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tel. +373-22-808719, fax +373-22-808519
e-mail: biosistem.mld@gmail.com

Anexa nr. 7
la Documentația standard
conform Ordin MF Nr. 115
din 15.09.2021

CERERE DE PARTICIPARE

Către: I.M.S.P. Centrul de Sanatate Vulcanesti

adresa: 5300, MOLDOVA, UTA Găgăuzia, or.Vulcănești (UTA Găgăuzia), Plotnikov nr.59

(denumirea autorității contractante și adresa completă)

Stimați domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene și/sau SIA RSAP MTender, nr. ocds-b3wdp1-MD-1740993556388 din 10.03.2025, privind aplicarea procedurii pentru atribuirea contractului de Reagenți, calibratori și material de control p/u analiz. hematologic automat 3-diff Mindray BC-3600; BC760 (sist. închis) (a.17 Ord.MS nr.374 din 05.05.14), accesorii /consumabile/piese de schimb (a.18 Ord.MS nr. 374 din 05.05.14), analizatorul portativ im

noi, SRL Biosistem mld, am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavând obiecții la documentația de atribuire.

Data completării: 06.03.2025

Cu stimă,

Ofertant/candidat

SRL Biosistem mld

(semnătura autorizată)

Specificații tehnice

Numărul procedurii de achiziție:		ocds-b3wdp1-MD-1740993556388 din 10.03.2025						
Obiectul achiziției:		Reagenți, calibratori și material de control p/u analiz. hematologic automat 3-diff Mindray BC-3600; BC760 (sist. închis) (a.17 Ord.MS nr.374 din 05.05.14),accesorii /consumabile/piese de schimb (a.18 Ord.MS nr. 374 din 05.05.14), analizatorul portativ im						
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Modelul articolului	Tara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referință
1	2	3	4	5	6	7	8	9
1.1	Lot 1 Reagenți, calibratori și material de control p/u analiz. hematologic automat 3-diff Mindray BC-3600;(sist. închis) (a.17 Ord.MS nr.374 din 05.05.14),accesorii /consumabile/piese de schimb (a.18 Ord.MS nr. 374 din 05.05.14)	M-30 Diluent set 20 lit. p/u Mindray	A12-000047 M-30D DILUENT	China	Mindray	set 1 x 20 lit. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	set 1 x 20 lit. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE
1.2		Probe cleanser fl. 50 ml p/u Mindray	105-002225-00 PROBE CLEANSER (50ml)	China	Mindray/Arche m	flac 1 x 50 ml. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	flac 1 x 50 ml. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE
1.3		B-30 Material de control hematologic set 3 x 3,0 ml p/u Mindray	105-003227-00 BC-3D Control 3 x 3.0ml Tri-pack(1L, 1N, 1H)	China	Mindray	set 9 ml (3fl. x 3.0 ml). Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	set 9 ml (3fl. x 3.0 ml). Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE
2.1		DS Diluent 20L p/u Mindray	105-012283-00 DS Diluent (20L)	China	Mindray	1 x 20L. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	1 x 20L. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE
2.2		M-6LD Lyse set 1L x 4 p/u Mindray	105-012288-00 M-6 LD Lyse (1L×4)	China	Mindray	set 4 x 1 lit. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	set 4 x 1 lit. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE

