**INFORMATION**

**AMENDMENT No.1 TO PROCUREMENT DOCUMENTS**

**Issued on** **31st of August 2018**

**for** **Procurement of Medical Devices for The Obstetrics and Gynaecology Clinic “Višegradska”- Clinical Centre of Serbia**, **No. IOP/18-2018/RD**

In accordance with the Clause 8. Part 1. Bidding Procedures, Section I. Instructions to Bidders, Contents of Bidding Documents, Amendment of Bidding Documents of the Procurement Documents, Public Investment Management Office, No. 11 Nemanjina street, Republic of Serbia, as the Purchaser, hereby notifies all persons concerned Procurement of Medical Devices for The Obstetrics and Gynaecology Clinic “Višegradska”-Clinical Centre of Serbia, No. IOP/18-2018/RD**,** that there has been an amendment made in the Technical specifications:

**LOT 1 - Intervention and diagnostic equipment**

For the **Item 1.8.1** **Surgical Light for the OR with HD camera, receiver and monitor**, the new line is added under point 20 and reads as follows:

|  |  |
| --- | --- |
| **20** | **Recording: Documentation of surgeries in the OR, full HD resolution** |

For the Item **1.9 OR Video Management System**, the new line is added under point 11 and reads as follows:

|  |  |
| --- | --- |
| **11** | **Installation on pendant shelf inside OR. Weight of the unit max 25kg.Celling pendant which allows a complete installation inside OR: - pneumatic brake for the pendant; - min. 4 shelfs (ca. 530 x 480mm) ; - min. 12 Power sockets; min. 4 Circuit cable adapters**  |

**LOT 2 Auxiliary hospital and medical equipment**

The new Item **2.15 Automatic instrument washer - disinfector and dryer** was added with the following technical specification:

|  |  |  |
| --- | --- | --- |
| **2.15** | **Automatic instrument washer - disinfector and dryer** | **Qty.** |
| **1** |
| **1** | Free standing automatic washer - disinfector |   |
| **2** | Capacity 8 DIN trays for instruments, |   |
| **3** | Intended for washing and disinfection and drying of surgical instruments |   |
| **4** | Cycle time up to 60min. |   |
| **5** | Chamber made of high quality stainless steel AISI 316L, thickness min. 1.5 mm |   |
| **6** | Dosing unit for detergent |   |
| **7** | Flow control for dosing unit |   |
| **8** | Foam control |   |
| **9** | High pressure pump, capacity min 350 l/min |   |
| **10** | HEPA filter class: H13 |   |
| **11** | Drainage system with pump and valve |   |
| **12** | A0 value temperature and disinfection control |   |
| **13** | Media saving system |   |
| **14** | Operating panel with LCD display for machine control |   |
| **15** | Built in cycle printer |   |
| **16** | Temperature monitoring |   |
| **17** | Thermal protection against overheating |   |
| **18** | Possibility of connection to PC and barcode reader through different interface |   |
| **19** | Acoustic signal at program end |   |
| **20** | Automatic maintenance reminder |   |
| **21** | Machine panelling made of stainless steel AISI 304 or better |   |
| **22** | Chamber volume 200-230 l |   |
| **23** | Machine must comply with the following standards: EN ISO 15883, EN ISO 13485 |   |
|  | Equipment delivered with the machine: |   |
| **24** | 4-level instrument rack for 8 standard instrument trays, 1 pc |   |
| **25** | 1-level AN rack, 1 pc  |   |
| **26** |  Adequate water preparation system for RO water, with water softener |   |

**LOT 4 - OR and ICU**

For the **Item 4.3**, **Patient monitors with central station**, there is a change in Quantities.

In line 1. Monitor for patient monitoring in the ICU or OR (optionally), the new **Quantity is 25**.

In line 41. Central station the new **Quantity is 2.**

**LOT 6 Laboratory**

For Item **6.18 Multi-Room Incubator with integrated pH measurements**, the new lines are added:

