



Declaration of Conformity



according to Directive 98/79/EC, on in vitro diagnostic medical devices

Maker (Name, Address)	Getein Biotech, Inc. No. 9 Bofu Road, Luhe District, Nanjing, 211505, China		
Authorized Representative (Name, Address)	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.		
Medical device	Description :		FIA8000 Quantitative Immunoassay Analyzer FIA8600 Quantitative Immunoassay Analyzer Cardiac Troponin I Fast Test Kit One Step Test for cTnI (Colloidal Gold) cTnI Rapid Test (Colloidal Gold Assay) One Step Test for NT-proBNP (Colloidal Gold) One Step Test for NT-proBNP/cTnI (Colloidal Gold) One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) One Step Test for hs-CRP+CRP (Colloidal Gold) One Step Test for D-Dimer (Colloidal Gold) One Step Test for PCT (Colloidal Gold) One Step Test for β 2-MG (Colloidal Gold) One Step Test for mAlb (Colloidal Gold) One Step Test for NGAL (Colloidal Gold) One Step Test for CysC (Colloidal Gold) One Step Test for HCG+ β (Colloidal Gold) One Step Test for HbA1c (Colloidal Gold) One Step Test for PCT/CRP (Colloidal Gold) One Step Test for CK-MB/cTnI/H-FABP (Colloidal Gold) One Step Test for H-FABP (Colloidal Gold) One Step Test for CK-MB/cTnI (Colloidal Gold) One Step Test for CK-MB (Colloidal Gold) One Step Test for TSH (Colloidal Gold) One Step Test for T4/T3 (Colloidal Gold) One Step Test for T3 (Colloidal Gold) One Step Test for T4 (Colloidal Gold) One Step Test for 25-OH-VD (Colloidal Gold) One Step Test for FOB (Colloidal Gold) One Step Test for <i>H. pylori</i> (Colloidal Gold) One Step Test for SAA (Colloidal Gold) Getein1100 Immunofluorescence Quantitative Analyzer Getein1600 Immunofluorescence Quantitative Analyzer Getein1180 Immunofluorescence Quantitative Analyzer Getein1200 Immunofluorescence Quantitative Analyzer Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) NT-proBNP Fast Test Kit (Immunofluorescence Assay) hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) D-Dimer Fast Test Kit (Immunofluorescence Assay)

		PCT Fast Test Kit (Immunofluorescence Assay) β2-MG Fast Test Kit (Immunofluorescence Assay) mAlb Fast Test Kit (Immunofluorescence Assay) NGAL Fast Test Kit (Immunofluorescence Assay) CysC Fast Test Kit (Immunofluorescence Assay) CK-MB Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay) HCG+β Fast Test Kit (Immunofluorescence Assay) HbA1c Fast Test Kit (Immunofluorescence Assay) PCT/CRP Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay) H-FABP Fast Test Kit (Immunofluorescence Assay) 25-OH-VD Fast Test Kit (Immunofluorescence Assay) TSH Fast Test Kit (Immunofluorescence Assay) T3 Fast Test Kit (Immunofluorescence Assay) T4 Fast Test Kit (Immunofluorescence Assay) 25-OH-VD Fast Test Kit (Immunofluorescence Assay) FOB Fast Test Kit (Immunofluorescence Assay) <i>H. pylori</i> Fast Test Kit (Immunofluorescence Assay) SAA Fast Test Kit (Immunofluorescence Assay) LH Fast Test Kit (Immunofluorescence Assay) FSH Fast Test Kit (Immunofluorescence Assay) AMH Fast Test Kit (Immunofluorescence Assay) PRL Fast Test Kit (Immunofluorescence Assay) CK-MB Control cTnI Control Myo Control NT-proBNP Control D-Dimer Control CRP Control PCT Control β2-MG Control mAlb Control NGAL Control CysC Control H-FABP Control HbA1c Control HCG+β Control CK-MB/cTnI/Myo Control CK-MB/cTnI Control NT-proBNP/cTnI Control TSH Control T4/T3 Control T3 Control T4 Control	
	Classification of products according to directive	:	Others
	Batch/serial No. Type, production term (if applicable)	:	



Applicable coordination standards:	EN ISO 14971:2012	EN ISO 23640:2015	EN ISO 13485:2016
	EN 13612:2002	EN ISO15223-1:2012	EN ISO 18113-2:2011
	EN 1041:2008	EN ISO 18113-1:2011	EN ISO 18113-3:2011
	IEC 61010-1:2010	IEC 61010-2-081:2015	IEC 61010-2-101:2015
	IEC 61326-1:2013	IEC 61326-2-2:2013	

