СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

CERTIFICATE

This is to certify that the Quality Management System of

Titan Surgical Limited Liability Company

100, Vosstaniya Str. building 177 office 2, 420095, Kazan,
Republic of Tatarstan, Russia

has been assessed and found to be in accordance with the requirements of

ISO 13485:2016

in respect of design, development, manufacture and sales of medical and microsurgical instruments

No: 18.0658.026
of 26th February, 2019

Management system certified since 2018

This certificate is valid until **18th May, 2021**

Director General of Certification
Association "Russian Register"

Specification of the certification scope is provided in Annex. This certificate becomes invalid if conditions of certification are not fulfilled (http://www.rusregister.ru/doc/004.00-105.pdf). This Certificate is the property of Certification Association "Russian Register".

10-000154

RUSSIAN REGISTER РУССКИЙ РЕГИСТР

Certification Association "Russian Register": 101 Rimskogo-Korsakova Ave., 190121, Saint Petersburg, Russia

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

Annex to the Certificate
№ 18.0658.026
of 26th February, 2019
registration form № 10-000154

Certification scope of management system of Titan Surgical Limited Liability Company

1. Product / service: design, development, manufacture and sales of medical and microsurgical instruments.
2. Processes of product realization in compliance with ISO 13485:2016:

    7.1. Planning of product realization
    7.2. Customer-related processes
    7.3. Design and development
    7.4. Purchasing
    7.5. Production and service provision
    7.6. Control of monitoring and measuring devices

3. Exclusions from the processes of product realization: 7.5.3, 7.5.5, 7.5.7, 7.5.9.2

Director General of Certification
Association "Russian Register" A. Vladimirtsev

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

Certification Association "Russian Register" has issued an IQNet recognized certificate that the organization:

Titan Surgical Limited Liability Company

100, Vosstaniya Str. building 177 office 2, 420095, Kazan, Republic of Tatarstan, Russia

has implemented and maintains a

Quality Management System

for the following scope:

design, development, manufacture and sales of medical and microsurgical instruments

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: ***26th February, 2019***
Expires on: ***18th May, 2021***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: ***RU-18.0658.026***

Alex Stoichitoiu
President of IQNet

Arkady Vladimirtsev,
Director General of
Russian Register

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.
* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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THE INTERNATIONAL CERTIFICATION NETWORK

ANNEX 1 to IQNet Certificate Number RU-18.0658.026

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Alex Stoichitoiu
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"Titan Surgical" LLC
Kazan, Russia, 420095, 100, Vosstaniya St., Bld.177, Office 2
Phone : +7(843) 212-56-00,212-56-01,212-56-02 Fax:+7(843) 212-56-05
email : sales@titansurgical.com www.TitanSurgical.com

EC DECLARATION OF CONFORMITY

Manufacturer's Name and Address	"Titan Surgical" LLC Kazan, Russia, 420095, 100, Vosstaniya St., Bld.177, Office 2
Product Categori	Reusable surgical instruments for Microvascular and Ophthalmic surgical operations
Model Numbers and Type	CA,PD,PR,PT,RE,VD,VE,VF,VH,VL,VS,VZ,ZT,OB,OC,OCT,OD,OE,OF,OG,OH,OJ, OK,OKD,OKE,OKT,OKZ,OL,OM,ON,ONK,ONV,OP,OPT,OR,ORT,OS,OSD,OT,OQ OV,OVB,OVC,OVN,OW,OZ and their modifications.
EC Directives	Medical Device Directive 93/42/EEC
Class	The Medical Device is in Class I (Non-Steril) ,according to annex-II of the Medical Device Directive.
Quality Assurance System	ISO 13485:2016– Quality System – Quality assurance model for design, development, manufacturing, sales and associated services (Registration number № RU-18.0658..026)

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

EC Representative	Medlane, 45 Chemin du Moulin Carron, Dardilly, 69570, France, Tel+33 472 52 11 52 ,Fax+33 4 78 47 51 76

We , the undersigned ,hereby declare that the equipment specified above conforms to Annex-II of the MDD 93/42/EEC and by amended directive 2007/47/EC concerning medical devices : **"Titan Surgical"LLC**

Mr. Andrey Sukhorskiy

General Director

«Титан серджикл»
ИНН
1658119529