FORMULARUL OFERTEI (F3.1)

Data: **27.11.2018**

Licitaţie deschisă

Către: **I.M.S.P. Spitalul Cancelariei de Stat**

SRL Sanmedico declară că:

a) Au fost examinate şi nu există rezervări faţă de documentele de licitaţie, inclusiv modificările nr. (n/a);

b) **SRL Sanmedico** se angajează să furnizeze, în conformitate cu documentele de licitaţie şi condiţiile stipulate în specificaţiile tehnice şi de formare a preţurilor, următoarele bunuri şi/sau servicii: **„Achiziţionarea reagenţilor de laborator necesare pentru anul 2019"**;

c) Preţul total al ofertei constituie: Suma totală fără TVA: **216 318,08 lei (Două sute şaisprezece mii trei sute optsprezece lei, 08 bani);**

d) Suma totală cu TVA: **235 354,53 lei (Două sute treizeci şi cinci mii trei sute cincizeci şi patru lei, 53 bani);**

e) Prezenta ofertă va rămîne valabilă pentru perioada de timp specificată în **FDA4.8.**, începînd cu data-limită pentru depunerea ofertei, în conformitate cu **FDA5.2.**, va rămîne obligatorie şi va putea fi acceptată în orice moment pînă la expirarea acestei perioade;

f) În cazul acceptării prezentei oferte, **SRL Sanmedico** se angajează să obţină o Garanţie de bună execuţie în conformitate cu **FDA7**, pentru executarea corespunzătoare a contractului de achiziţie publică;

g) Nu sîntem în nici un conflict de interese, în conformitate cu punctul **IPO5.4**;

h) Compania semnatară, afiliaţii sau sucursalele sale, inclusiv fiecare partener sau subcontractor ce fac parte din contract, nu au fost declarate neeligibile în baza prevederilor legislaţiei în vigoare sau a regulamentelor cu incidenţă în domeniul achiziţiilor publice, în conformitate cu punctul **IPO5.5**;

Semnat: _____ L.Ş.

Nume: **Vitalie Goreacii**

În calitate de: **Administrator**

Ofertantul: **SRL Sanmedico**

Adresa: **mun. Chisinau, str. Petricani 88/1 of.10,**

Data: **27 Noiembrie 2018**

ORDIN DE PLATA NR.: 597 TIP.DOC. 1

DATA EMITERII:26 noiembrie 2018

PLATITI: 2164-00 LEI: Doua Mii Una Suta Sasezeci si Patru lei 00 bani

PLATITOR: (R) SRL SANMEDICO CODUL IBAN:MD34VI0222414000000157MDL
CODUL FISCAL :1003602008154 /

PRESTATORUL PLATITOR CODUL BANCII:
BC VICTORIABANK SA Fil 14 Chisinau :VICBMD2X446:

BENEFICIAR (R)ACSR SR CODUL IBAN:MD25ML0000000022518062 81:
CODUL FISCAL :1006601003968

PRESTATORUL BENEFICIAR CODUL BANCII:
BC"Moldindconbank"S.A. suc."Telecentru" Chisinau :MOLDMD2X306:

DESTINATIA PLATII:PLATA PENTRU GARANTIA PENTRU OFERTA LA LICITATIA DESCHISA DIN 27.11.2018 Fara TVA.

TIPUL TRANSFERULUI NORMAL/URGENT : N:

L.S.

CODUL TRANZACTIEI:001
DATA PRIMIRII:26/11/2018
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

SEMNATURA PRESTATORULUI

MOTIVUL REFUZULUI

L.S.

FORMULAR INFORMATIV DESPRE OFERTANT (F3.3)

Data: **27.11.2018**

Licitaţie deschisă

A. Ofertanţi individuali

1.	**Informaţii generale**	
1.1.	Numele juridic al ofertantului	SRL „Sanmedico"
1.2.	Adresa juridică a ofertantului în ţara înregistrării	Republica Moldova, MD2012, mun. Chişinău, str. A.Corobceanu, 7A, ap.9
1.3.	**Statutul juridic al ofertantului**	Societate cu Răspundere Limitată
	Proprietate	Privată
	Formă de organizare juridică	Societate cu Răspundere Limitată
	Altele	--
1.4.	Anul înregistrării ofertantului	30 Decembrie, anul 1998
1.5.	**Statutul de afaceri al ofertantului**	Comerţul cu ridicata pe bază de tarife sau contracte
	Producător	--
	Agent local/Distribuitor al producătorului străin	--
	Intermediar	--
	Companie de antrepozit	--
	Altele	--
1.6.	**Informaţia despre reprezentantul autorizat al ofertantului**	--
	Numele	--
	Locul de muncă şi funcţia	--
	Adresa	mun. Chişinău, str. Petricani 88/1, of. 10
	Telefon / Fax	(022) 62-30-32
	E-mail	sanmedico@yandex.ru
1.7.	Numărul de înregistrare pentru TVA	1200885
1.8.	Numărul de identitate al ofertantului pentru impozitul pe venit (pentru ofertanţii străini)	--
1.9.	Ofertantul va anexa copiile următoarelor documente:	Conform FDA
2.	**Informaţii de calificare**	
2.1.	Numărul de ani de experienţă generală a ofertantului în livrări de bunuri şi servicii	19 ani
2.1.	Numărul de ani de experienţă specifică a ofertantului în livrarea/prestarea bunurilor şi/sau serviciilor similare	17 ani