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager: Enben Su

Nha Trang, 25th, Jul, 2019

(place and date of issue)

(name and signature or equivalent
marking of authorized person)



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Getein Biotech, Inc.
No.9 Bofu Road
Luhe District
Nanjing
Jiangsu
211505
China

基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
沿江工业开发区
博富路9号
邮编: 211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay). Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay).
研发, 生产和销售化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂。
研发, 生产和销售用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂配套使用的分析仪。



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-05-29

Latest Revision Date: 2020-07-22

Effective Date: 2020-07-26

Expiry Date: 2023-07-25

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...making excellence a habit.™

Letter of Authorization

To whom it may concern,

We, Getein Biotech, Inc. (No.9 BoFu Road, Luhe District, Nanjing, 211505, China), hereby authorize Sanmedico SRL as our official distributor for registering, promoting, selling, distributing, taking part in tenders, maintaining & after sale technical services of under-mentioned product in the territory of Moldova:

Sanmedico SRL will comply with the laws and regulations of the countries and regions where they are located in and where they are selling mentioned product to, otherwise, the risks and losses arising therefrom shall be undertaken by Sanmedico SRL

This authorization starts from Jan 1, 2022 and will be valid to December 31 2023

Getein Biotech, Inc. has the right to terminate the authorization before validity and will inform Sanmedico SRL with 10 days in advance.

Getein Biotech, Inc.

Name: Steven Zhou

Position: Overseas Sales Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.



Exclusive Distributor Agreement

This agreement is made and entered into by and between the parties concerned on 1th Jan, 2022 in Nanjing, China on the basis of equality and mutual benefit to develop business on terms and conditions mutually agreed upon as follows:

1. The Parties Concerned

Party A: Getein Biotech, Inc.

Add: No.9 Bofu Road, Luhe District, Nanjing (211505) China.

Tel: 86-25-68568519

Fax: 86-25-68568500

Party B: Sanmedico SRL

Add: Republic of Moldova, Chisinau, MD-2059, Petricani street, 88/1, office 10

Tel: 373 22 62 30 32

2. Appointment

Party A hereby appoints Party B as its exclusive distributor in the Republic of Moldova for the promotion, sales, and after-sale services etc. of products (Refer to Item3) from Party A and Party B accepts and assumes such appointment.

3. Products

List A

One Step Test for CK-MB/cTnI/Myo (Colloidal Gold)(Quantitative)
Cardiac Troponin I Fast Test Kit(Colloidal Gold)(Quantitative)
One Step Test for CK-MB (Colloidal Gold)(Quantitative)
One Step Test for CK-MB/cTnI (Colloidal Gold)(Quantitative)
One Step Test for H-FABP(Colloidal Gold)(Quantitative)
One Step Test for NT-proBNP/cTnI(Colloidal Gold)(Quantitative)
One Step Test for hs-CRP(Colloidal Gold)(Quantitative)
One Step Test for D-Dimer(Colloidal Gold)(Quantitative)
One Step Test for NT-proBNP(Colloidal Gold)(Quantitative)
One Step Test for HbA1c(Colloidal Gold)(Quantitative)
One Step Test for PCT(Colloidal Gold)(Quantitative)
One Step Test for HCG(Colloidal Gold)(Quantitative)
One Step Test for mAlb(Colloidal Gold)(Quantitative)
One Step Test for β 2-MG(Colloidal Gold)(Quantitative)
One Step Test for CysC(Colloidal Gold)(Quantitative)
One Step Test for NAGL(Colloidal Gold)(Quantitative)
One Step Test for TSH(Colloidal Gold)(Quantitative)

CK-MB/cTnl/Myo Fast Test Kit(Immunofluorescence Assay)
Cardiac Troponin I Fast Test Kit(Immunofluorescence Assay)
NT-proBNP/cTnl Fast Test Kit(Immunofluorescence Assay)
hs-CRP Fast Test Kit(Immunofluorescence Assay)
D-Dimer Fast Test Kit(Immunofluorescence Assay)
NT-proBNP Fast Test Kit(Immunofluorescence Assay)
PCT Fast Test Kit(Immunofluorescence Assay)
mAlb Fast Test Kit(Immunofluorescence Assay)
B2-MG Fast Test Kit(Immunofluorescence Assay)
CysC Fast Test Kit(Immunofluorescence Assay)
NAGL Fast Test Kit(Immunofluorescence Assay)
HbA1c Fast Test Kit(Immunofluorescence Assay)
TSH Fast Test Kit(Immunofluorescence Assay)
T3 Fast Test Kit(Immunofluorescence Assay)
T4 Fast Test Kit(Immunofluorescence Assay)
PRL Fast Test Kit(Immunofluorescence Assay)
LH Fast Test Kit(Immunofluorescence Assay)
FSH Fast Test Kit(Immunofluorescence Assay)
AMH Fast Test Kit(Immunofluorescence Assay)
tPSA Fast Test Kit(Immunofluorescence Assay)
25-OH-VD Fast Test Kit(Immunofluorescence Assay)
Gepin 1100 Immunofluorescence Quantitative Analyzer
Gepin 1600 Immunofluorescence Quantitative Analyzer

