

STATEMENT

ЗАЯВЛЕНИЕ

We, "Technology-Standard" Ltd. having a registered office at 116/95, Kalinin Prospekt, Barnaul, 656037, Russia, assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EC.

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

"Technology-Standard" Ltd
116/95 Kalinin Prospekt
City of Barnaul, 656037, Russia
SRL SANMEDICO
A. Corobceanu street 7A, apt. 9,
Chişinău MD-2012, Moldova

Date: 01.12.2017

Director: Mr. A. F. [Signature]

Signature: _____



Мы, ООО «Технология-Стандарт», имеющее зарегистрированный офис по адресу 116/95, проспект Калинина, г. Барнаул, 656037, Россия, поручают SRL SANMEDICO, имеющую зарегистрированный офис на улице А.Коробчану 7А, кв. 9, Кишинёв MD-2012, Молдова, быть в качестве уполномоченного представителя в соответствии с условиями директивы 98/79/ЕС.

Мы заявляем, что упомянутая выше компания имеет право регистрировать, уведомлять, обновлять или возобновлять регистрацию медицинских изделий на территории Республики Молдова.

ООО Фирма «Технология-Стандарт»
656037 Россия г.Барнаул,
пр-кт Калинина 116/95
SRL SANMEDICO,
г. Кишинёв MD-2012, Молдова
ул. А.Коробчану 7А, кв. 9

Дата: 01.12.2017

Директор: А. Ф. [Signature]

Подпись: _____





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international

SNAS

Reg. No. 305/Q-054

СЕРТИФИКАТ

Настоящий сертификат удостоверяет, что Система Менеджмента Качества организации

ООО Фирма «Технология-Стандарт»

656037, Россия, Барнаул, проспект Калинина 116 / 95

соответствует требованиям стандарта систем менеджмента качества

EN ISO 13485:2012

(ISO 13485:2003 + Cor 1:2009)

в области:

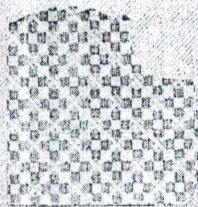
**РАЗРАБОТКА, ПРОИЗВОДСТВО И РЕАЛИЗАЦИЯ
ДИАГНОСТИЧЕСКИХ НАБОРОВ И РЕАГЕНТОВ ДЛЯ IN VITRO
ДИАГНОСТИКИ СИСТЕМЫ ГЕМОСТАЗА**

Сертификат N°: M-0379/16

Дата выставления: 05.08.2016

Дата регистрации: 05.08.2016

Этот сертификат, при условии постоянного успешного функционирования Системы Менеджмента Качества организации, действителен до: 01.03.2019. По вопросам действия сертификата звоните по тел.: +421 (0)2 5831 8343.



Katarina Srdosova
Dr. Katarina Srdosova
Руководитель Органа по сертификации



Выставил: ZEC International a.s., Hraničná 18, 821 05 Bratislava, Словацкая Республика





Declaration of Conformity

Document ref.: Doc2015 vs. 02
Page: 1 of 6**DECLARATION OF CONFORMITY**

1) **Manufacturer** (Name, department): "Technology-Standard" Ltd
Address: 116/95, Kalinin Prospekt, Barnaul, 656037, Russia
and

2) **European authorized representative**: CEpartner4U BV,
Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu
(on product labels printed as:
CEpartner4U, ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) **Product(s)** (name, type or model/batch number, etc.):
- Kits and reagents for in vitro diagnostics of haemostasis system
see appendix

4) **The product(s) described above is in conformity with:**

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) **Additional information** (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):
Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive,
Annex III

Registration nr.: **NL-CA002-2015-34420**



Barnaul, Russia; 2015-03-17 **Andrey Momot, Director "Technology-Standard" Ltd**
(Place & date of issue (yyyy-mm-dd)) (name, function and signature of manufacturer)

Declaration form: Standard ISO/IEC 17050-1:2010

vs. 2011.X



Declaration of Conformity

Document ref.: Doc2015 vs. 02
Page: 2 of 6**Appendix**

Date: 2015-02-09

List of devices:

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Techplastin-test» The kit of reagents for the determination of prothrombin time	607, 131, 608, 140	Low	13 02 01 01/ 30539	09.02.2015
«SFMС-test» The kit of reagents for the determination of soluble fibrin monomer complexes in blood plasma	081, 007	Low	13 02 03 03/ 43421	09.02.2015
«APTT-test» The kit of reagents for the determination of activated partial thromboplastin time	152, 001	Low	13 02 01 02/ 32392	09.02.2015
«Tech-Fibrinogen-Test» The kit of reagents for the determination of fibrinogen concentration in blood plasma	324, 094, 225	Low	13 02 02 01/ 30541	09.02.2015
«ChromoTech-Plasminogen» The kit of reagents for the determination of plasminogen concentration in blood plasma	092	Low	13 02 05 05/ 30578	09.02.2015

* See EDMS codes: <http://www.edma-ivd.be/> (products classification)/Preference GMD





SE	Declaration of Conformity	Document ref.: DoC2015 vs. 02
		Page: 3 of 6

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Chromo-Tech-Antithrombin» The kit of reagents for the determination of antithrombin concentration in blood plasma	192	Low	13 02 06 02/ 33156	09.02.2015
«Plasma-control» The kit of control blood plasma for the study of haemostasis	400	Low	13 02 50 02/ 30590	09.02.2015
«Thrombo-test» The kit of reagents for the determination of thrombin time	151, 609, 610	Low	13 02 01 03/ 30540	09.02.2015
«Tech-Factor VIII-test» The kit of reagents for the determination of factor VIII activity in blood plasma	274	Low	13 02 02 07/ 30547	09.02.2015
«PARUS-test» The kit of reagents for the determination of disorders in protein C system	164	Low	13 02 06 08/ 30588	09.02.2015
«APTT-EI-test» The kit of reagents for the determination of activated partial thromboplastin time	649, 652	Low	13 02 01 02/ 32392	09.02.2015
«Soluble thromboplastin with calcium» A reagent for determination of prothrombin time	643, 638	Low	13 02 01 01/ 30539	09.02.2015
«Thrombin» A reagent for the study of haemostasis	323, 017	Low	13 02 01 03/ 30540	09.02.2015



SE	Declaration of Conformity	Document ref.: DoC2015 vs. 02
		Page: 4 of 6

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Tech-Factor IX-test» The kit of reagents for the determination of factor IX activity in blood plasma	679	Low	13 02 02 08/ 30548	09.02.2015
«RNP-plasma» Reference normal pooled plasma	012	Low	13 02 50 02/ 30590	09.02.2015
«Pathoplasma» Pathologic plasma	013	Low	13 02 50 02/ 32394	09.02.2015
«Techplaslin-test (K)» The kit of reagents for the determination of prothrombin time, prothrombin ratio and INR in blood	144	Low	13 02 01 01/ 30539	09.02.2015
«Tech-Antithrombin-test» The kit of reagents for the determination of antithrombin III activity	688	Low	13 02 06 02/ 33156	09.02.2015
«Lupus-test» The kit of reagents for the determination of anticoagulants of lupus type	011	Low	13 02 06 07/ 30587	09.02.2015
«Express-Lupus-test» The kit of reagents for the determination of lupus anticoagulant	193	Low	13 02 06 07/ 30587	09.02.2015
«Fibrinolysis-test» The kit of reagents for the study of Xlla-kininogenase-dependent, spontaneous and induced euglobulin fibrinolysis	009	Low	13 02 05 90/ 0	09.02.2015





Your **Trusted** Partner

San Diego July 11th, 2018

We, ACON Laboratories Inc. having a registered office at 10125 Mesa Rim Road. San Diego, CA 92121, USA assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

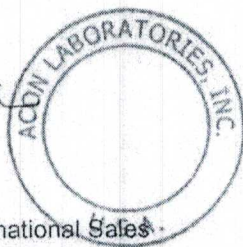
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

ACON reserves the right to cancel this authorization at any time with a one month notice. If this is the case, ACON will honor any obligation to supply to our representative SanMedico SRL all the products distribution acquired or in the process of being acquired in Public Price bids and Public Tenders process.