2.2.	Valoarea monetară a livrărilor de bunuri similare pe parcursul perioadei prevăzute în IPO 11.1 (a)	*"Nu se aplică"*
2.3	Disponibilitate de resurse financiare (bani lichizi sau capital circulant, sau de resurse creditare, extras din cont bancar etc.). Enumeraţi şi anexaţi copiile documentelor justificative	*"Nu se aplică"*
2.4	Detalii privind capacitatea de producere/ echipamente disponibile	*"Nu se aplică"*
3. Informaţii financiare		
3.1.	Rapoarte financiare sau extrase din bilanţul financiar, sau declaraţii de profit / pierderi, sau rapoartele auditorilor pentru ultimul an de activitate. Enumeraţi mai jos şi anexaţi copii. **Se anexează.**	
3.2.	Denumirea, adresa, numerele de telefon, telex şi fax ale băncilor care pot oferi caracteristici despre ofertant în cazul contactării de către autoritatea contractantă: **BC Victoriabank S.A. filiala Nr.14, mun. Chişinău, Republica Moldova**	
3.3.	Informaţie privind litigiile în care ofertantul este sau a fost implicat: **Nu sunt.**	
	a) Orice proces pe parcursul ultimilor 3 ani:	
	Cauza litigiului	Rezultatul sau sentinţa şi suma implicată
	b) Procese curente, pe parcursul anului fiscal curent:	
	Cauza litigiului	Situaţia curentă a procesului
Notă: Alte cerinţe şi detalii pot fi adăugate de către autoritatea contractantă, după caz		

B. Partenerii individuali ai Asociaţiei

4.1.	Fiecare partener al Asociaţiei va depune toată informaţia solicitată în formularul de mai sus, în compartimentele 1-3.
4.2.	Anexaţi procura/împuternicirea pentru fiecare semnatar autorizat al ofertei în numele Asociaţiei.
4.3.	Anexaţi acordul semnat între toţi partenerii ai Asociaţiei (care va purta caracter obligatoriu în mod juridic pentru toţi partenerii).
Notă: Alte cerinţe şi detalii pot fi adăugate de către autoritatea contractantă, după caz.	

Specificaţii tehnice (F4.1)

Licitaţie deschisă		Data: „27" Noiembrie 2018	Alternativa nr.: _____	
Denumirea licitaţiei:	**"Achiziţionarea reagenţilor de laborator necesare pentru anul 2019"**	Lot: _____	Pagina: __din __	

Nr. Lot/ pozitie	Cod CPV	Denumirea bunurilor şi/sau a serviciilor	Modelul articolului	Ţara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referinţă
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*
4		**Reagenţi,calibratori şi material de control pentrucoagulometru semiautonat <START-4>,Diagnostica Stago. Franta**						
4.1	33696200-7	Timpul protrombinic (TP), activitatea tromboplastinei 11-15 sec., ISI 1,1-1,2 cu CaCl2 si plasma de control	TS735	Federaţia Rusă	Tehnologia Standard	Set 4 fl x 5 ml + plasma de control 1 fl, set 100 teste	Set 4 fl x 5 ml + plasma de control 1 fl, set 100 teste	Certificat ISO
4.2	33696200-7	Timpul tromboplastinic partial active (APTT)	TS652	Federaţia Rusă	Tehnologia Standard	Liofilizat (teste)	Liofilizat (100 teste)	Certificat CE; ISO
4.3	33696200-7	Timpul trombinic (TT)	TS609	Federaţia Rusă	Tehnologia Standard	Liofilizat (teste)	Liofilizat (50 teste)	Certificat CE; ISO
4.4	33696200-7	Fibrinogen (fara diluţie privintive a plasmei)	TS711	Federaţia Rusă	Tehnologia Standard	Fibrinogen (fara diluţie privintive a plasmei) (teste)	Fibrinogen (fara diluţie privintive a plasmei) (100 teste)	Certificat CE; ISO
4.5	33696200-7	Plasma de control pentru hemostaza cu nivelul normal la 7 parametri inclusiv testul INR	TS774	Federaţia Rusă	Tehnologia Standard	1 flacon x 1 ml	1 flacon x 1 ml	Certificat ISO
4.6	33696200-7	Plasma de control pentru hemostaza cu nivelul patologic la 7 parametri inclusiv testul INR	TS775	Federaţia Rusă	Tehnologia Standard	1 flacon x 1 ml	1 flacon x 1 ml	Certificat ISO
7		**Regenţi pentru analizatorul automat imunologic cantitativ Getein FIA 8000 (sistem inchis)**						
7.1	33696200-7	D-Dimer	D-Dimer	China	Getein Biotech		D-Dimer	Certificat CE; ISO
7.2	33696200-7	Troponina I	cTnI	China	Getein Biotech		Troponina I	Certificat CE; ISO
7.3	33696200-7	CK-MB	CK-MB	China	Getein Biotech		CK-MB	Certificat CE; ISO
7.4	33696200-7	HbAlc	HbAlc	China	Getein Biotech		HbAlc	Certificat CE; ISO

