

## Anexa 4 la formularul Specificatii Tehnice Anexa 23

**Lotul nr. 4 Analizator biochimic automat cu discuri microfluidice si reactivi preinstalati**

Nr.	Analizator biochimic automat cu discuri microfluidice si reactivi preinstalati destinat analizelor biochimice		Specificații tehnice oferite
	<b>Descriere</b>	Analizator biochimic automat cu discuri microfluidice si reactivi preinstalati destinat analizelor biochimice	Analizator biochimic automat cu discuri microfluidice si reactivi preinstalati destinat analizelor biochimice, model LOC-200
	<b>Parametru</b>	<b>Specificația</b>	
	<b>Sistem analitic</b>	Analizator automat cu ecran touch screen si imprimanta externa	Analizator automat cu ecran touch screen si imprimanta incorporata
	<b>Tip proba</b>	Ser	Ser
		Plasma	Plasma
		Singe integru (colectat in eprubeta cu Litiu Heparin)	Singe integru (colectat in eprubeta cu Litiu Heparin)
	<b>Program de control al calitatii pentru monitorizarea procesului de testare</b>	da	Da
	<b>Calibrare automata prin QR cod</b>	da	Da
	<b>Cititor coduri de bare integrat</b>	da	da
	<b>Volumul probei</b>	≤100 μL	100μl
	<b>Temperatura de reactie</b>	37 grade celsius	37 grade celsius
	<b>Interfata de comunicare</b>	WLAN	DA
		USB	DA
		Ethernet	DA
		LIC	DA
	<b>Interfata cu utilizatorul</b>	Touch screen	≥4.3 inch 7inch capacitative touch screen
	<b>Memorie interna</b>	≥ 50000 teste	500 000 teste
	<b>Tip reactivi</b>	<b>Discuri microfluidice</b>	da
		<b>Reactivi preinstalati</b>	Da
		<b>Discuri configurate pentru multiple teste concomitent</b>	da

	<b>Diluent pentru dizolvarea reactivelor preinstalati</b>	da	da
<b>Teste efectuate</b>	TP, ALB, ALT, AST, GGT, ALP, TBIL, DBIL, CK, CK-MB, LDH, $\alpha$ -HBDH, TG, CHOL, HDL-C, GLU, GSP, AMY, CRE, UREA, UA, K <sup>+</sup> , Na <sup>+</sup> , Cl <sup>-</sup> , Ca <sup>2+</sup> , P, Mg <sup>2+</sup> , CO <sub>2</sub> , NH <sub>3</sub>	TP, ALB, ALT, AST, GGT, ALP, TBIL, DBIL, CK, CK-MB, LDH, $\alpha$ -HBDH, TG, CHOL, HDL-C, GLU, AMY, CRE, UREA, UA, K <sup>+</sup> , Na <sup>+</sup> , Cl <sup>-</sup> , Ca <sup>2+</sup> , P, Mg <sup>2+</sup> , CO <sub>2</sub> .	
Timp de testare	7-12min	8-12min	
Temperatura de operare	10-30 <sup>0</sup> C	10-30 <sup>0</sup> C	
Umiditatea de operare	40-85%	40-85%	
Greutatea	≤2.5kg	4.5kg	
Alimentarea	220V, 50Hz	110-240V, 50-60Hz	



**LOC-200**

**Automatic Biochemistry Analyzer**

LOC-200 Automatic Biochemistry Analyzer is designed to perform the blood biochemistry and electrolyte item analysis(35 parameters),delivering reliable and accurate results in 8-12 minutes by 3 drops of blood sample(90-120 μL).



**Easy Operation-3 Steps**



Add 100μL sample



Insert the disc



Read the results



## Key Features

### Space Saving

Small size and bench top design, weight only 4.5kg

### Quick & Reliable Result

Get result in 8-12 minutes, intelligent IQC system monitors the entire test process.

### Broad Test Menu

8 different reagent panels covering biochemistry, electrolyte analysis items.



