基蛋生物 GeteinBiotech Getein Biotech,Inc.
No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

STATEMENT

We, **Getein Biotech Inc.** having a registered office at No.9 Bofu Road, Luhe District, Nanjing (211505) China, assign **Sanmedico SRL** having a registered office at A.Corobceanu str., apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: 2018.02.23

Sales Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Steven Zhou

Digitally signed by Rodnițchii Andrei
Date: 2019.11.01 10:06:58 EET
Reason: MoldSign Signature
Location: Moldova

Declaration of Conformity

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

Maker (Name, Address)	Getein Biotech, Inc. No. 9 Bcfu 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 β2-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 *H. pylori* (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) *H. pylori* 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

Nan Jing, 20th, Jul, 2019

(place and date of issue)

(name and signature or equivalent marking of authorized person)

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 Global Co., Ltd** 15 Alexandra Road, London UK, NW8 0DP		
Medical device	Description	:	FIA8000 Quantitative Immunoassay Analyzer Cardiac Troponin I Fast Test Kit 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 CK-MB/cTnI (Colloidal Gold) One Step Test for CK-MB (Colloidal Gold) One Step Test for HbA1c (Colloidal Gold) One Step Test for TSH (Colloidal Gold) One Step Test for TSH/T3/T4 (Colloidal Gold)
	Classification of products according to directive	:	Others
	Batch/serial No. type, production term (if applicable)	:	
Applicable coordination standards:	EN ISO 14971:2012 EN 980:2008 EN-ISO 18113-2:2011 EN ISO 18113-2:2011 EN-IEC 61326-1:2013 EN-IEC 61326-2-2:2013	EN ISO 23640:2015 EN 13612:2002 EN 1041:2008 EN ISO 18113-3:2011 EN-IEC 61010-1:2010	EN ISO 13485:2016 EN ISO15223-1:2012 EN ISO 18113-1:2011 IEC 61010-2-101:2015

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

Nanjing, 15th, June, 2016

(place and date of issue)

(name and signature or equivalent marking of authorized person)

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 Global Co., Ltd 1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom		
Medical device	Description	:	Getein1100 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) β_2-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/cTnI Fast Test Kit (Immunofluorescence Assay) HCG+β Fast Test Kit (Immunofluorescence Assay) HbA1c Fast Test Kit (Immunofluorescence Assay) TSH Fast Test Kit (Immunofluorescence Assay) TSH/T3/T4 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)		
	Classification of products according to directive	:	Others
	Batch/serial No. Type, production term (if applicable)	:	
Applicable coordination standards:	EN ISO 14971:2012 EN 980:2008 EN 1041:2008 EN ISO 18113-3:2011 IEC 61010-2-101:2015	EN ISO 23640:2015 EN 13612:2002 EN ISO 18113-1:2011 EN-IEC 61326-1:2013 EN-IEC 61326-2-2:2013	EN ISO 13485:2016 EN ISO15223-1:2012 EN ISO 18113-2:2011 EN-IEC 61010-1:2010

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

Nanjing, 3rd, Jan, 2017

(place and date of issue)

(name and signature or equivalent marking of authorized person)

2nd Jan 2017 London

Lotus Global CO.,Ltd
Tel:0044-20-75300010,Fax:0044-20-73006187
1Four Seasons Terrace West Drayton,Middlesex
London.UB7 9GG.United Kingdom

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Getein Biotech, Inc.
No. 9 Bofu Road
Luhe District
211505 Nanjing
China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-07-27
Certificate Registration No.:	SX 60121593 0001
An audit was performed. Report No.:	15093039 002
This Certificate is valid until:	2020-07-25

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2017-07-27

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: SX 60121593 0001
Report No.: 15093039 002

Organization: Getein Biotech, Inc.
No. 9 Bofu Road
Luhe District
211505 Nanjing
China

Scope: Manufacture and distribution of in-vitro diagnostic test kits in use of Clinical Chemistry and Immunochemistry, Analyzers in use of Quantitative Immunoassay and Immunofluorescence-Assay, Automatic Chemiluminescence Immunoassay Analyzers

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüflaboratorium

Date: 2017-07-27

X. Ren