



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**



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".



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**

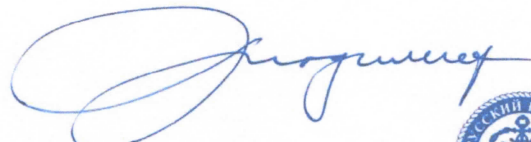
Expires on: **18th May, 2021**

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

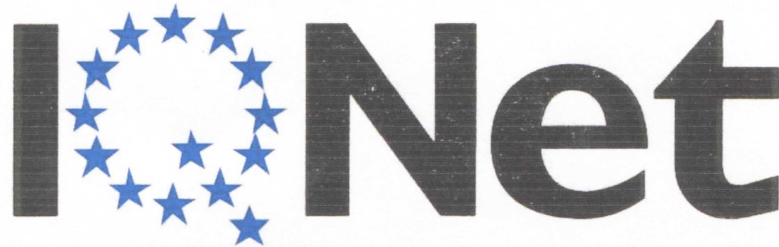

Arkady Vladimirtsev,
Director General of
Russian Register



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
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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



THE INTERNATIONAL CERTIFICATION NETWORK


ANNEX 1 to IQNet Certificate

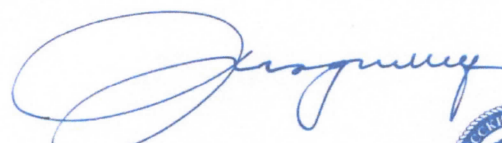
Number RU-18.0658.026

Certification scope of the 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
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Alex Stoichitoiu
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SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
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"Titan Surgical" LLC

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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 Category 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