7.5	33696200-7	NT-proBNP	NT-proBNP	China	Getein Biotech		NT-proBNP	Certificat CE; ISO
7.6	33696200-7	hs-CRP	hs-CRP	China	Getein Biotech		hs-CRP	Certificat CE; ISO
7.7	33696200-7	mAlb	mAlb	China	Getein Biotech		mAlb	Certificat CE; ISO
8		**HbsAg**						
8.1	33696200-7	HbsAg	I231-1021	SUA	ACON	Cerinţe generale*, de asemenea să fie incluşi, in afară de controlul „+"şi „-„ calibratori. Metoda ELISA	Cerinţe generale*, incluşi controlul „+"şi „-„. Metoda ELISA	Certificat ISO
9		**Anti-HbsAg**						
9.1	33696200-7	Anti-HbsAg	I231-1271	SUA	ACON	Cerinţe generale*, de asemenea să fie incluşi, in afară de controlul „+"şi „-„ calibratori. Metoda ELISA	Cerinţe generale*, incluşi controlul „+"şi „-„. Metoda ELISA	Certificat ISO
10		**Anti-HCV sumar**						
10.1	33696200-7	Anti-HCV sumar	I231-1031	SUA	ACON	Cerinţe generale*, de asemenea să fie incluşi, in afară de controlul „+"şi „-„ calibratori. Metoda ELISA	Cerinţe generale*, incluşi controlul „+"şi „-„. Metoda ELISA	Certificat ISO
11		**ASLO-LATEX**						
11.1	33696200-7	ASLO-LATEX	8.00.02.0.0100	Marea Britanie	Atlas Medical	Metoda LATEX. (teste)	Metoda LATEX. (teste)	Certificat CE; ISO
12		**CRP-LATEX**						
12.1	33696200-7	CRP-LATEX	8.00.00.0.0100	Marea Britanie	Atlas Medical	Metoda LATEX. (teste)	Metoda LATEX. (teste)	Certificat CE; ISO
13		**RF-LATEX**						
13.1	33696200-7	RF-LATEX	8.00.04.0.0100	Marea Britanie	Atlas Medical	Metoda LATEX. (teste)	Metoda LATEX. (teste)	Certificat CE; ISO
15		**D-Dimer**						
15.1	33696200-7	D-Dimer	8.00.17.0.0050	Marea Britanie	Atlas Medical	D-Dimer latex-test	D-Dimer latex-test	Certificat CE; ISO
16		**Troponina I,metoda imunocromatografică**						
16.1	33696200-7	Troponina I,metoda imunocromatografică	75001	SUA	Lumiquick	Ambalaj -l test ,fără bufer. Sensibilitatea < 0,5 ng/ml	Ambalaj -l test ,fără bufer. Sensibilitatea < 0,5 ng/ml	Certificat CE; ISO
20		**Expres teste la glucoza. cetone. ph**						
20.1	33696200-7	Expres teste la glucoza. cetone. ph	Mission 3G	SUA	ACON	teste	teste	Certificat CE; ISO

Semnat: _____ Numele, prenumele: Goreacii Vitalie. În calitate de: Administrator

Ofertantul SRL Sanmedico Adresa: Mun Chişinău, str. A.Corobceanu 7A, ap.9

Anexa nr.7 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № B1811128 **din** / от 21.11.2018

1. Destinatar / Получатель

pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
S.R.L. SANMEDICO	1003602008154
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
A. Corobceanu nr.7A of.9	0120-SEC.BUIUCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Автоматизированной Информационной Системы

La data emiterii prezentului certificat restanța la bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 06.12.2018

5. Autentificarea organului fiscal / Подтверждение налогового органа

Sef DDF Buiucani
Funcția / Должность

Semnătura / Подпись

Albina Iscova
Numele și prenumele / Фамилия и имя

L.Ș. / М.П.

Executat: C. Coșanu
Numele și prenumele / Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 21.11.2018 ora 10:46:29
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (34,16)

VICTORIABANK
PRIMA BANCĂ DIN MOLDOVA

www.victoriabank.md

Bd. Mircea cel Bătrân 17/3
MD-2075, mun. Chişinău
Republica Moldova
Tel.: (+373 22) 78-46-75
Tel.: (+373 22) 78-46-79
SWIFT: VICBMD2X446
IDNO 1002600001338
Capital social - 250 000 910 lei
www.victoriabank.md

Nr. 177 din "16" Februarie 2017

La Nr. _____ din "____" _____ 201

CERTIFICAT

Prin prezentul, confirmăm că SANMEDICO SRL cod fiscal 1003602008154, deţine în Filiala nr.14 Chişinău a BC "VICTORIABANK" SA (codul băncii: VICBMD2X446), următorul cont curent:

- Nr. MD34VI022241400000157MDL în lei moldoveneşti (MDL);

Certificatul este eliberat pentru a fi prezentat la solicitare.

Andrieş Denis
Director Filiala nr.14
B.C. "Victoriabank" S.A.

Ţărnă Elena
Contabil şef Filiala nr.14
B.C. "Victoriabank" S.A.

REPUBLICA MOLDOVA, mun. CHIŞINĂU
BANCA COMERCIALĂ "VICTORIABANK" S.A.
FILIALA Nr.14 CHIŞINĂU
Nr. 1002600001338

Ex. Popovici Raisa
tel.022 63-09-15

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATE CU RĂSPUNDERE LIMITATĂ

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ

"SANMEDICO"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1003602008154

Data înregistrării	**30.12.1998**
Data eliberării	**07.12.2006**

Motpan Svetlana, registrator de stat

Funcţia, numele, prenumele persoanei care a eliberat certificatul

semnătura

MD 0059379

CAMERA ÎNREGISTRĂRII DE STAT

"SANMEDICO" S.R.L. IDNO 1003602008154 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Adresa: Republica Moldova,
MD-2059, mun. Chişinău, str. Petricani 88/1, oficiul 10
tel/fax: (022) 62 30 32
email: sanmedico@yandex.ru
sanmedico.office@gmail.com
web: www.sanmedico.md

SANMEDICO

Către grupul de lucru Achiziții Publice al
I.M.S.P. Spitalul Cancelariei de Stat
Licitația deschisă din 27.11.2018

Data: 27.11.2018

DECLARAȚIE

Prin prezenta, compania **SRL Sanmedico**, pentru pozițiile câștigătoare la **Licitația deschisă din 27.11.2018**, confirmă experiența de peste 17 ani de în livrarea bunurilor similare.

Cu respect,

Goreacii Vitalie
Administrator SRL „SANMEDICO"

STATEMENT

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.

"Tecnology-Standart" 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. [illegible]

Signature: _____

ЗАЯВЛЕНИЕ

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/EC.

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.[illegible]

Подпись: _____

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602006154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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;**
(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)*

"SANMEDICO" S.R.L.