2.3	Lot nr. 2 : Reagenți, calibratori și material de control p/u analiz. hematologic automat 3-diff Mindray BC760 (sist. închis) (a.17 Ord.MS nr.374 din 05.05.14),accesorii /consumabile/piese de schimb (a.18 Ord.MS nr. 374 din 05.05.14)	M-6FD DYE set 12 ml x 4 p/u Mindray	105-012298-00 M-6 FD Dye (12mL×4)	China	Mindray	set 4 x 12 ml. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	set 4 x 12 ml. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE
2.4		M-6LH Lyse set 1L x 4 p/u Mindray	105-012292-00 M-6 LH Lyse (1L×4)	China	Mindray	set 4 x 1 lit. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	set 4 x 1 lit. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE
2.5		ESR Solution Reagent 1L x 4 p/u Mindray	105-026689-00 ESR Solution Reagent (1L×4)	China	Mindray	set 4 x 1 lit. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	set 4 x 1 lit. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE
2.6		BC-6D Control 6 x 4.5ml Tri-pack(2L, 2N, 2H)	105-002424-00 BC-6D Control 6 x 4.5ml Tri-pack(2L, 2N, 2H)	China	Mindray	set 6 x 4.5 ml. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	set 6 x 4.5 ml. Reactivii să dispună de certificat, sau declaratia CE, certificatul de compatibilitate a reactivilor cu analizorul Mindray (sistem închis), eliberat de catre producătorul utilajului, Reactivii să fie obligatoriu în ambalajul producătorului, Firma furnizoare de reactivi să dispună de ingineri calificați, certificați de producătorul echipamentului pentru deservirea gratuită a echipamentului de laborator pe perioada de utilizarea a reactivilor, Toate pozițiile lotului să fie produse de același producător.	ISO, CE
3.1	Lot nr. 3: Reagenți (teste) pentru analizatorul portativ imunologic LS-1100 (sistem închis) (a.17Ord.MS nr.374din05.05.14),accesorii /consumabile/piese de schimb(a.18 Ord.MS nr.374din05.05.14)	Test pentru determinarea "TSH" (cutie 25 teste) TSH - Hormonul de stimulare tiroidiană (tiotropina)	*** Test pentru determinarea "TSH" (cutie 25 teste) TSH - Hormonul de stimulare tiroidiană (tiotropina)	China	Lansionbio	Cerințe generale Marcaj CE, material pentru investigații – sânge. Ambalaj – cutie 25 teste. Compatibil cu analizatorul portativ imunologic LS-1100 (sistem închis).	Cerințe generale Marcaj CE, material pentru investigații – sânge. Ambalaj – cutie 25 teste. Compatibil cu analizatorul portativ imunologic LS-1100 (sistem închis).	ISO, CE
3.2		Test pentru determinarea "TT3" (cutie 25 teste) TT3 – Triiodotironin	*** Test pentru determinarea "TT3" (cutie 25 teste) TT3 – Triiodotironin	China	Lansionbio	Cerințe generale Marcaj CE, material pentru investigații – sânge. Ambalaj – cutie 25 teste. Compatibil cu analizatorul portativ imunologic LS-1100 (sistem închis).	Cerințe generale Marcaj CE, material pentru investigații – sânge. Ambalaj – cutie 25 teste. Compatibil cu analizatorul portativ imunologic LS-1100 (sistem închis).	ISO, CE
3.3		Test pentru determinarea "TT4" (cutie 25 teste) TT4 - Tiroxina	*** Test pentru determinarea "TT4" (cutie 25 teste) TT4 - Tiroxina	China	Lansionbio	Cerințe generale Marcaj CE, material pentru investigații – sânge. Ambalaj – cutie 25 teste. Compatibil cu analizatorul portativ imunologic LS-1100 (sistem închis).	Cerințe generale Marcaj CE, material pentru investigații – sânge. Ambalaj – cutie 25 teste. Compatibil cu analizatorul portativ imunologic LS-1100 (sistem închis).	ISO, CE

3.4		Test pentru determinarea "PSA" (cutie 25 teste) PSA – Antigenul specific prostatic	*** Test pentru determinarea "PSA" (cutie 25 teste) PSA – Antigenul specific prostatic	China	Lansionbio	Cerințe generale Marcaj CE, material pentru investigații – sânge. Ambalaj – cutie 25 teste. Compatibil cu analizatorul portativ imunologic LS-1100 (sistem închis).	Cerințe generale Marcaj CE, material pentru investigații – sânge. Ambalaj – cutie 25 teste. Compatibil cu analizatorul portativ imunologic LS-1100 (sistem închis).	ISO, CE
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Semnat: _____ Numele, Prenumele: Poiata Vitalie În calitate de: Administrator

