-
IgG/IgM)
Anti-Centromere B Antibodies (CENP-
B)
Anti-Citrullinated Protein Antibodies
(ACPA)
Anti-Deamidated Gliadin Peptides IgA
(DGP IgA)
Anti-Deamidated Gliadin Peptides IgG
(DGP IgG)
Anti-dsDNA Antibodies
Anti-GBM Antibodies - EIA (GBM)
Anti-Gliadin Antibodies (AGA-IgG/IgA)
Anti-Histones Antibodies (HIST)
Anti-Insulin Antibodies (INS)
Anti-Jo1 Antibodies
Anti-M2 Antibodies (M2)

Anti-MPO Antibodies
Anti-Nucleosome Antibodies (NCL)
Anti-Phospholipid IgG/IgM (APLA)
Anti-PR3 Antibodies
Anti-Ribosomal P Antibodies (Rib P)
Anti-Scl70 Antibodies
Anti-Sm Antibodies
Anti-Sm/RNP Antibodies
Anti-SSA (Ro) Antibodies
Anti-SSB (La) Antibodies
Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Thyroid Peroxidase Antibodies
(Anti-TPO)
Anti-tTransglutaminase IgA Antibodies
(Anti- tTG IgA)
Anti-tTransglutaminase IgG Antibodies
(Anti- tTG IgG)
ASCA-IgG/IgA (ASCA)
ENA 4-Profile
ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS:

AUTOIMMUNITY – INSTRUMENTS:

iPRO



RAPID TESTS – LATEX AGGLUTINATION:

Anti-Streptolysin O (ASO) - Slide
C-Reactive Protein (CRP) - Slide

Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon

TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening

Febrile Serodiagnostics Salmonella

Brucella abortus

Brucella abortus, Rose Bengal

Proteus Ox19

Salmonella paratyphi AH

Salmonella paratyphi AO

Salmonella paratyphi BH

Salmonella paratyphi BO

Salmonella paratyphi CH

Salmonella paratyphi CO

Salmonella typhi H

Salmonella typhi O

Brucella Positive Control

Proteus Positive Control

Salmonella Positive Control

Serology Negative Control

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

Certificate Holder: **BIOSYSTEMS S.A.**
Costa Brava, 30
08030 Barcelona
Spain

(including the locations according to annex)

Scope: Design, development, manufacture, distribution, installation and servicing of:
- Instruments and reagents for clinical diagnostic.
- Instruments and reagents for agro-alimentary analysis.
Distribution and servicing of instruments and reagents for veterinary diagnosis.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2017-12-13 until 2019-12-18.
First certification 1996

2017-12-14


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

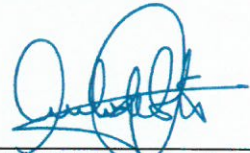
Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

| No. | Location | Scope |
|-----|--|---|
| /01 | BIOSYSTEMS, S.A. Pl. Can Tapioles nous 7-12-13 08110 Montcada i Reixac Spain | Labelling and assembling of reagents. Warehousing and shipment of: -Instruments and Reagents for clinical diagnostic. -Instruments and Reagents for agro-alimentary analysis. -Instruments and Reagents for veterinary diagnosis. |

2017-12-14



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 1 of 1

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

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

**Design and development, manufacture, distribution and
servicing of instruments and reagents for
clinical diagnostic
(see attachment for sites included)**

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: 2017-11-28
Certificate Registration No.: SX 60124804 0001
An audit was performed. Report No.: 28300434 002
This Certificate is valid until: 2019-12-12

Certification Body



Date 2017-11-28



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>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60124804 0001
Report No.: 28300434 002

Organization: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope:

Site included:
Polígono Industrial "Can Tapioles"
Naves 7, 12 y 13
08110 Montcada i Reixac (Barcelona)
Spain

Scope:
Labelling and Assembling of reagents and
Warehousing and Shipment of instruments and
reagents for clinical diagnostic

Certification Body



Date: 2017-11-28

