



# Declaration of Conformity



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

<b>Maker</b> (Name, Address)	<b>Getein Biotech, Inc.</b> No. 9 Bofu Road, Luhe District, Nanjing, 211505, China	
<b>Authorized Representative</b> (Name, Address)	<b>Lotus NL B.V.</b> Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.	
<b>Medical device</b>	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 $\beta$ 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+ $\beta$ (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)



		<p>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/cTnl 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/cTnl/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  cTnl 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/cTnl/Myo Control  CK-MB/cTnl Control  NT-proBNP/cTnl Control  TSH Control  T4/T3 Control  T3 Control  T4 Control</p>	
	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, 20th, Jul, 2019  
 (place and date of issue)

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 (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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