Ofertantul: SRL Biosistem mld Adresa: str. Albișoara 16/1 of.7, or. Chișinău

Specificații de preț

Numărul procedurii de achiziție:				ocds-b3wdp1-MD-1740993556388 din 10.03.2025								
Obiectul achiziției:				Reagenți, calibratori și material de control p/u analiz. hematologic automat 3-diff Mindray BC-3600; BC760 (sist. închis) (a.17 Ord.MS nr.374 din 05.05.14),accesorii /consumabile/piese de schimb (a.18 Ord.MS nr. 374 din 05.05.14), analizatorul portativ im								
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Unitatea de măsură	Cantitatea	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/ prestare	Cod CPV	Clasificație bugetară (IBAN)	Discount %
1	2	3	4	5	6	7	8	9	10	11	12	13
1.1	Lot 1 Reagenți, calibratori și material de control p/u analiz. hematologic automat 3-diff Mindray BC-3600;(sist. închis) (a.17 Ord.MS nr.374 din 05.05.14),accesorii /consumabile/piese de schimb (a.18 Ord.MS nr. 374 din 05.05.14)	M-30 Diluent set 20 lit. p/u Mindray	set	3	861.53	930.45	2 584.59	2 791.35	la solicitare, timp de 30 zile	24950000-8	-	-
1.2		Probe cleanser fl. 50 ml p/u Mindray	set	22	427.20	512.64	9 398.40	11 278.08	la solicitare, timp de 30 zile	24950000-8	-	-
1.3		B-30 Material de control hematologic set 3 x 3,0 ml p/u Mindray	set	4	2 136.53	2 307.45	8 546.12	9 229.80	la solicitare, timp de 30 zile	24950000-8	-	-
2.1	Lot nr. 2 : Reagenți, calibratori și material de control p/u analiz. hematologic automat 3-diff Mindray BC760 (sist. închis) (a.17 Ord.MS nr.374 din 05.05.14),accesorii /consumabile/piese de schimb (a.18 Ord.MS nr. 374 din 05.05.14)	DS Diluent 20L p/u Mindray	set	13	1 061.12	1 146.01	13 794.56	14 898.13	la solicitare, timp de 30 zile	24950000-8	-	-
2.2		M-6LD Lyse set 1L x 4 p/u Mindray	set	4	6 764.65	7 305.82	27 058.60	29 223.28	la solicitare, timp de 30 zile	24950000-8	-	-
2.3		M-6FD DYE set 12 ml x 4 p/u Mindray	set	7	4 907.69	5 300.31	34 353.83	37 102.17	la solicitare, timp de 30 zile	24950000-8	-	-
2.4		M-6LH Lyse set 1L x 4 p/u Mindray	set	1	7 162.57	7 735.58	7 162.57	7 735.58	la solicitare, timp de 30 zile	24950000-8	-	-
2.5		ESR Solution Reagent 1L x 4 p/u Mindray	set	3	12 127.10	13 097.27	36 381.30	39 291.81	la solicitare, timp de 30 zile	24950000-8	-	-
2.6		BC-6D Control 6 x 4.5ml Tri-pack(2L, 2N, 2H)	set	6	7 371.04	7 960.72	44 226.24	47 764.32	la solicitare, timp de 30 zile	24950000-8	-	-
3.1	Lot nr. 3: Reagenți (teste) pentru analizatorul portativ imunologic LS-1100 (sistem închis) (a.17Ord.MS nr.374din05.05.14),accesorii /consumabile/piese de schimb(a.18 Ord.MS nr.374din05.05.14)	Test pentru determinarea "TSH" (cutie 25 teste) TSH - Hormonul de stimulare tiroidiană (tirotropina)	set	100	49.99	53.99	4 999.00	5 399.00	la solicitare, timp de 30 zile	24950000-8	-	-
3.2		Test pentru determinarea "TT3" (cutie 25 teste) TT3 – Triiodotironin	set	100	49.99	53.99	4 999.00	5 399.00	la solicitare, timp de 30 zile	24950000-8	-	-

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Anexa nr. 23
la Documentația standard
conform Ordin MF Nr. 115
din 15.09.2021

3.3	Test pentru determinarea "TT4" (cutie 25 teste) TT4 - Tiroxina	set	100	49.99	53.99	4 999.00	5 399.00	la solicitare, timp de 30 zile	24950000-8	-	-
3.4	Test pentru determinarea "PSA" (cutie 25 teste) PSA – Antigenul specific prostatic	set	100	89.97	97.17	8 997.00	9 717.00	la solicitare, timp de 30 zile	24950000-8	-	-
					TOTAL Oferta	207 500.21	225 228.52				

Semnat: _____ Numele, Prenumele: Poiata Vitalie În calitate de: Administrator

Ofertantul: SRL Biosistem mld Adresa: str. Albișoara 16/1 of.7, or. Chișinău

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:

We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The conformity assessment route is according to 98/79/EC Annex III (not includes Section 6).

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

Product Category(ies): Clinical Chemistry Analyzer, Hematology Analyzer, Microplate washer, Microplate reader, Urine Analyzer, Chemiluminescence Immunoassay Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Reagents for Chemiluminescence Immunoassay Analyzer, Urinalysis reagent strips.

Products: Attachment I

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

We hereby certify that the forgoing is a true and accurate statement.

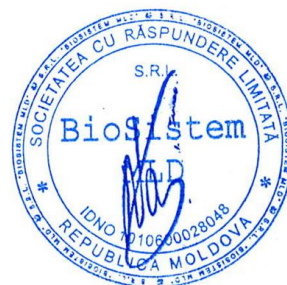
Place, Date Of Issue : Shenzhen, **2016-09-01**



Signatory name: Chuanbin Tan

signatory title: Technical Regulation Manager

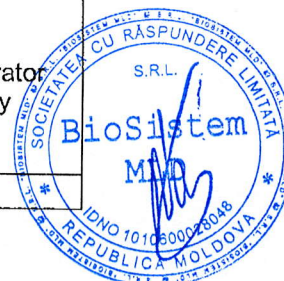
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.