Appendix

Date: 2015-02-09

List of devices:

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	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
«SFMC-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

[1] See EDMS codes: http://www.edma-ivd.be/ (products classification)/Preference GMDN code

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«ChromoTech-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-El-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

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	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
«Techplastin-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 XIIa-kininogenase-dependent, spontaneous and induced euglobulin fibrinolysis	009	Low	13 02 05 90/ 0	09.02.2015

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«MultiTech-Fibrinogen» The kit of reagents for the determination of fibrinogen concentration by automated and semi-automated coagulometers	711, 712	Low	13 02 02 01/ 30541	09.02.2015
«Fibrinogen-Calibrator» The kit of calibrators for the determination of fibrinogen concentration	714	Low	13 02 50 02 / 39413	09.02.2015
«ADP» The kit of reagents for the determination of ADP-aggregation of platelets	030	Low	13 02 04 01/ 30569	09.02.2015
Ristomycin The kit of reagents for the determination of ristomycin-aggregation of platelets	197	Low	13 02 04 01/ 30569	09.02.2015
«Collagen» The kit of reagents for the determination of collagen-aggregation of platelets	095	Low	13 02 04 01/ 30569	09.02.2015
«Adrenaline» The kit of reagents for the determination of adrenaline-aggregation of platelets	031	Low	13 02 04 01/ 30569	09.02.2015

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«Aggrescreen-test» The kit of reagents for the express assessment of platelet haemostasis	010	Low	13 02 04 01/ 30569	09.02.2015
«Human platelets»	132	Low	13 02 04 01/ 32409	09.02.2015
«Sodium citrate» A reagent for the stabilization of blood in the study of haemostasis	028	Low	13 02 80 02/ 0	09.02.2015

SNAS
Reg. No. 305/Q-054

3EC®
International

CERTIFICATE

This certifies that the Quality management system for medical devices of company

«Technology-Standard» LTD

116/95, Kalinin Prospekt, City of Barnaul, 656037
RUSSIA

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2012

(ISO 13485:2003 + Cor 1:2009)

for the following scope:

DEVELOPMENT, PRODUCTION AND SALES OF DIAGNOSTIC KITS AND REAGENTS FOR IN VITRO DIAGNOSTICS OF HEMOSTASIS SYSTEM

Certificate No.: M-0379/16 **Date of issuance: August 5th, 2016** **Original date of approval: August 5th, 2016**

This certificate is valid from **August 5th, 2016** to **March 1st, 2019** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.

"SANMEDICO" S.R.L.

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

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)

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 13485:2012
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

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

Date: 2016-05-30

X. Rep

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 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

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

Date: 2016-05-30

X. Rep

Atlas Medical

Date: 30/06/2018

STATEMENT

We, **Atlas Medical** having a registered office at William James House, Cowley Road, Cambridge, CB4 0WX, UK 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/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.

On behalf of the Manufacturer
General Manager
Haya Amawi

Atlas Medical

Head Office William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom.
Tel: +44 (0) 1223 858910, Fax: +44 (0) 1223 858524
Middle East Site : King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box: 204, Amman 11512, Jordan

Declaration Ref No: DC11-0051

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: +44 1223 858 910
Fax: +44 1223 858 524
Email: info@atlas-site.co.uk

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (Annexl) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2003) issued by Lloyd's Register Quality Assurance.
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2012 , EN ISO 13532: 2002, EN ISO 14971:2012, EN ISO 13640:2002, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And

Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
William James House, Cowley Rd.,
Cambridge, CB4 0WX, UK

	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
Atlas Medical	December.2011	21st of March,2018		

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Catalouge No	Description
Latex Kits	
8.00.00	CRP latex Kits
8.00.01	CRP latex Kits with buffer
8.00.02	ASO latex Kits
8.00.03	ASO latex Kits with buffer
8.00.04	RF Latex Kits
8.00.05	RF Latex Kits with buffer
8.00.07	hCG Latex Kits
8.00.08	IM (Hourse Stroma)Latex Kits
8.00.11	SLE Latex kits
8.00.12	Staphylococcus Latex Kits
8.00.13	Streptococcus Latex kits
8.00.15	E.Coli Latex Kits
8.00.16	Rota Virus Latex Kits
8.00.17	D-Dimer Latex kits
8.00.21	Waaler rose Latex Kits
Febrile Antigen Kits	
8.01.00	Brucella Rose Bengal
8.01.01	Salmonella OA Reagent
8.01.02	Salmonella OB Reagent
8.01.03	Salmonella OC Reagent
8.01.04	Salmonella OD Reagent
8.01.05	Salmonella HA Reagent
8.01.06	Salmonella HB Reagent
8.01.07	Salmonella HC Reagent
8.01.08	Salmonella HD Reagent
8.01.10	Brucella Abortus Reagent
8.01.11	Brucella Melitensis Reagent
8.01.12	Proteus OX2 Reagent
8.01.13	Proteus OX19 Reagent
8.01.14	Proteus OXK Reagent
8.01.15	Brucella Antigens Kits
8.01.16	Salmonella Antigen Sets
8.01.17	Febrile Antigen Set (10 Antigens)
8.01.17	Febrile Antigen Set (10 Antigens) With controls
8.01.18	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD)
8.01.18	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD) with controls
8.01.19	Febrile Antigens Positive Control
8.01.20	Febrile Antigens Negative Control
Co-agulation Reagents	
8.02.40	PT Calcium Rabbit Brain Thromboplastin, liquid
8.02.41	APTT (PTT) Micronised Silica Platelet Substitute, Liquid
8.02.60	Normal Coaggulation Control
8.02.61	Abnormal Coaggulation Control
8.02.44	PT Kit
8.02.45	APTT (PTT) Kit