### Fully Automatic Design

No need centrifuge & calibration, dilution and mixing are performed automatically.

### Little Maintenance

No need calibration, no need to change parts.

### Lower Sample Volume

Only 100 µl (3 drops) of whole blood, serum or plasma.

## Disposable Reagent Discs

### 8 different Panels with 35 parameters, 12 Minutes to Result. Easy Operation

Based on Micro-fluidic technology, LOCMEDT reagent discs are designed to perform all the steps required to convert 3 drops of blood sample to several accurate results.



#### General Chemistry I Lyophilized Kit 18

TP ALB TBIL ALT AST GGT ALP GLU  
CHOL TG HDL-C HCY CRE UA UREA  
GLOB\* LDL-C\* A/G\*



#### General Chemistry II Lyophilized Kit 18

TP ALB TBIL ALT AST GGT ALP GLU AMY  
CHOL TG HDL-C CRE UA UREA GLOB\* LDL-C\*  
A/G\*



#### General Chemistry III Lyophilized Kit 15

ALB TBIL DBIL ALT AST GLU FRUC AMY  
CHOL TG HDL-C CRE UREA LDL-C\* IBIL\*



#### Clinical Emergency Lyophilized Kit 15

AST GLU AMY K<sup>+</sup> Na<sup>+</sup> CL<sup>-</sup> Co<sub>2</sub> CRE UA  
UREA CK CK-MB LDH α-HBDH AG\*



#### Liver Function Lyophilized Kit 14

TP ALB TBIL DBIL ALT AST GGT ALP  
CHE GLU AMY GLOB\* A/G\* IBIL\*



#### Electrolyte & Renal Function Lyophilized Kit 11

K<sup>+</sup> Na<sup>+</sup> CL<sup>-</sup> Ca Mg<sup>2+</sup> P Co<sub>2</sub> CRE UA UREA  
AG\*



#### Renal Function Glucose and Lipid Lyophilized Kit 10

GLU FRUC CHOL TG HDL-C HCY CRE UA  
UREA LDL-C\*



#### Myocardial Enzyme and Lipid Lyophilized Kit 10

AST CHOL TG HDL-C HCY CK CK-MB LDH α-HBDH  
LDL-C\*

## Specification

Sample Type	lithium-heparinized whole blood, lithium-heparinized plasma or serum	Display	7 inch capacitive touch screen Multi-language
Sample Volume	90-120 µl	Storage	Max 500,000 results
Testing Time	8-12 mins/sample	Printer	Built-in thermal printer
Working Condition	Temperature:10-30°C Humidity: 40%-85%	Data Transmission	WIFI, LIS
QC & Calibrate	Automatic and Real-time	Size	256mm(L)*172mm(W)*350mm(H)
Temperature	37°C±0.2°C	Weight	4.5KG
Supply	AC110-240V, 50-60Hz	Power Rating	120W



# EU Declaration of Conformity

**Manufacturer:**

**Name:** Tianjin LOCMEDT Technologies Co., Ltd.  
**Address:** Floor 4, Building B3, Huaming High-tech Industrial Zone,  
No.6 Huafeng Road, Dongli District, Tianjin,300300, China  
**Tel:** +86-22-58601276  
**SRN:** CN-MF-000025773

**Whose Authorized Representative:**

**Name:** Lotus NL B.V.  
**Address:** Koningin Julianaplein 10,1e  
Verd, 2595AA, The Hague,  
Netherlands.  
**E-mail:** peter@lotusnl.com  
**SRN:** :NL-AR-000000121

We, Tianjin LOCMEDT Technologies Co., Ltd. (Manufacturer), here declare that the below mentioned medical device meets the REGULATION (EU) IVDR 2017/746 which apply to them. The declaration of conformity is exclusively under the responsibility of Tianjin LOCMEDT Technologies Co., Ltd. (Manufacturer).