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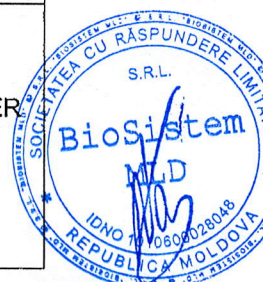
ATTACHMENT I

Product Name	Product Model	Accessories
Hematology Analyzer	BC-2300、 BC-2100	M-23CFL LYSE M-23D DILUENT M-23E E-Z CLEANSER M-23P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-1800、 BC-1900、 BC-2900	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator BC-3D Hematology Control SC-CAL PLUS Hematology Calibrator
Auto Hematology Analyzer	BC-3000 Plus	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3200、 BC-3200CT	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-5500、	M-50D DILUENT



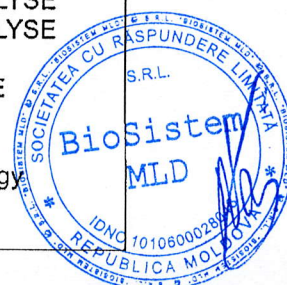
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	BC-5200	M-50LH LYSE M-50LEO(I)LYSE M-50LEO(II)LYSE M-50LBA LYSE M-50 CLEANSER M-50P PROBE CLEANSER BC-5D Hematology Control CBC-5DMR Hematology Control SC-CAL PLUS Hematology Calibrator S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5300、 BC-5100	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5380、 BC-5180	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-2800、 BC-2600	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology



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		Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300、 BC-3300CT、 BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5800、 BC-5600	M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-6600、 BC-6800	M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator BR60 Hematology Control
Auto Hematology Analyzer	BC-5310	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control



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Auto Hematology Analyzer	BC-5390	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5150、 BC-5000、 HM-500X	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER S50 Calibrator B55 Hematology Control BC-5D Hematology control SC-CAL PLUS Hematology Calibrator
Urine Analyzer	UA-66、UA-600、 UA-600T	Urinalysis reagent strips
Auto Hematology Analyzer	BC-20s、BC-21s、 BC-30s、BC-31s、 HM-200X	M-30D DILUENT M-30CFL LYSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5390 CRP BC-5180 CRP	M-53D DILUENT M-5 LEO(I) LYSE M-5 LEO(II) LYSE M-53 LH LYSE LC LYSE Probe Cleanser S50 Calibrator B55 Hematology Control C-reactive Protein Control C-reactive Protein (CRP) Calibrator C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
Auto Sample Processing System	CAL 8000	/
Auto Slide Maker & Stainer	SC-120	M-68DS DILUENT PROBE CLEANSE
Automated Glycohemoglobin Analyzer	H50 H50P	Analytical Column Eluent A Eluent B Hemolysis Solution M-30P PROBE CLEANSER Hemoglobin A1c Control



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		Hemoglobin A1c Calibrator
Flow Cytometer	BriCyte E6	Sheath Fluid Cleaning Solution
Lysing Solution	/	/
CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent	/	/
CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent		
HLA-B27 Reagent		
Laboratory Data Management Software	/	/
Mindray labXpert Software	/	/
Specific Protein Analyzer	CRP-M100	M-68DS Diluent LC Lyse CRP Cleanser Probe Cleanser
Auto Hematology Analyzer	BC-5120 BC-5130 BC-5140	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER
Chemistry Analyzer	BS-300、BS-320	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit
Chemistry Analyzer	BS-400、BS-420	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette

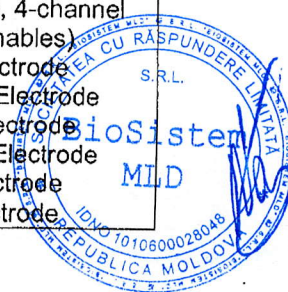


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		Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	Perfect plus	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	BS-380、BS-390	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit
Chemistry Analyzer	BS-350、BS-330	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode



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		Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Semi-auto Chemistry Analyzer	BA-88A	/
Chemistry Analyzer	BS-120、BS-130、BS-180	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200、BS-220	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200E/BS-220E BS-330E/BS-350E	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode



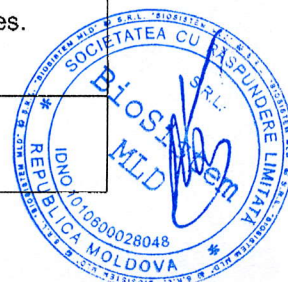
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		Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Microplate reader	MR-96A	/
Microplate washer	MW-12A	/
Chemistry Analyzer	BS-800、BS-820、 BS-800M、 BS-820M、 BS-1800、BS-1800 plus	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System (RMS)
Chemistry Analyzer	BS-2000、 BS-2000M、 BS-2200、 BS-2200M	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System (RMS)



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		Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit Probe clog detection module
Chemistry Analyzer	BS-230、BS-240	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code reader(optional)
Chemiluminescence Immunoassay Analyzer	CL-2000i、 CL-2200i	Hand-held bar code reader External vacuum pump Reaction cuvette Waste Bin
Chemiluminescence Immunoassay Analyzer	CL-1000i、 CL-1200i	Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. waste container
α -Amylase (α -AMY) Kit (IFCC Method)	/	/



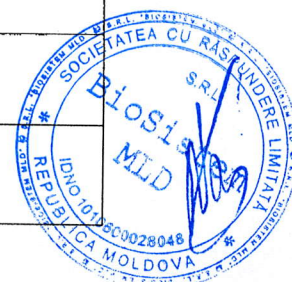
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Aspartate Aminotransferase (AST) Kit (IFCC Method)	/	/
Gamma-Glutamyltransferase (GGT) Kit (Szasz Method /IFCC stand.)	/	/
Lactate Dehydrogenase (LDH) Kit (IFCC Method)	/	/
Alanine Aminotransferase (ALT) Kit (IFCC Method)	/	/
C-Reactive Protein Kit(Turbidimetry Method)	/	/
Apolipoprotein B Kit (Turbidimetry Method)	/	/
Apolipoprotein A1 Kit (Turbidimetry Method)	/	/
Triglycerides Kit(GPO-POD Method)	/	/
Bilirubin Total Kit(DSA Method)	/	/
Creatinine Kit(Modified Jaffe Method)	/	/
Albumin Kit(Bromocresol Green Method)	/	/
Bilirubin Direct Kit(DSA Method)	/	/
Total Protein Kit(Biuret Method)	/	/
Magnesium Kit(Xylidyl Blue Method)	/	/
α -Hydroxybutyrate Dehydrogenase Kit(DGKC Method)	/	/
Total Cholesterol kit(CHOD-POD Method)	/	/
Alkaline Phosphatase Kit(IFCC Modified Method)	/	/
Urea Kit(Urease-GLDH,UV Method)	/	/
Uric Acid Kit(Uricase-peroxidase Method)	/	/



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Glucose Kit (GOD-POD Method)	/	/
Phosphorus Kit(Phosphomolybdate Method)	/	/
Calcium Kit(Arsenazo III Method)	/	/
Lipoprotein(a) Kit(Turbidimetry Method)	/	/
Complement C3 Kit(Turbidimetry Method)	/	/
Complement C4 Kit(Turbidimetry Method)	/	/
Immunoglobulin M Kit(Turbidimetry Method)	/	/
Immunoglobulin G Kit(Turbidimetry Method)	/	/
Prealbumin Kit(Turbidimetry Method)	/	/
Glucose Kit (HK Method)	/	/
Immunoglobulin A Kit(Turbidimetry Method)	/	/
Bilirubin Total Kit(VOX Method)	/	/
Creatine Kinase Kit(IFCC Method)	/	/
Total Bile Acids Kit(Enzymatic Cycling assay)	/	/
Creatinine Kit(Sarcosine Oxidase Method)	/	/
HDL-Cholesterol kit(Direct Method)	/	/
Bilirubin Direct Kit(VOX Method)	/	/
LDL-Cholesterol Kit(Direct Method)	/	/
Creatine Kinase-MB Kit(IFCC Method)	/	/



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HDL&LDL Cholesterol Control P	/	/
Prealbumin Control N&P	/	/
Lipids Calibrator	/	/
Specific Proteins Calibrator	/	/
Multi Sera Calibrator	/	/
CK-MB Calibrator	/	/
Lipoprotein(a) Calibrator	/	/
Multi Control Sera N Multi Control Sera P	/	/
Prealbumin Calibrator	/	/
Lipoprotein(a) Control N&P	/	/
Lipids Control N Lipids Control P	/	/
CK-MB Control N CK-MB Control p	/	/
Specific Proteins Control N Specific Proteins Control P	/	/
Cholinesterase(CHE) Kit (DGKC Method)	/	/
Carbon Dioxide (CO2) Kit (Enzymic Method)	/	/
Iron (Fe) Kit (Colorimetric Assay)	/	/
Fructosamine (FUN) Kit(Colorimetric Assay)	/	/
Antibodies Against Streptolysin O Kit(Particle-enhanced Immunoturbidimetric Assay Method	/	/
Homocysteine Kit(Enzymatic Assay Method)	/	/
Rheumatoid Factor Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/