Catalouge No	Description
8.02.48	Calcium Chloride
8.02.69	Fibrinogen Reagent
Hemoglobin Reagents	
8.02.46	Drabkins Reagent, 40x
8.02.50	Hemoglobin Standard, 15g/dL
Sickle Cell Kits	
8.02.67	Sickle Cell Kit
8.02.68	Sickle Cell positive & negative control set
Urine Reagent Strips	
8.03.00	URS 1 Parameter: Glucose
8.03.01	URS 1 Parameter: Protein
8.03.02	URS 1 Parameter: Ketone
8.03.03	URS 2 Parameters:Glucose,Ketone
8.03.04	URS 2 Parameters:Glucose, Protein
8.03.05	URS 2 Parameters: Urobilinogen, Bilirubin (Liver Function Test)
8.03.06	URS 3 Parameters: Protein, pH, Glucose
8.03.07	URS 3 Parameters:Glucose, Protein, Ketone
8.03.15	URS 9 Parameters:Nitrite, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.03.16	URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.03.17	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
8.03.18	URS 11 Parameters: Leucocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
Fertility Rapid Tests	
8.04.00	hCG Test Cassette, Urine
8.04.01	hCG Test Cassette, Urine/Serum
8.04.04	hCG Test Strip, 5.0mm, Urine
8.04.05	hCG Test Strip, 3.5mm, Urine
8.04.06	hCG Test Strip, 2.5mm, Urine
8.04.10	hCG Test Strip, 5.0mm, Urine/Serum
8.04.12	hCG Test Strip, 2.5mm, Urine/Serum
8.04.88	hCG Test Strip, 3.5 mm, Urine/Serum
8.04.90	hCG Test Strip, 2.5 mm, Urine/Serum
8.04.14	LH Test Cassette, Urine
8.04.15	LH Test Strip, 3.5mm, Urine
Infectious Disease Rapid Test - Antibody Testing	
8.04.20	H.pylori Antibody Test Cassette, Whole Blood/Serum/Plasma

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Catalouge No	Description
8.04.21	H.pylori Antibody Test Cassette, S/P
8.04.22	H.pylori Antibody Test Strip, S/P
8.04.41	Syphilis Antibody Test Cassette, Whole Blood/Serum/Plasma
8.04.42	Syphilis Antibody Test Cassette, S/P
8.04.43	Syphilis Antibody Test Strip, S/P
8.04.44	Dengue IgM/IgG Test Cassette WB/S/P
Infectious Disease Rapid Test - Antigen Testing	
8.04.23	H.pylori Antigen Test Cassette, Stool Sample
8.04.24	H.pylori Antigen Test Strip, 3.5mm, Stool Sample
8.04.69	Rotavirus Antigen Test Cassette, Stool Sample
8.04.70	Rotavirus Antigen Test Strip, 3.5mm, Stool Sample
8.04.71	Adenovirus Antigen Test Cassette, Stool Sample
8.04.72	Adenovirus Antigen Test Strip, 3.5mm, Stool Sample
8.04.73	Rota-Adeno Antigens Combotest Cassette, Stool Sample
8.04.74	Rota-Adeno Antigens Combotest Strip, 3.5mm, Stool Sample
8.16.42	Rota Virus Positive Control
8.16.43	Adeno Virus Positive Control
8.04.86	Influenza A+B Test Cassette, Nasal
8.04.96	Influenza A+B Test Strip, Nasal Sample
8.04.97	Astro Virus Test Cassette, Nasal Sample, Buffer to be supplied in Extraction Tube
8.04.98	Astro VirusTest Strip, Stool Sample, Buffer to be supplied in Extraction Tube
8.16.20	RSV Test Cassette, Swab Sample
8.16.22	RSV Test Strip, Swab Sample
8.16.31	Giardia test Cassette,stool sample
8.16.30	Giardia test strip,stool sample
Cancer Markers Rapid Tests	
8.04.38	Fecal Occult Blood Test (FOB) Test Cassette, Stool Sample
8.04.85	Fecal Occult Blood Test (FOB) Test Strip
Cardiac Markers Rapid Tests	
8.04.45	Troponin I Test Cassette, WB/S/P
8.04.48	Cardiac Triple Test Cassette (Troponin I, CK-MB, Myoglobin)
DOA Rapid Tests	
8.04.49	Morphine Test Cassette, Urine
8.04.50	Morphine Test Strip, Urine
8.04.51	Marijuana (THC) Test Cassette,Urine
8.04.52	Marijuana (THC) Test Strip, Urine
8.04.53	Amphetamine Test Cassette, Urine
8.04.54	Amphetamine Test Strip, Urine
8.04.55	Barbiturates Test Cassette, Urine
8.04.56	Barbiturates Test Strip, Urine
8.04.57	Benzodiazepines Test Cassette, Urine
8.04.58	Benzodiazepines Test Strip, Urine

Catalouge No	Description
8.05.03	Alkaline Phosphatase Kinetic, DGKC Method (Tablets)