4. Territory:

In Republic of Moldova only.

Meanwhile Party B will not distribute for competitive firms identical or similar products, nor will associate directly or indirectly with the competitive firms in the field of products covered by this agreement; otherwise, party A has the right to decide whether to terminate the contract immediately or not.

5. Prices

Prices are stable for 12 months from the start of this agreement. Party A will not increase the prices subjectively, unless the raw material suppliers increase their prices. In case price increases have to be announced, Party B has to be informed at least one month (30 days) in advance.

This agreement shall come into force from Jan 1st,2022to Jan 1st,2024,is valid for 24 months.

6.Delivery

Party A shall establish a delivery term for each Party B's order, which shall not exceed 4 weeks after the payment is received. Party A will advise Party B about the day of dispatching, with all requested information concerning the dispatched products.

7. FORCE MAJEURE

If the performance of any part of this agreement interfered with new laws or governmental restrictions, war, civil commotions, riots, strike lockout, acts of God such as flood, fire or any other similar causes which are beyond the control of the parties, no party shall be responsible for delay or failure of performance of this agreement for such length of time and to the extent performance is made impossible. In this case, the parties shall immediately negotiate to what extent deliveries that could not be executed can be carried out executed.

8. Payment Term

Every order Party B shall pay 50% by TT in advance, the rest of 50% will be paid within 30-60 days after the goods arrives. Due to financial audition, all the credit payment should be cleared by December 31th, 2022.

If Party B is unable to pay, Party B will agree to use fixed assets or real estate to offset the loan. Party A has the right to bring a lawsuit against Party B in China according to relevant Chinese laws.

9. Sales target

Yearly sales volume is 200,000 USD, which include both analyzers and strips. Party B agrees and accepts the sales volume...

10. Governing Law

The agreement is subject to the International Trade Law. Any dispute concerning this agreement shall be settled in accordance with the International Trade Law either through negotiation or through legal proceedings if negotiation has failed.

11. Declaration of Conformity.

Getein Biotech, Inc. declares herein the above mentioned device (Refer to Item3) meets the basic requirements of the European Parliament and the Council' s in vitro diagnostic medical devices directive: 98/79/EC Annex III.

This declaration of conformity is based on European Parliament and the Council' s 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

12. Intellectual Property Agreement

Party A reserves the right of goods design, drawing, plane graph specification, technology, data and information, technological process, the marketing plan of intellectual property rights which included the

Party A provide technical services to the Party B in the process of producing intellectual achievements . Without the Party A 's written consent, the Party B shall not disassemble the goods and the accompanying software, decoding, encoding, or any other reverse engineering by themselves or other third party.

13. Final Provisions

Attachments are an integral part of this contract, have the same legal effect with this contract; This contract was made in English with two originals, each party holds one, it is effective at the same time, and have the same legal effect.

Any change, modification, cancellation of this contract, to be replaced shall be made after agreed by both parties in writing.

Party A: Getein Biotech, Inc.

Date:

Represented by: Steven Zhou

Regional Sales Manager

Party B: Sanmedico SRL

Date:

Represented by: Vitalie Goreacii

Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

Completion of Getein Products Technical and Operational Training
& Qualification of After-sales Service

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.



IVD Industry
POCT Leading Brand

FIA8000

Quantitative Immunoassay Analyzer

PREMIUM POINT OF CARE SOLUTION



FIA8000 *Quantitative Immunoassay Analyzer*



►► Highlights

- ◆ **Portable Design** Small in size (250 x 250 x 120mm); Light in weight (1.8kg)
- ◆ **Multiplex Test Items** Cardiac; Inflammation monitoring; Diabetes mellitus; Fertility; Renal function etc.
- ◆ **Easy to Use** Ready-to-use cassette, one-step test, automatic print, quantitative result
- ◆ **Reliable Performance** $CV \leq 1\%$; $r \geq 0.990$
- ◆ **LIS and HIS Connectivity**