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Lipase Kit(Enzymatic Colorimetric Assay Method)	/	/
Hemoglobin A1c Kit (Enzymatic Assay Method)	/	/
Unsaturated Iron Binding Capacity (UIBC) Kit (Colorimetric Method)	/	/
Microalbumin (MALB) Kit	/	/
Ferritin (FER) Kit	/	/
Transferrin (TRF) Kit	/	/
TRF Calibrator	/	/
TRF Control	/	/
FER Calibrator	/	/
Multimun Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
α -L-Fucosidase Kit (CNPF method)	/	/
5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/
Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
β 2-Microglobulin Kit (Turbidimetry Method)	/	/
5'-NT Calibrator	/	/
5'-NT Control	/	/
ADA Control	/	/
ADA Calibrator	/	/
AFU Control	/	/
ASO Calibrator	/	/
CysC Calibrator	/	/



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CysC Control	/	/
HbA1c Calibrator	/	/
HCY Calibrator	/	/
HS-CRP Calibrator	/	/
RF Calibrator	/	/
TBA Control	/	/
β 2-MG Calibrator	/	/
β 2-MG Control	/	/
Free Triiodothyronine (CLIA)	/	/
Free Thyroxine (CLIA)	/	/
Total Triiodothyronine (CLIA)	/	/
Total Thyroxine (CLIA)	/	/
Thyroid-stimulating Hormone (CLIA)	/	/
Follicle Stimulating Hormone (CLIA)	/	/
Luteinizing Hormone (CLIA)	/	/
Prolactin (CLIA)	/	/
Estradiol (CLIA)	/	/
Estriol (CLIA)	/	/
Testosterone (CLIA)	/	/
Progesterone (CLIA)	/	/
Total β Human Chorionic Gonadotropin (CLIA)	/	/
Free T3 Calibrators	/	/
Free T4 Calibrators	/	/
Total T3 Calibrators	/	/
Total T4 Calibrators	/	/
TSH Calibrators	/	/
FSH Calibrators	/	/
LH Calibrators	/	/
Prolactin Calibrators	/	/
Estradiol Calibrators	/	/
Estriol Calibrators	/	/
Testosterone Calibrators	/	/
Progesterone Calibrators	/	/
Total β HCG Calibrators	/	/



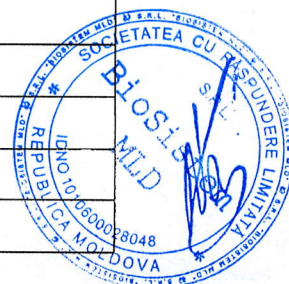
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Thyroid Function Multi Control	/	/
Reproductive Multi Control	/	/
Carcinoembryonic Antigen (CLIA)	/	/
Alpha-fetoprotein (CLIA)	/	/
Cancer Antigen 125 (CLIA)	/	/
Cancer Antigen 15-3 (CLIA)	/	/
Carbohydrate Antigen 19-9 (CLIA)	/	/
CEA Calibrators	/	/
AFP Calibrators	/	/
CA125 Calibrators	/	/
CA15-3 Calibrators	/	/
CA19-9 Calibrators	/	/
Ferritin (CLIA)	/	/
Ferritin Calibrators	/	/
Wash Buffer	/	/
Substrate solution	/	/
Antistreptolysin "O" (ASO) Kit (Latex Immunoturbidimetric Method)	/	/
Antistreptolysin "O" Calibrator	/	/
ASO/CRP/RF triple Control	/	/
Cystatin C (CysC) Kit (Latex Immunoturbidimetric Method)	/	/
Cystatin C Calibrator	/	/
Cystatin C Control	/	/
Full Range C-Reactive Protein (FR-CRP) Kit(Latex Immunoturbidimetric Method)	/	/
C-reactive Protein Calibrator	/	/
Rheumatoid Factor (RF) Kit(Immunoturbidimetric Method)	/	/
Rheumatoid Factor Calibrator	/	/
β 2-Microglobulin (β 2-MG) Kit (Latex Immunoturbidimetric Method)	/	/
β 2-Microglobulin Control	/	/
β 2-Microglobulin Calibrator (for Serum)	/	/
β 2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/