<b>Product Name</b>	Automatic Biochemistry Analyzer LOC-200	<b>Model</b>	LOC-200
<b>Basic UDI-DI</b>	697564135ABIOALOC200UC	<b>EMDN</b>	W0201010101
<b>Intended Use</b>	Automatic Biochemistry Analyzer LOC-200 is used with the kit produced by Tianjin LOCMEDT Technologies Co., Ltd to carry out quantitative determination of clinical biochemical items on samples. This product is suitable for clinical biochemical analysis of lithium-heparinized whole blood, plasma or serum.		
<b>Classification</b>	A (IVDR, Annex VIII Rule 5)		

**Conformity Assessment Route:** Annex IX of REGULATION (EU) 2017/746.

**Applicable Standards:**

EN ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 23640:2015

EN ISO 18113-3:2011

IEC 61010-2-101:2018

ISO 15223-1:2021

EN 61326-1:2021

EN 62366-1:2015/A1:2020



EN 61326-2-6:2021

EN 13612:2002/AC:2002

EN 61010-1:2010+A1:2019



The aforementioned device has been assigned to class A according to Appendix VIII of the Regulation (EU) 2017/746. The above-mentioned declaration of conformity is exclusively under the responsibility of Tianjin LOCMEDT Technologies Co., Ltd.

<b>Name Of Authorized Signatory</b>	Zhiyi,Kang
<b>Position Held In The Company</b>	General Manager
<b>Signature</b>	
<b>Date</b>	7 <sup>th</sup> April, 2022
<b>Place</b>	Tianjin, China
<b>Seal (Manufacturer)</b>	



# EC Declaration of Conformity

**Manufacturer:**

**Name:** Tianjin LOCMEDT Technologies Co.,Ltd.  
**Address:** Floor 4,Building B3, Huaming High-tech Industrial Zone,  
No.6 Huafeng Road,Dongli District,Tianjin,300300,China  
**Tel:** +86-22-58601276  
**Email:** service@locmedt.com

**Whose Authorized Representative:**

**Name:** Lotus NL B.V.  
**Address:** Koningin Julianaplein 10,1e  
Verd, 2595AA, The Hague, Netherlands.  
**E-mail:** peter@lotusnl.com

We, the manufacturer, here with declare that the product(s)

<b>Product Name</b>	General Chemistry I Lyophilized Kit 18 General Chemistry II Lyophilized Kit 18 General Chemistry III Lyophilized Kit 15 Clinical Emergency Lyophilized Kit 15 Liver Function Lyophilized Kit 14 Electrolyte &Renal Function Lyophilized Kit 11 Renal Function Glucose and Lipid Lyophilized Kit 10 Myocardial Enzyme and Lipid Lyophilized Kit 10
<b>Classification</b>	Others

**Conformity Assessment Route:** IVDD98/79/EC Annex III.

**Applicable Standards:**

*EN ISO 13485:2016*  
*EN ISO 14971:2019*  
*EN ISO 18113-1:2011*

*EN ISO 18113-2:2011*  
*EN 13641:2002*  
*EN ISO 15223-1:2021*

*EN 13612:2002/AC:2002*  
*EN ISO 23640:2015*  
*IEC 62366-1:2015*



We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop,implement and maintain a documented post-production monitoring process.