Catalouge No	Description
8.04.59	Cocaine Test Cassette, Urine
8.04.60	Cocaine Test Strip, Urine
8.04.61	Methamphetamine Test Cassette, Urine
8.04.62	Methamphetamine Test Strip, Urine
8.04.63	Methadone Test Cassette, Urine
8.04.64	Methadone Test Strip, Urine
8.04.65	Phencyclidine Test Cassette, Urine
8.04.66	Phencyclidine Test Strip, Urine
8.04.67	Tricyclic Anti-Depressants Test Cassette, Urine
8.04.68	Tricyclic Anti-Depressants Test Strip, Urine
8.04.99	Buprenorphine Test Cassette, Urine
8.16.23	Buprenorphine Test Strip, Urine
8.16.15	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Cassette, Urine
8.16.05	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Strip, Urine
8.16.06	Opiates Test Cassette, Urine
8.16.07	Opiates Test Strip, Urine
8.16.68	Tramadol Test Cassette, Urine
8.16.44	Tramadol Test Strip, Urine
8.16.58	Cotinine Test Cassette, Urine
8.16.59	Cotinine Test Strip, Urine
8.16.60	Dolantin Test Cassette, Urine
8.16.61	Dolantin Test Strip, Urine
8.16.62	Oxycodone Test Cassette, Urine
8.16.63	Oxycodone Test Strip, Urine
8.16.64	Ketamine Test Cassette, Urine
8.16.65	Ketamine Test Strip, Urine
8.16.66	Proxyphene Test Cassette, Urine
8.16.67	Proxyphene Test Strip, Urine
8.16.69	EDDP Test Cassette, Urine
8.16.70	EDDP Test Strip, Urine
8.04.93	DOA Panel: 2 Drugs,Urine
8.04.94	DOA Panel: 3 Drugs,Urine
8.04.95	DOA Panel: 4 Drugs,Urine
8.04.79	DOA Panel: 5 Drugs,Urine
8.04.80	DOA Panel: 6 Drugs,Urine
8.04.81	DOA Panel: 7 Drugs,Urine
8.04.82	DOA Panel: 8 Drugs,Urine
8.04.83	DOA Panel: 9 Drugs,Urine
8.04.84	DOA Panel: 10 Drugs,Urine
8.16.03	DOA Panel: 11 Drugs,Urine
8.16.04	DOA Panel: 12 Drugs,Urine
Kidney Function Rapid Tests	
8.16.52	Microalbumin Test Cassette
Clinical Chemistry Kits	
8.05.00	Albumin Bromocresol Green
8.05.01	Amylase
8.05.02	Acid Phosphatase Kinetic, Hillmann Method (Tablets)
8.05.02	Acid Phosphatase Kinetic, Hillmann Method (Tablets)

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8.05.04	Alkaline Phosphatase Kinetic, DGKC
8.05.72	Alkaline Phosphatase Colorimetric Method
8.05.05	Bilirubin Total (DMSO Method)
8.05.07	Bilirubin Total & Direct (DMSO Method)
8.05.08	Calcium Arsenazo III
8.05.09	Calcium O-Cresophthalein
8.05.10	Chloride Thyocianate Colorimetric
8.05.11	Cholesterol Liquid (CHOD-POD)
8.05.26	HDL Cholesterol Precipitating Reagent
8.05.51	HDL Choelsterol, Enzymatic Colorimetric Direct Method
8.05.12	CK-MB Kinetic (Tablets)
8.05.13	CK-MB Kinetic (Liquid)
8.05.14	CK-NAC Kinetic (Tablets)
8.05.15	CK-NAC Kinetic (Liquid)
8.05.16	Creatinine Jaffe Coler-Kinetic
8.05.17	Glucose GOD-POD (Liquid)
8.05.18	GOT (AST) IFCC Kinetic (Tablets)
8.05.19	GOT (AST) IFCC Kinetic (Liquid)
8.05.20	GOT (AST) Reitman-Frankel Colorimetric
8.05.21	GPT (ALT) IFCC Kinetic (Tablets)
8.05.22	GPT (ALT) IFCC Kinetic (Liquid)
8.05.23	GPT (ALT) Reitman-Frankel Colorimetric
8.05.24	Gamme GT Kinetic, Carboxy Substrate (Tablets)
8.05.25	Gamme GT Kinetic, Carboxy Substrate (Liquid)
8.05.27	Iron Ferrozine Colorimetric
8.05.28	LHD IFCC Kinetic (Tablets)
8.05.29	LDH IFCC Kinetic (Liquid)
8.05.30	Lipase Kinetic (Liquid)
8.05.31	Magnesium Calmagite Colorimetric
8.05.32	Phosphorus Phosphomolybdate UV
8.05.33	Potassium Colorimetric
8.05.34	Sodium Colorimetric
8.05.35	TIBC (Total Iron Binding Capacity)
8.05.36	Total Lipids Phosphovalnilline Colorimetric
8.05.37	Total Protein Biuret Colorimetric
8.05.38	Total Protein in CSF
8.05.39	Triglycerides GPO-POD Colorimetric
8.05.40	Urea Urease-GLDH Kinetic (UV)
8.05.41	Urea Berthelot Colorimetric
8.05.42	Uric Acid Uricase-PAP Colorimetric
8.05.71	Uric Acid Uricase-PAP Colorimetric (Mono Reagents)

Catalouge No	Description
8.05.43	Pathological Control for Clinical Chemistry
8.05.44	Normal Control for Clinical Chemistry, Lyophilized, Human Source
Hormone Elisa Kits	
8.10.01	hCG Elisa Kit
8.10.03	FSH Elisa Kit
8.10.04	LH Elisa Kit
8.10.05	Prolactin Elisa Kit
8.12.00	T3 Elisa Kit
8.12.01	T4 Elisa Kit
8.12.02	TSH Elisa Kit
8.12.03	Free T4 Elisa Kit
8.12.04	Free T3 Elisa Kit
Alcohol Tests	
8.25.01	Saliva Alcohol Test Strip
8.25.02	Breath Alcohol Test (0.02%)
8.25.03	Breath Alcohol Test (0.05%)
8.25.04	Breath Alcohol Test (0.08%)
Home Test (OTC)	
70170001	Atlas Home Pregnancy Test Cassette, 1 Test/Box
70180001	Atlas Home Pregnancy Test Strip (With Handle), 1 Test/Box
70171001	Atlas Home Pregnancy Test Cassette, 1 Test/Box
70172001	Atlas Home Pregnancy Test Cassette, 1 Test/Box
70174001	Atlas Home Ovulation Test Cassette, 5 Tests/Box
70175001	Atlas Home Ovulation Test Midstream, 3 Tests/Box
70177001	Atlas Home Menopause Test Cassette, 1 Test/Box
70178001	Atlas Home Menopause Test Midstream, 1 Test/Box
70004001	Atlas Home Diabetes Test, 2Tests/Box
70021001	Atlas Home Urinary Tract Infection Test, 2 Tests/Box
70022001	Atlas Home Kidney Function Test, 2 Tests/Box
70023001	Atlas Home Liver Function Test, 2 Tests/Box