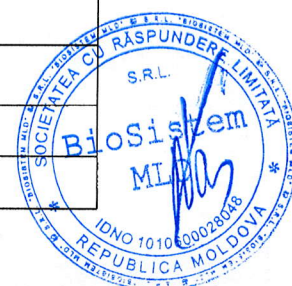
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Retinol Binding Protein (RBP) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Glucose-6-Phosphate Dehydrogenase (G6PD) Kit (UV Enzymatic Method)	/	/
Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Immunoglobulin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
β -Hydroxybutyrate (β -HB) Kit (Enzymatic Colorimetric Method)	/	/
High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
HbA1c control N	/	/
HbA1c control P	/	/
Rheumatism Control N	/	/
Rheumatism Control P	/	/
HCY Control N	/	/
HCY Control P	/	/
FUN Control P	/	/
CO2 Control N	/	/
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/
MYO Calibrator	/	/
IgE Calibrator	/	/
β -HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
β -HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I (CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide (CLIA)	/	/
BNP Calibrators	/	/
Myoglobin (CLIA)	/	/
MYO Calibrators	/	/



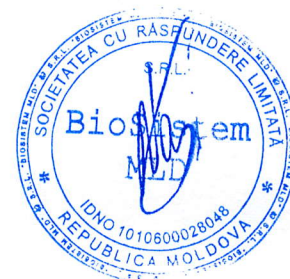
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Creatine kinase MB(CLIA)	/	/
CK-MB Calibrators	/	/
Thyroglobulin(CLIA)	/	/
Thyroglobulin Calibrators	/	/
Antibody to thyroglobulin(CLIA)	/	/
Anti-Tg Calibrators	/	/
Antibody to thyroid peroxidase(CLIA)	/	/
Anti-TPO Calibrators	/	/
Insulin(CLIA)	/	/
Insulin Calibrators	/	/
C-Peptide(CLIA)	/	/
C-Peptide Calibrators	/	/
Cortisol(CLIA)	/	/
Cortisol Calibrators	/	/
Dehydroepiandrosterone sulfate(CLIA)	/	/
DHEA-S Calibrators	/	/
Adrenocorticotrophic hormone(CLIA)	/	/
ACTH Calibrators	/	/
Cardiac Marker Multi Control	/	/
Thyroid Function Multi Control	/	/
Immunoassay Multi Control	/	/
ACTH Control	/	/
Anti-thyroid Antibodies Control	/	/
System Detection Solution	/	/
System Wash Solution	/	/
ClinChem Multi Control (level 1)	/	/
ClinChem Multi Control (level 2)		
Sample Diluent	/	/
HCY Control	/	/
Homocysteine (HCY) Kit (Enzymatic Cycling Method)	/	/
Total Protein in Urine/CSF(TPUC) Kit (Pyrogallol Red-Molybdate Method)	/	/
TPUC Control	/	/
25-OH-Vitamin D Total (CLIA)	/	/



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 Tel: +86 755 26582888
 Fax: +86 755 26582500

25-OH-Vitamin D Total Calibrators	/	/
Parathyroid hormone (CLIA)	/	/
PTH Calibrators	/	/
Calcitonin (CLIA)	/	/
Calcitonin Calibrators	/	/
Folate(CLIA)	/	/
Folate Calibrators	/	/
Vitamin B12(CLIA)	/	/
Vitamin B12 Calibrators	/	/
Metabolic Multi Control	/	/
Red Blood Cell Folate Releasing Reagent	/	/
Cancer Antigen 72-4 (CLIA)	/	/
Neuron-specific enolase (CLIA)	/	/
CYFRA 21-1 (CLIA)	/	/
Antibody to Treponema pallidum (CLIA)	/	/
CA72-4 Calibrators	/	/
Cyfra21-1 Calibrators	/	/
Anti-TP Calibrators	/	/
NSE Calibrators	/	/
Tumor Marker Multi Control	/	/
NSE Control	/	/
Anti-TP Control	/	/





DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-1100 Dry Fluorescence Immunoassay Analyzer

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Place: Nanjing, China

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-2100 Dry Fluorescence Immunoassay Analyzer

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Place: Nanjing, China

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.





DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-4000 Dry Fluorescence Immunoassay Analyzer (Handheld)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015

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

Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- cTnI Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015

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Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- CK-MB Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- Myo Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015

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Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- NT-proBNP Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015

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Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- D-Dimer Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015

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Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- CRP Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

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

Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

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

Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT/CRP Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

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.

Signed on:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2024

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- SAA Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

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.

