

FORMULARUL OFERTEI (F3.1)

Data: **24 ian 2020, 16:00 - 28 ian 2020, 17:00**
Licităția nr.: **ocds-b3wdp1-MD-1579786394071**
Invitație la licitația nr.:
Alternativa nr.:
Către: **Institutul Neurologie și Neurochirurgie**

Biosistem-mld SRL declară că:

a) Au fost examinate și nu există rezervări față de documentele de licitație, inclusiv modificările nr.

b) Biosistem-mld SRL se angajează să furnizeze, în conformitate cu documentele de licitație și condițiile stipulate în specificațiile tehnice și de formare a prețurilor, următoarele bunuri și/sau servicii

Reagenți și Reactive pentru laboratorul clinic

c) Suma totală a ofertei fără TVA constituie:

21,344.60 lei

d) Suma totală a ofertei cu TVA constituie:

23,472.96 lei

e) Prezenta ofertă va rămâne valabilă pentru perioada de timp specificată în FDA4.8., începînd cu data-limită pentru depunerea ofertei, în conformitate cu FDA5.2., va rămîne obligatorie și va putea fi acceptată în orice moment pînă la expirarea acestei perioade;

f) În cazul acceptării prezentei oferte, Biosistem-mld SRL se angajează să obțină o Garanție de bună execuție în conformitate cu FDA7, pentru executarea corespunzătoare a contractului de achiziție publică.

g) Nu sîntem în nici un conflict de interese, în conformitate cu punctul IPO5.4.

h) Compania semnatară, afiliații sau sucursalele sale, inclusiv fiecare partener sau subcontractor ce fac parte din contract, nu au fost declarate neeligibile în baza prevederilor legislației în vigoare sau a regulamentelor cu incidență în domeniul achizițiilor publice, în conformitate cu punctul IPO5.5.

Semnat: _____

Nume: Poiata Vitalie

În calitate de: Director

Ofertantul: Biosistem-mld SRL

Adresa: mun.Chisinau, Albisoara 16/1 of.7

Data: 24 ian 2020, 16:00 - 28 ian 2020, 17:00

Specificații tehnice (F4.1)

Numărul licitației:			ocds-b3wdp1-MD-1579786394071					Data:	24 ian 2020, 16:00 - 28 ian 2020, 17:00		Alternativa nr.:
Denumirea licitației:			Reagenți și Reactive pentru laboratorul clinic					Lot:			Pagina 1 din
Nr. Lot	Denumire Lot	Cod CPV	Denumirea bunurilor și/sau a serviciilor	Modelul articolului	Țara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant		Standarde de referință	
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>		<u>10</u>	
1	Reactive pentru analizatorul Hematologic MINDRAY BC-3600 (sistem închis)	33600000-6	M-30D DILUENT	M-30D DILUENT	China	Mindray	valabilitatea reagentilor nu mai puțin de 2-3 ani Certificat ISO al producătorului; CE Marca	valabilitatea reagentilor nu mai puțin de 2-3 ani Certificat ISO al producătorului; CE Marca		ISO, CE	
1		33600000-6	M-30CFL LYSE	M-30CFL LYSE	China	Mindray	valabilitatea reagentilor nu mai puțin de 2-3 ani Certificat ISO al producătorului; CE Marca	valabilitatea reagentilor nu mai puțin de 2-3 ani Certificat ISO al producătorului; CE Marca		ISO, CE	
1		33600000-6	M-30R RINSE11	M-30R RINSE (II)	China	Mindray	valabilitatea reagentilor nu mai puțin de 2-3 ani Certificat ISO al producătorului; CE Marca	valabilitatea reagentilor nu mai puțin de 2-3 ani Certificat ISO al producătorului; CE Marca		ISO, CE	
1		33600000-6	Control Hemo 3 nivele	Control 3 x 3.0ml Tri-pack (1L, 1N, 1H)	China	Mindray	Certificat ISO al producătorului; CE Marca	Certificat ISO al producătorului; CE Marca		ISO, CE	
1		33600000-6	Probe Cleanser	Probe Cleanser	China	Mindray	Certificat ISO al producătorului; CE Marca	Certificat ISO al producătorului; CE Marca		ISO, CE	

Semnat: _____ Numele, prenumele: Poiata Vitalie

Ofertantul: Biosistem-mld SRL

În calitate de: Director

Adresa: mun.Chisinau, Albisoara 16/1 of.7

Specificații de preț (F4.2)