Sincerely,

Jassy Alvarenga

Account Manager, International Sales



ACON Laboratories





Product Service

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

For the product(s)/product category (ies):

- On Call Plus Blood Glucose Monitoring System,
- On Call Plus Blood Glucose Test Strips,
- On Call EZ II Blood Glucose Monitoring System,
- On Call Redi Blood Glucose Monitoring System,
- On Call Redi II Blood Glucose Test Strips,
- On Call Advanced Blood Glucose Monitoring System,
- On Call Advanced Blood Glucose Test Strips,
- On Call Platinum Blood Glucose Monitoring System,
- On Call Platinum Blood Glucose Test Strips,
- On Call Chosen Blood Glucose Monitoring System,
- On Call Chosen Blood Glucose Test Strips,
- On Call Vivid Blood Glucose Monitoring System (OGM-101),
- On Call Vivid Blood Glucose Test Strips (OGS-101),
- On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),
- On Call Sharp Blood Glucose Monitoring System (OGM-121),
- On Call Sharp Blood Glucose Test Strips (OGS-121)
- On Call Plus II Blood Glucose Monitoring System (OGM-171),
- On Call Plus II Blood Glucose Test Strips (OGS-171),
- On Call Extra Blood Glucose Monitoring System (OGM-191),
- On Call Extra Blood Glucose Test Strips (OGS-191),
- On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
- On Call Blood Ketone Test Strips (OGS-161),
- D-ONE Blood Glucose Monitoring System,
- D-ONE Blood Glucose Test Strips,
- Urinalysis Reagent Strips (Urine),
- UTI Urinary Tract Infection Test Strips,
- Toxoplasma IgG EIA Test Kit,
- Toxoplasma IgM EIA Test Kit,
- Rubella IgG EIA Test Kit,
- Rubella IgM EIA Test Kit,
- CMV IgG EIA Test Kit,
- CMV IgM EIA Test Kit.



ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ ЗЕРТИФІКАТ ◆ 證書 ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ ЗЕРТИФІКАТ ◆



Product Service

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

- Total PSA EIA Test Kit,
- PT Coagulation Monitoring System (CCM-121),
- PT Coagulation Test Strips (CCS-121),
- Cholesterol Monitoring System (CCM-111),
- CHOL Total Cholesterol Test Devices (CCS-111),
- TRIG Triglycerides Test Devices (CCS-112),
- HDL High Density Lipoprotein Test Devices (CCS-113),
- 3-1 Lipid Panel Test Devices (CCS-114),
- Cholesterol CTRL Control Devices,
- Cholesterol Monitoring System (CCM-101),
- CHOL Total Cholesterol Test Strips (CCS-101),
- PT/INR Monitoring System (CCM-151),
- PT/INR Test Strips (CCS-151),
- Hemoglobin Testing System (CCM-141),
- Hemoglobin Test Strips (CCS-141),
- hCG Pregnancy Rapid Test Cassette (Urine),
- Pregnancy Rapid Test Midstream

Munich, MHS-CRT, 2017-08-30

Stefan Proff

Stefan Proff
Certification Medical Technology





基蛋生物
GeteinBlotech

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

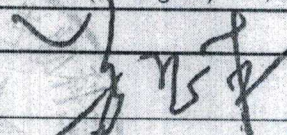




Declaration of Conformity



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 ISO 23640:2015	EN ISO 13485:2016
	EN 980:2008	EN 13612:2002	EN ISO15223-1:2012
	EN-ISO 18113-2:2011	EN 1041:2008	EN ISO 18113-1:2011
	EN ISO 18113-2:2011	EN ISO 18113-3:2011	
	EN-IEC 61326-1:2013	EN-IEC 61010-1:2010	IEC 61010-2-101:2015
	EN-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			
Nanjing, 15th, June, 2016 (place and date of issue)		 (name and signature or equivalent marking of authorized person)	





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 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date: 2016-07-26
Certificate Registration No.: SX 60109576 0001
An audit was performed. Report No.: 15093039 001
This Certificate is valid until: 2019-07-25



Certification Body



Date 2016-05-30

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 805-1271 Fax: +49 221 805-3835 e-mail: cert-validity@de.tuv.com http://www.tuv.com/dakks



Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

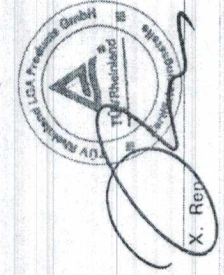
Attachment to
Certificate
Registration No.: SX 60109576 0001
Report No.: 15093039 001

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



Date: 2016-05-30