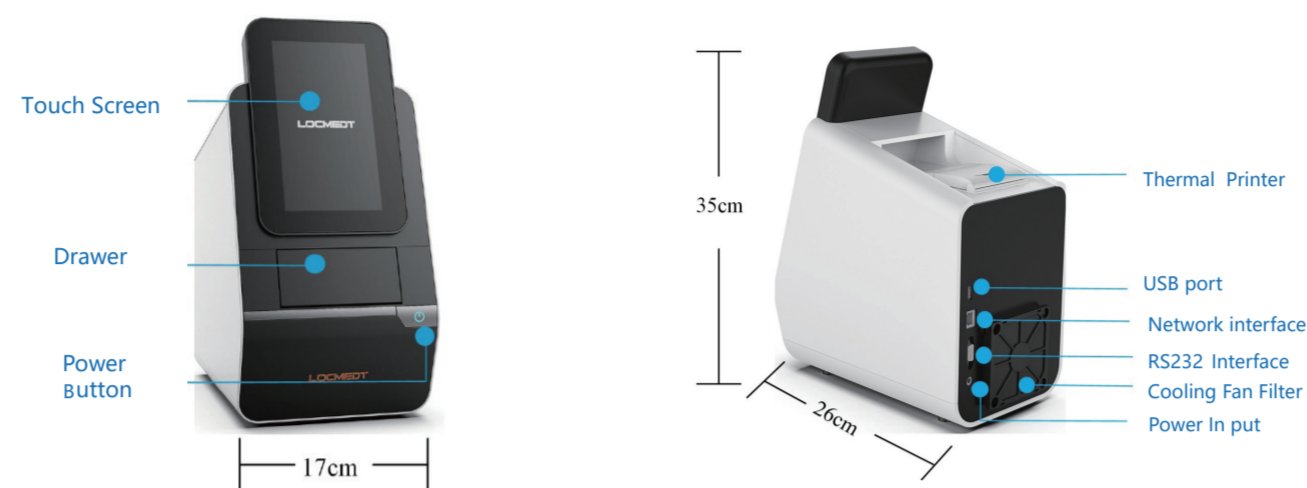
<b>Name of General Manager</b>	Zhiyi,Kang
<b>Signature</b>	
<b>Date</b>	7 <sup>th</sup> April,2022
<b>Place</b>	Tianjin,China
<b>Seal (Manufacturer)</b>	



# LOC-200 Automatic Biochemistry Analyzer

## Quick Reference Guide

### Analyzer Overview

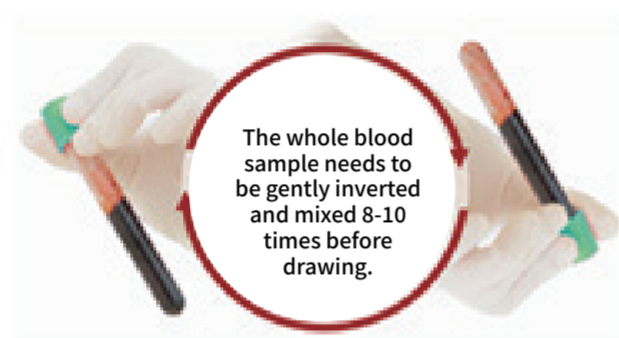


### Sample preparation-Whole blood sample

**Whole blood sample** (Use only Lithium Heparin anticoagulation vacuum blood collection tube)

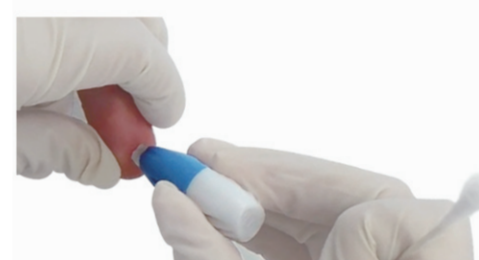
#### 1. Venous blood collection

- Use only butterfly needle and lithium heparin anticoagulation vacuum blood collection tube for venous blood collection. Remove the blood collection needle immediately after the blood collection is completed.
- Gently invert up and down for 8-10 times to mix the blood sample and anticoagulant thoroughly.



#### 2. Peripheral blood collection (Use only Lithium Heparin anticoagulation vacuum blood collection tube)

- Heel blood is recommended for infants under 1 year old, fingertip blood can be used for patients older than 1 year old, in case of insufficient blood collection, choose venous blood collection.
- Use only peripheral blood collection needles and lithium heparin peripheral blood collection tubes.
- After puncturing the fingertip with a blood collection needle, use the wall of the peripheral blood collection tube to scrape the blood sample into the tube. Please ensure that the blood collection volume is sufficient (not less than 0.5ml).
- After puncture, do not pressurize the blood collection site to avoid hemolysis and affect the test results.
- Gently invert up and down for 8-10 times to mix the blood sample and anticoagulant thoroughly.