Atlas Medical

Catalouge No	Description
Antibiotic Sensitivity Mono Discs	
8.39.01	AMIKACIN (30 µg) – AK (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.02	AMOXICILLIN (10 µg) – AX (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.03	AMOXICILLIN /CLAVULANIC ACID (20 µg+ 10 µg) - AC (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.04	AMPICILLIN (10 µg)–AP (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.05	AMPICILLIN /SULBACTAM (10 µg -10 µg – AS (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.06	AZITHROMYCIN (15 µg)–AZ(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.07	AZTREONAM (30 µg)–AT (5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.08	CEFACLOR (30 µg) - CG (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.09	CEFADROXIL (30 µg) - CD(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.10	CEFAZOLIN (30 µg) - CF (5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.11	CEFDINIR (5µg) - CN(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.12	CEFIXIME (5 µg)-FX (5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.13	CEFOPERAZONE (75 µg)-PZ(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.14	CEFOPERAZONE / SULBACTUM (75 µg 30 µg) - CS (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.15	CEFOTAXIME (30 µg)- CX (5 Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.16	CEFPIROME (30 µg) - CE (5 Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.17	CEFPODOXIME (10µg)–CO(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.18	CEFPROZIL (30 µg) - FP (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.19	CEFTAZIDIME (30 µg)–CZ(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.20	CEFTIZOXIME (30 µg) - FO(5 Cartridgex50 Discs with Cartridge Applicator per Box)
8.39.21	CEFTRIOXONE (30 µg) - FR(5 Cartridgex 50 Discs with Cartridge Applicator per Box)
8.39.22	CEFUROXIME (30 µg)-CR(5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.23	CEPHALEXIN (30 µg)-CP(5Cartridgex50 Discs with Cartridge Applicator per Box)

Catalouge No	Description
8.39.24	CEPHALORIDINE (30 µg)-CH(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.25	CEPHALOTHIN (30 µg) -CA(5Cartridgex 50 Discs with Cartridge Applicator per Box)
8.39.26	CHLORAMPHENICOL (30 µg)-CK(5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.27	CIPROFLOXACIN (5 µg) - CL (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.28	CLARITHROMYCIN (15 µg) - CL (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.29	CLINDAMYCIN (2 µg)-CM(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.30	CLOXACILLIN (5 µg) - CV (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.31	CO-TRIMOXAZOLE (25 µg)-CT(5Cartridgex 50 Discs with Cartridge Applicator per Box)
8.39.32	DOXYCYCLINE (30 µg) - DO (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.33	ERYTHROMYCIN (15 µg) - ER (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.34	FURAZOLIDONE (100 µg)-FZ(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.35	GATIFLOXACIN (5 µg) - GF (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.36	GENTAMYCIN (10 µg) - GM (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.37	IMIPENEM / CILASTATIN (10 µg + 10 µg) - IS (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.38	KANAMYCIN (30 µg)- KA(5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.39	LEVOFOLXACIN (5 µg) - LV (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.40	LINCOMYCIN (15 µg) - LN (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.41	LINEZOLID (30 µg) - LI (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.42	LOMEFLOXACIN (10 µg) - LF (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.43	MEROPENEM (10 µg)-MR (5 Cartridge x 50 Discs with Cartridge Applicator per Box)

Atlas Medical

Catalouge No	Description
8.39.44	MINOCYCLINE(30µg)-MN(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.45	MOXIFLOXACIN (5µg)-MF(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.46	NALIDIXIC ACID (30 µg)-NA(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.47	NITROFURANTOIN (300 µg) - FU (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.48	NORFLOXACIN (10µg)-NF(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.49	OFLOXACIN (5 µg) - OF (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.50	PEFLOXACIN (5 µg) – PF (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.51	PENICILLIN–G(10 IU)–PG(5Cartridgex50 Discs with Cartridge Applicator per Box)
8.39.52	PIPERACILLIN(100µg)–PC(5Cartridgex50 Discs with Cartridge Applicator per Box)
8.39.53	PIPERACILLIN / TAZOBACTAM (100 µg + 10 µg) - PT (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.54	RIFAMPIN (5 µg) – RN (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.55	ROXITHROMYCIN (30µg)–RO(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.56	SPARFLOXACIN(5µg)–SP(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.57	STREPTOMYCIN (10 µg)–ST(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.58	SULPHADIAZINE (300µg)–SD (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.59	TEICOPLANIN (30µg)–TC(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.60	TETRACYCLINE(30µg)–TE(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.61	TICARCILLIN / CLAVULANIC ACID (75 µg + 2.5 µg)-TC (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.62	TOBRAMYCIN (10µg)–TO(5 Cartridgex 50 Discs with Cartridge Applicator per Box)
8.39.63	TRIMETHOPRIM(5µg)–TR(5Cartridgex50 Discs with Cartridge Applicator per Box)
8.39.63	TRIMETHOPRIM(5µg)–TR(5Cartridgex50 Discs with Cartridge Applicator per Box)
Glucose Monitoring	
8.16.73	Blood Glucose Visual Test Strip
8.40.00	HbA1c Direct Enzymatic Colorimetric Kit