►► Test Items

CARDIAC	cTnI	NT-proBNP	NT-proBNP/cTnI	CK-MB/cTnI/Myo
	H-FABP	CK-MB/cTnI/H-FABP		
VENOUS THROMBOEMBOLISM		D-Dimer		
INFLAMMATION MONITORING		hs-CRP	PCT	
DIABETES CARE		HbA1c		
FERTILITY		HCG+β		
RENAL FUNCTION		β ₂ -MG	mAlb	CysC
				NGAL

►► Application Department

The analyzer can be widely applied to clinical departments including Cardiology Dept., Clinical Laboratory, Emergency Dept., ICU, Oncology Dept., Nephrology Dept., Pediatrics Dept., Endocrinology Dept., Gynecology Dept., Respiratory Dept., Gastroenterology Dept., Urology Dept. etc.

Flexible Operation Modes

Inside Mode (Automatic Timing)



Sample dispense



Test card insert



Press "ENT" button



Result printed automatically after reaction

Outside Mode (Manual Timing)



Sample dispense



Timing the reaction manually



Test card insert



Result printed automatically in 5-8s

Technical Data

Assay Method	Lateral Flow Chromatography (Colloidal Gold)	
Test Result	Quantitative	
Language	Chinese/English/German/Spanish/Serbian (French,Russian,Arabic,Vietnamese etc. are under developing)	
Display	5.6 Inch Touch Screen; Resolution 640×480	
Printer	Internal Thermal Printer	
Working Environment	Temperature	+15℃ - 35℃
	Relative humidity	10% - 85%
	Air pressure	70.0kPa - 106.0kPa
Power Supply	AC 100~240V, 50~60 Hz	
Data Storage	10,000 results can be saved	
Dimensions	Height	120mm
	Width	250mm
	Length	250mm
Weight	1.8kg	

FIA8000 Parameters

Cat.#	Test Item	Disease	Measuring Range	Sample	Cut-off Value	Reaction Time
CG 1001	cTnI	Myocardial infarction	0.5~50.0ng/ml	S/P/W.B	0.5ng/ml	15min
CG 1002	NT-proBNP	Heart failure	100~35000pg/ml	S/P/W.B	300pg/ml	15min
CG 1003	hs-CRP	Cardiovascular inflammatory diseases; Inflammatory disorders	0.5~200mg/L	S/P/W.B/ Fingertip blood	3mg/L 10mg/L	90s
CG 1004	NT-proBNP /cTnI	Heart failure; Acute coronary syndrome	100~12000pg/ml	S/P/W.B	300pg/ml	18min
			0.5~50.0ng/ml		0.5ng/ml	
CG 1005	CK-MB	Myocardial injury	2.5~80.0ng/ml	S/P/W.B	5ng/ml	15min
	/cTnI		0.5~50.0ng/ml		0.5ng/ml	
	/Myo		30~1000ng/ml		70ng/ml	
CG 1006	D-Dimer	Venous thromboembolism; Pulmonary embolism	0.1~10.0mg/L	P/W.B	0.5mg/L	7min
CG 1007	PCT	Sepsis; Septic shock	0.1~50ng/ml	S/P/W.B	0.1ng/ml	15min
CG 1008	CysC	Early diagnosis of kidney disease; Detection of kidney damage for surgery patients	0.5~10.0mg/L	S/P/W.B	0.51~1.09 mg/L	3min
CG 1009	mAlb	Early diagnosis and evaluation of diabetic nephropathy	10~200mg/L	Urine	20mg/L	3min
CG 1010	NGAL	The best indicator of early renal injury	50~5000ng/ml	S/Urine	Serum:200ng/ml	3min
					Urine:100ng/ml	
CG 1011	β_2 -MG	Kidney damage for diabetic & hypertensive patients	0.5~20.0mg/L	S/P/W.B	0.8~3.0 mg/L	3min
CG 1012	CK-MB /cTnI	Myocardial injury	2.5~80.0ng/ml	S/P/W.B	5ng/ml	15min
			0.5~50.0ng/ml		0.5ng/ml	
CG 1013	HCG+ β	Pregnancy early test	5~10000mIU/ml	S/P/W.B	5.1mIU/ml	10min
CG 1017	HbA1c	Diabetes mellitus	2%~14%	W.B	3.8%~5.8%	3min
CG 1018	CK-MB	Myocardial injury	2.5~80.0ng/ml	S/P/W.B	5ng/ml	15min

 **Getein Biotech, Inc.**

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Email:sales@getein.com.cn;tech@getein.com.cn

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