### Sample preparation-Plasma/serum sample

**Plasma sample** (Use only Lithium Heparin anticoagulation vacuum blood collection tube)

Use a lithium heparin anticoagulated vacuum blood collection tube (green cap) to collect blood, centrifuge at 4000rpm for 5-7 minutes (centrifugation radius is 5-10cm), separate the plasma from the blood cells, stand vertically for sample pipetting.



**Serum sample** (Use only serum tube)

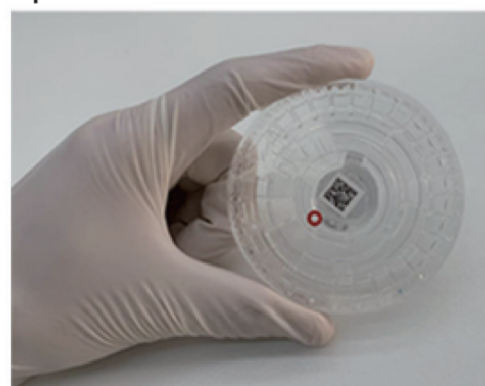
When using a serum tube for blood collection, the blood and coagulant should be fully mixed and placed vertically for more than 30 minutes. After sufficient coagulation, centrifuge at 4000 rpm for 5-7 minutes (the centrifugation radius is 5-10 cm), the serum and blood clot are completely separated, stand vertically for sample pipetting.



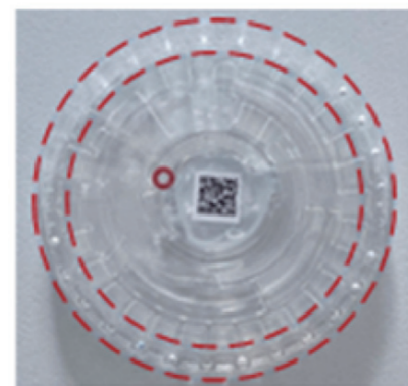
### Preparing for the test

#### 1. Handle the reagent disc only by its edges as shown below picture 1.

Avoid fingerprints and contamination in the annular area identified by the red dotted line, as shown below picture 2.



Picture 1

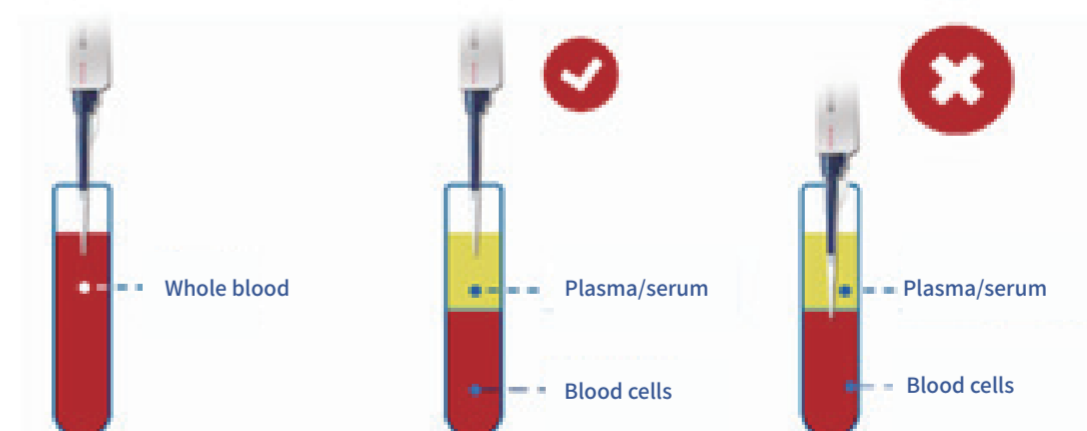


Picture 2

#### Note:

1. When drawing blood samples, it is necessary to ensure that no air bubbles are generated in the pipette tip, otherwise the sample volume will be inaccurate;
2. When drawing whole blood samples, make sure that the blood samples are free of clots;
3. When drawing plasma/serum samples, avoid drawing the underlying blood cells.