Numărul licitației:		ocds-b3wdp1-MD-1579786394071						Data:	24 ian 2020, 16:00 - 28 ian 2020, 17:00	Alternativa nr.:
Denumirea licitației:		Reagenți și Reactive pentru laboratorul clinic						Lot:		Pagina 1 din
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Cod CPV	Cantitatea	Unitatea de măsură	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/ prestare
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>	<u>11</u>
1	Reactive pentru analizatorul Hematologic MINDRAY BC-3600 (sistem închis)	M-30D DILUENT	33600000-6	200	litri	24.76	26.74	4,952.00	5,348.00	La comanda
1		M-30CFL LYSE	33600000-6	3000	ml	1.35	1.46	4,050.00	4,380.00	La comanda
1		M-30R RINSE11	33600000-6	100	litri	32.74	35.36	3,274.00	3,536.00	La comanda
1		Control Hemo 3 nivele	33600000-6	36	ml	156.35	168.86	5,628.60	6,078.96	La comanda
1		Probe Cleanser	33600000-6	1000	ml	3.44	4.13	3,440.00	4,130.00	La comanda
TOTAL Oferta							21,344.60	23,472.96		

Semnat: _____ Numele, prenumele: Poiata Vitalie

Ofertantul: Biosistem-mld SRL

În calitate de: Director

Adresa: mun.Chisinau, Albisoara 16/1 of.7

Сертификат

Nasedchin Alexandr

компания: SRL Biosistem MLD

Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-30s
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

Дата: 09 октября 2015 года

Центр поддержки клиентов Mindray Medical Russia Ltd.



Сертификат

Poiate Vitalie

компания: SRL Biosistem MLD

Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-30s
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

Центр поддержки клиентов Mindray Medical Russia Ltd.



Дата: 09 октября 2015 года

To,
Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

26.02.2019

MANUFACTURERS AUTHORIZATION

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** ("Mindray") manufacturer of Hematology analyzers, hereby authorize: **Biosistem-mld SRL**, with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, to submit bids and subsequently negotiate and sign Contracts for reagents and consumables for all auto-hematology analyzers supplied by company **Biosistem-mld SRL**.

The authorization period is valid one year from issue date and automatically renewable if no termination letter is issued by either part.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of Product, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,



Luan Haijiao

Deputy Manager of International Sales and Marketing System,
Commonwealth of Independent States
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China

Tel: +86 755 81888998

Fax: +86 755 26582680

Website: www.mindray.com

Declaration of Conformity **CE**

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Auto Hematology Analyzer
Model: BC-3600

Including reagents as following:

M-30D DILUENT
M-30CFL LYSE
M-30R RINSE
PROBE CLEANSER

Classification: The device not in IVDD annex II and not for self
testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the
provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical
Devices. All supporting documentations are retained under the premises
of the manufacturer.

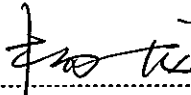
Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be
provided as attachment.

Start of CE-Marking: 2011-01-14

Place, Date of Issue: Shenzhen, 2011-01-14

Signature:



Name of Authorized Signatory: Mr. Yang Long

Position Held in Company: Management Representative



Product Service

CERTIFICATE

No. Q5 17 03 44751 089

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA



Certification Mark:



Scope of Certificate: Design and development, production and distribution of Active medical devices (intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro diagnostic instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits (intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1705528

Valid from: 2017-09-01

Valid until: 2020-08-31

Date, 2017-06-28

Stefan Preiß



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Product Service

CERTIFICATE**No. Q5 17 03 44751 089****Applied Standard(s):**

EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech
Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Bldg 9-13, Baiwangxin High-Tech Industrial Park,
Baimang, Xili Town, Nanshan, 518108 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Shenzhen Mindray Biomedical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106
Shenzhen, PEOPLE'S REPUBLIC OF CHINA



Product Service

Attachment for Certificate No. Q5 17 03 44751 089
Dated: 2017-06-28

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder,
 Anesthesia Machine and Accessories, Ventilator,
 Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System,
 Ultrasonic Diagnostic Equipment and Accessories,
 Digital Radiography System, Radiography System, Magnetic Resonance Imaging System
 Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader,
 Microplate Washer for invitro diagnostic use, Chemiluminescence Immunossay Analyzer,
 Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer,
 Glycohemoglobin Analyzer, Specific Protein Analyzer,
 Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer,
 Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer,
 Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask,
 Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Munich, CRT, 2017-06-28

Stefan Preiß

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America

CERTIFICATE

No. QS5 17 07 44751 097

Certificate Holder:

Shenzhen Mindray Bio-Medical
Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger,

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

M2606

Effective Date:

2017-07-01

Expiry Date:

2020-06-30

Earl Buckmiller

Director, Quality Systems & MS Cert. Body



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TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®





America

CERTIFICATE

No. QS5 17 07 44751 097

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan, 518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Bldg 9-13, Baiwangxin High-Tech Industrial Park
Baimang, Xili Town
Nanshan, 518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Manufacturing of Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine, Ventilator, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System. Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Effective Date: 2017-07-01
 Expiry Date: 2020-06-30

Earl Buckmiller
 Director, Quality Systems & MS Cert. Body

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TÜV SÜD America Inc.
 10 Centennial Drive
 Peabody, MA 01960
 USA

TÜV®





America

CERTIFICATE

No. QS5 17 07 44751 097

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue
Guangming District
518016 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories (Ultrasonic Transducer), Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Effective Date: 2017-07-01
Expiry Date: 2020-06-30

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