|  |  |
| --- | --- |
| **25** | **CO2 analyzer** |
| **26** | electronic CO2 analyzer to monitor CO2 , O2 and temperature for the verification of IVF incubators |
| **27** | Calibration of inbuilt CO2 sensor in CO2 incubators |
| **28** | Calibration of inbuilt temperature sensor CO2 incubators |
| **29** | Measurement of CO2 and O2 levels in CO2 incubators |
| **30** | Measurement of temperature in CO2 incubator |
| **31** | dual temperature probes |
| **32** | Built in display with LED back light |
| **33** | Built in gas moisture removal |
| **34** | Gas Measured CO2 with dual wavelength infra-red cell reference channel  |
| **35** | Gas Measured O2 with internal electrochemical cell |
| **36** | Pump flow 100cc/min  |
| **37** | Range CO2 …………….0-20%  |
| **38** | Range O2 ………………0-100% |
| **39** | Measurement Accuracy CO2 ± (1% range +2% of reading) at reference conditions. |
| **40** | Temperature dependence ± 0.2% reading ºC (typical at 5% CO2 ) . |
| **41** | Pressure dependence ± 0.02% of reading/hPa (typical at 5% CO2 )  |
| **42** | Measurement Accuracy O2…… ±1.0%  |
| **43** | Temperature Accuracy, Typical ± 0.2ºC from 32 to 44ºC, ± 0.5ºC over the rest of range |
| **44** | Visual and Audible Alarm Selectable CO2 and O2 alarm levels |
| **45** | Communications USB type B mini-connector |
| **46** | HID device class |
| **47** | Data Storage 1000 reading sets +270 events |
| **48** | Battery Li Ion rechargeable |
| **49** | **pH monitoring** |
| **50** | Connections possibility up to eight (8) incubators  |
| **51** | Touch screen display  |
| **52** | Magnetically mount |
| **53** | Historical pH results and output data to USB flash drive |
| **54** | Continual reading: up to 7 days |
| **55** | pH Accuracy: ± 0.05 (range 7.0 to 7.6) |
| **56** | pH Resolution: 0.01 |
| **57** | Connection to sensors with disposable florescent membrane |
| **58** | Real time pH (reading every 30min) |

The new Items

6.21 Freezer

6.22 Analytical scale

6.23 Platelet agitator with incubator

6.24 Centrifuge

6.25 Blood gas analyzer

6.26 PATHFAST analyzer (“Point of care” analyzer)

6.27 Rotem analyzer

6.28 Vortex shaker

were added with the following technical specifications:

|  |  |  |
| --- | --- | --- |
| **6.21** | **Freezer** | Qty. |
| 1 |
| **1** | Upright laboratory freezer |  |
| **2** | Dimension (WxDxH) 65x185x75 cm±2cm |  |
| **3** | Volume gross up to 310 l |  |
| **4** | Volume net up to 270 l |  |
| **5** | Energy class A+ |  |
| **6** | Climate class SN, N, ST, T |  |
| **7** | Power cut safe time 28h |  |
| **8** | Noise level 42 dB |  |
| **9** | Right/left door opening |  |
| **10** | Door material: metal |  |
| **11** | Electronic control behind the door |  |
| **12** | 6 shelves  |  |
| **13** | Neto weight 70 kg |  |
| **14** | Conected load 120W |  |
| **15** | Energy consumption kWh/24h 0,79 |  |
| **16** | Freezing capacity 25 kg |  |
| **17** | 1 compressor |  |
| **6.22** | **Analytical scale** | 1 |
| **1** | Maximum capacity 220 g |  |
| **2** | Minimum load 10 mg |  |
| **3** | Readability 0,1 mg |  |
| **4** | Linearity ± 0,2 mg |  |
| **5** | Stabilization time 2 s |  |
| **6** | LCD touh display |  |
| **7** | 2 programmable proximity sensors |  |
| **8** | Weighting pan Ǿ100 mm |  |
| **9** | Internal adjustment with verification |  |
| **6.23** | **Platelet agitator with incubator** | 1 |
| **1** | Capacity 48 random bags/ 16 apheresis bags |  |
| **2** | Operating temperature range from +20°C to + 35°C, factory set to+22°C  |  |
| **3** | Forced-air refrigeration system and precision pulse heating |  |
| **4** | Bacteria-resistant powder coated interior and exterior |  |
| **5** | Digital temperature display |  |
| **6** | Integrated temperature chart recorder |  |
| **7** | Auto-Stop/Start pauses agitator when incubator door is opened and automatically resumes when door is closed |  |
| **8** | Single-pane tempered glass door |  |
| **9** | Key lock and password protected configuration |  |
| **10** | One-piece removable perforated drawers for uniform air circulation |  |
| **11** | Built-in motion alarm |  |
| **12** | Automatic high/low temperature alarm testing (Peltier based) |  |
| **13** | Log of alarm conditions |  |
| **14** | Audible and visual alarms |  |
| **15** | Door ajar alarm |  |
| **16** | Power failure alarm |  |
| **17** | No battery alarm |  |
| **6.24** | **Centrifuge** | 2 |
| **1** | Maximum speed 6000 RPM |  |
| **2** | Maximum RCF 4 226 |  |
| **3** | Maximum capacity 4x100 mL |  |
| **4** | Running time 1-99 min |  |
| **5** | Microprocessor control, LCD display |  |
| **6** | Centrifuging chamber of stainless steel |  |
| **7** | Ergonomic operating and information panel |  |
| **8** | Switches from RPM to RCF |  |
| **9** | Possibility of manually stopping centrifugation |  |
| **10** | Swing-out rotor - 90 degrees |  |
| **11** | Rotor capacity 28 x 15 mL tubes; 68 x 5 mL tubes; 28 x 4-7 Ml tubes |  |
| **12** | Power supply 240V/50 Hz |  |
| **6.25** | **Blood gas analyzer** | 1 |
| **1** | Measuring parameters: pH, pO2, pCO2, Na, K, Cl, Ca, Glu, Lac, tHb, Hct, HHb, O2Hb, COHb, MetHb, SO2, nBili |  |
| **2** | Calculating parameters: ctO2, p50, O2cap, FiO2, pO2(A)T, pO2(A-a), pO2(a-A), RI, AvDO2, AV, VO2, DO2, Qs/Qt |  |
| **3** | Maintenance free cartridge based technology |  |
| **4** | Bio-safe hands-free automatic sampling with clot detection and clot management  |  |
| **5** | Cartridge life on board minimum 26 days |  |
| **6** | Multiple sample types including whole blood (arterial and venous), pleural fluid and dialysate |  |
| **7** | Intuitive touch-screen interface and integrated bar-code reader: just scan, insert, and analyze with results in approximately 60 seconds  |  |
| **8** | All components required to measure the critical analytes in a single cartridge without gas tanks and reagent bottles |  |
| **9** | Sample port designed to minimize bubbles and detect and clear clots |  |
| **10** | Port design automates sample aspiration making hands-free testing process bio-safe and independent of operator technique |  |
| **11** | Single sample port accepts syringe or capillary samples without adapters |  |
| **12** | Fully automated calibration and quality control systems help ensure accuracy and support compliance without operator interaction |  |
| **13** | Integrated Bar-Code scanner |  |
| **14** | Connectivity to LIS/HIS |  |
| **6.26** | **PATHFAST analyzer (“Point of care” analyzer)** | 1 |
| **1** | Measurement of sCD14 – ST ( PRESEPSIN ) – marker for diagnostics of sepsis and simultaneous determination of other analyses: hs Troponin I, D – dimer, B-HCG, hs – CRP,… |  |
| **2** | Fully automated immunoassay analyzer with chemi-luminescence tehnology |  |
| **3** | Whole blood sample material and plasma have to be used as samples ( volume of samples for testing is 100uL (microliter)) |  |
| **4** | Results are available in 15 minutes |  |
| **5** | Six independent measurement channels  |  |
| **6** | Uses single reagent cartridge with all needed reagents included in |  |
| **6.27** | **Rotem analyzer** | 1 |
| **1** | Working principle- thromboelastometry –Optical mechanical detection of clot formation |  |
| **2** | Uses 0,3 ml whole blood samples for testing  |  |
| **3** | Differential diagnosis by the combination of up to 5 different assays |  |
| **4** | Fast assessment of clot formation in intrinsic and extrinsic pathway (Screening tests IN-TEM and EX-TEM) |  |
| **5** | Independent tests for conformation fibrinogen status (FIB-TEM), detection of heparin effects (HEP-TEM) and conformation hiperfibrinolysis (AP-TEM) |  |
| **6** | Analyzer has four channels for measurement  |  |
| **7** | Pre-warming position for patient samples  |  |
| **8** | Results in 5-10 minutes  |  |
| **9** |  Automated pipette for standardized volumes  |  |
| **10** |  Two levels of quality controls  |  |
| **11** |  Integrated user administration  |  |
| **12** |  Possibility of HIS/LIS connection for comprehensive data transfer  |  |
| **13** | Small dimensions and easy to move analyzer  |  |
| **14** | Measurement insensitive to shock and vibrations  |  |
| **15** | Data base holds more than 20.000 patient record  |  |
| **16** |  LCD *touch screen*  |  |
| **17** |  Simplified interpretation of results via colour coded TEMograms  |  |
| **18** | USB printer  |  |
| **19** | Provides information about hyperfibrinolysis, dilutional coagulopathies, substitution of fibrinogen, factors or platelets as well as the controls of heparin and protamine dosage  |  |
| **6.28** | **Vortex shaker** | 2 |
| **1** | Adjustable stirring speed (up to 3000 rpm) |  |
| **2** | Continuous or touch mode |  |
| **3** | Structure which ensures optimum chemical resistance |  |
| **4** | 4 anti sliding feet |  |
| **5** | Soft start |  |
| **6** | Controlled ramping |  |
| **7** | Weight approximatly 2,5 kg |  |
| **8** | Power supply 240V/50 Hz |  |

Updated version of technical specifications is given in excel file and is constituent part of this amendment.

In order to prepare correct bids, regarding lots in which changes were made, the Bids should be prepared in accordance with the latest amendment, published on the website of the Purchaser.

In all other aspects, Procurement Document for the Procurement of Medical Devices for The Obstetrics and Gynaecology Clinic “Višegradska”-Clinical Centre of Serbia, No. IOP/18-2018/RD**,** remains unchanged.

 Public Procurement Committee