Signed on:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2024

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- SAA/CRP Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Place: Nanjing,China

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TT3 Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Place: Nanjing,China

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.





DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TT4 Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TSH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

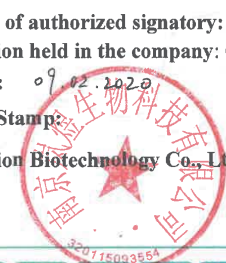
Name of authorized signatory:

Position held in the company: CTO

Date: 09.02.2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- AMH Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- 25-OH-VD Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015

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

Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- HbA1c Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015

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Signed on:

Place: Nanjing, China

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- β -HCG Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Place: Nanjing, China

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.





DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

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.

Signed on:

Name of authorized signatory:

Position held in the company: CTO

Date: 04.02.2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- FSH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

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.

Signed on:

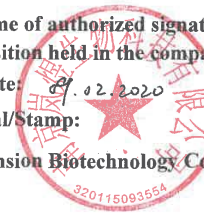
Name of authorized signatory:

Position held in the company: CTO

Date: 04.02.2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PRL Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

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.

Signed on:

Name of authorized signatory:
Position held in the company: CTO

Date: 09.02.2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- 25-OH-VD3 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

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.

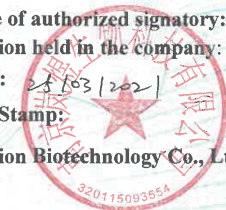
Signed on:

Name of authorized signatory:
Position held in the company: General Manager

Date: 25/03/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing, China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- BNP Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

EN ISO 18113-3:2011

EN 13612:2002

ISO 14971:2019

EN 13641:2002

ISO 23640:2015

EN ISO 18113-1:2011

ISO 15223-1:2016

EN 62366-1:2015

EN ISO 18113-2:2011

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.

Signed on:

Name of authorized signatory:

Position held in the company: General Manager

Date: 25/03/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- H-FABP Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

EN ISO 18113-3:2011

EN 13612:2002

ISO 14971:2019

EN 13641:2002

ISO 23640:2015

EN ISO 18113-1:2011

ISO 15223-1:2016

EN 62366-1:2015

EN ISO 18113-2:2011

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.

Signed on:

Name of authorized signatory:

Position held in the company: General Manager

Date: 25/03/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- IL-6 Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Place: Nanjing, China

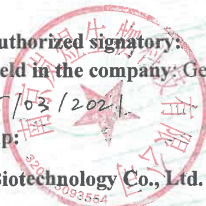
Name of authorized signatory:

Position held in the company: General Manager

Date: 25/03/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- hs-cTnI Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 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.

Signed on:

Place: Nanjing, China

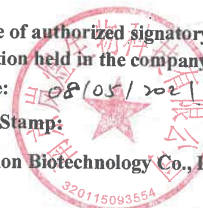
Name of authorized signatory:

Position held in the company: General Manager

Date: 08/05/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.





DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- Ferritin Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016
ISO 14971:2019

EN ISO 18113-3:2011
EN 13641:2002

EN 13612:2002
ISO 23640:2015

EN ISO 18113-1:2011

ISO 15223-1:2016

EN 62366-1:2015

EN ISO 18113-2:2011

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.

Signed on:

Place: Nanjing, China

Name of authorized signatory:

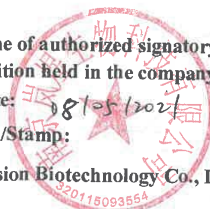
Position held in the company: General Manager

Date:

18/05/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PGI/PGII Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016
ISO 14971:2019

EN ISO 18113-3:2011
EN 13641:2002

EN 13612:2002
ISO 23640:2015

EN ISO 18113-1:2011

ISO 15223-1:2016

EN 62366-1:2015

EN ISO 18113-2:2011

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.

Signed on:

Place: Nanjing, China

Name of authorized signatory:

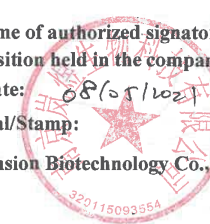
Position held in the company: General Manager

Date:

18/05/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.





DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lanson Biotechnology Co., Ltd.

Address: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT/IL-6 Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016

EN ISO 18113-3:2011

EN 13612:2002

ISO 14971:2019

EN 13641:2002

ISO 23640:2015

EN ISO 18113-1:2011

ISO 15223-1:2016

EN 62366-1:2015

EN ISO 18113-2:2011

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.

Signed on:

Name of authorized signatory:

Position held in the company: General Manager

Date: 12/08/2021

Seal/Stamp:

Lanson Biotechnology Co., Ltd.

Place: Nanjing, China