Atlas Medical

Catalouge No	Description
Blood Culture	
8.38.00	Blood Culture Bottles, Pediatric Size
8.38.01	Blood Culture Bottles, Adult Size
Syphilis Kits	
8.00.18	RPR Carbon Antigen (Coarse Grain) Kit
8.00.18.1	RPR Carbon Antigen (Fine Grain) Kit
8.00.19	TPHA Kit
8.00.20	VDRL Kit
Stains for Histology & Microbiology	
8.15.017	Carbol Fuchsin (Gram)
8.15.019	Carbol Fuchsin (Ziehl-Neelsen)
8.15.032	Crystal Violet (for Gram Stain)
8.15.037	Eosin Y (1% Aqueous)
8.15.038	Eosin Y (5% Aqueous)
8.15.039	Eosin Y (1% Alcoholic)
8.15.041	Field Stain (Solution A)
8.15.042	Field Stain (Solution B)
8.15.047	Giemsa Stain (Modified-Glycerol/ Methanol)
8.15.049	Gram's Iodine
8.15.051	Gram's Decolouriser
8.15.059	Haematoxylin Harris (no Acetic Acid)
8.15.060	Haematoxylin Harris (with Acetic Acid)
8.15.069	Leishman Stain
8.15.074	Lugol's Iodine,
8.15.076	Malachite Green (Aqueous)
8.15.078	May Grunwald Stain (Modified)
8.15.105	New Methylene Blue for Reticulocytes
8.15.110	Papanicolaou Stain EA35
8.15.111	Papanicolaou Stain EA36
8.15.112	Papanicolaou Stain EA65
8.15.114	Papanicolaou Stain EA50
8.15.115	Papanicolaou Stain OG6
8.15.126	Safranin (1% Aqueous)
8.15.143	Wright's Stain (Modified)
8.15.144	ZN Decolouriser
8.15.017	Carbol Fuchsin (Gram)
8.15.019	Carbol Fuchsin (Ziehl-Neelsen)
8.15.032	Crystal Violet (for Gram Stain)
8.15.037	Eosin Y (1% Aqueous)
8.15.038	Eosin Y (5% Aqueous)
8.15.039	Eosin Y (1% Alcoholic)
8.17.003	Periodic Acid Schiff (PAS) Stain Kit
8.17.004	Iron Stain Kit- Perl
8.17.009	Gram Stain Pack
8.17.010	Cold ZN- Kinyoun Stain Pack
8.17.011	ZN Pack Standard
8.17.015	Diff 3 stain pack
8.17.015	Papanicolau stain kit (EA35, EA65, OG6, EA50)

Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

Atlas Medical

King Abdullah II Industrial Estate, Street No. 19, Sahab Free Zone Area, Amman, 11512, Jordan

has been approved by LRQA to the following standards:

ISO 13485:2003

Basem Obaid - Area Operations Manager

Issued By: Lloyd's Register EMEA

for and on behalf of: Lloyd's Register Quality Assurance Limited

Current Issue Date: 23 March 2018
Expiry Date: 31 March 2019
Certificate Issue Number: 10067833

Original Approvals:
ISO 13485 28 February 2009

Approval Certificate Number: ISO 13485 – 0046833

The scope of this approval is applicable to:
ISO 13485:2003
Design Manufacturing and Supply of Medical Diagnostic Reagents and Kits

UKAS MANAGEMENT SYSTEMS
001

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 1-408-855-0061
Fax: 1-408-855-0063
E-mail: info@lumiquick.com
Website: www.lumiquick.com

Date: February 13, 2018

LETTER OF AUTHORIZATION

To whom it may concern:

We, LumiQuick Diagnostics Inc. having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA, assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, 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.

This authorization letter is valid until February 28, 2020.

Best regards,

Charles Yu
President

LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, California 95054 USA
Tel: 1-408-855-0061 Info@lumiquick.com
Fax: 1-408-855-0063 www.lumiquick.com

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 408-855-0061
Fax: 408-855-0063
E-mail: info@LumiQuick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Cardiac Marker Test Devices	
QuickProfile Troponin I Serum Test Card	75001
QuickProfile Troponin I Whole Blood Test Card	75002
QuickProfile Cardiac Panel Serum Test Card	75003
QuickProfile Cardiac Panel Whole Blood Test Card	75004
QuickProfile Myoglobin Serum Test card	75005
QuickProfile Myoglobin Whole Blood Test Card	75006
QuickProfile CK-MB Serum Test Card	75007
QuickProfile CK-MB Whole Blood Test Card	75008
QuickProfile Troponin I Strip	75009
QuickProfile CK-MB Strip	75010
QuickProfile Myoglobin Strip	75011

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

EC_Declaration_Letter_Emergo_E2R0_NewAddress

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

LumiQuick Diagnostics, Inc.
2946 Scott Blvd
Santa Clara
California
95054
USA

Holds Certificate No: **FM 574919**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostics test kits and reagents used in the diagnosis and management of disease status, including Infectious Diseases tests, Drugs of Abuse tests, Cardiac Monitor tests, Cancer Marker tests, Fertility Hormone tests, ELISA tests & Urine Chemistry tests.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2011-10-20
Latest Revision Date: 2017-10-09

Effective Date: 2017-10-20
Expiry Date: 2019-02-28

...making excellence a habit.

YourTrustedPartner

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,

ACON LABORATORIES, INC.

Jassy Alvarenga

Account Manager, International Sales

ACON Laboratories

"SANMEDICO" S.R.L.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 17 08 80997 017

Manufacturer: ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego CA 92121
USA

EC-Representative: Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover
GERMANY

Product Category(ies): In Vitro diagnostics for the detection of human infections and tumor markers, blood glucose measuring self-testing systems, self-testing devices for clinical chemistry, hematology and pregnancy

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: SH17743EXT01

Valid from: 2017-09-13
Valid until: 2022-09-12

Date, 2017-08-30

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)
No. V1 17 08 80997 017

Model(s): For Detail Models see attachment

Facility(ies): ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

Product Service

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,

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

Product Service

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 Preiß

Certification Medical Technology

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 05 42074 027

Holder of Certificate: **Acon Biotech (Hangzhou) Co., Ltd.**
No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
310030 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Test Kits and Related Instruments, Lancet and Lancing Device**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1610619

Valid from: 2016-07-15
Valid until: 2019-07-14

Date, 2016-07-08

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-21321-01-00

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SANMEDICO S.R.L.

DAkkS CRT2 / 10 13