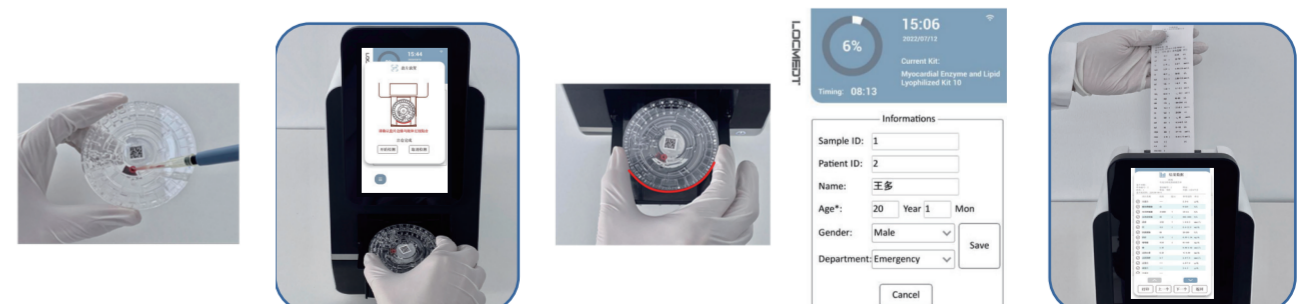
#### 2. Use a 100μL quantitative pipette to draw blood samples, first press the pipette discharge button to the first stop, then immerse the tip vertically 2-3mm below the liquid surface, release the button smoothly, remember not to be too fast, and draw 100μL Sample to be tested.



### Biochemical analysis

1. Add the blood sample to the sample injection hole (marked by the red circle) on the reagent disc. Note that the pipette tip is tilted 45 degrees when adding the sample to ensure that the sample is dispensed smoothly.
2. Click the "👉" button of the analyzer, select the type of test sample (whole blood/serum/plasma), the drawer opens automatically, place the disc in the drawer, and click "Start Test" to run the sample;
3. After about 10 minutes, the test is completed, the drawer will automatically pop up to display the test results, and the report will be printed.

Note: The report is automatically printed after the test is completed.





**Automatic Biochemistry Analyzer LOC-200**

**Specification Sheet**

Test sample	Lithium-heparinized whole blood, plasma or serum.
Sample size	100μl
Bar code read	Automatic reading of two-dimensional bar code
Test time	8-12mins/sample
Detection principle	Absorption spectrum colorimetry
Analysis method	End point method, rate assay
Temperature control precision	37±0.2℃
Linear range of absorbance	0-3.5Abs
Cross contamination rate	0
Work environment	Temperature: 10-30℃ Humidity: 40%-85%
Light source	5W xenon flash lamp with long lifespan
Power supply	Input: AC 110-240V, 50-60Hz
Rated power	120W
Light path system	9 wavelengths are detected synchronously, and the wavelengths are 340, 405, 450, 505, 550, 600, 630, 700, 800 (unit: nm).
Operation interface	7 inch LCD 1024*600, multi-point capacitive touch screen, multiple language options
Memory space	MAX 500,000 sample data + quality control data
Printer	Built-in thermal printer
Data interface	One USB port, one network port, and one RS232 port
Weight	Single machine weight 4.5Kg

Tianjin LOCMEDT Technologies Co.,Ltd

Add:Floor 4,Building B3, Huaming High-tech Industrial Zone, No.6 Huafeng Road,Dongli District,Tianjin,300300,China

TEL:+86-22-58601276



# LOCMEDT<sup>®</sup> Tianjin LOCMEDT Technologies Co. Ltd.

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Size	172mm(width)*256mm(thickness)*350mm(height)
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