



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: 18th May, 2021

Expires on: 18th May, 2024

*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-21.0599.026




Alex Stoichitoiu
President of IQNet


Arkady Vladimirtsev,
Director General of
Russian Register



IQNet Partners*:

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THE INTERNATIONAL CERTIFICATION NETWORK

ANNEX 1 to IQNet Certificate

Number RU-21.0599.026

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




Alex Stoichitoiu
President of IQNet


Arkady Vladimirtsev,
*Director General of
Russian Register*



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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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EC Declaration of Conformity
issued in accordance with EC Directive 93/42/EEC
relating to Medical Devices
CANNULAS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Manufacturer: TITAN SURGICAL LLC.,
100, Vosstaniya Street, bldg. 177, of.2, 420095 Kazan, Republic of Tatarstan, RUSSIA

European representative: CET MSU Portugal Unipessoal Lda
Avenida dos Bons Amigos, 5, 1B, 2735-076, Agualva – Cácem, Portugal

Product name: CANNULAS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Product description: steel and titanium microsurgical non sterile reusable instruments designed for minimally invasive and non-invasive operations in ophthalmic surgery

Class I Medical Device.

Applied directives: MD Directive 93/42/EEC

Applied harmonized standards: ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2007 Medical devices — Application of risk management to medical devices
ISO 7741: 1986 Instruments for surgery -- Scissors and shears -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Applied standards: GOST R ISO 50444-92 Medical instruments, apparatus and equipment. General specifications
GOST 19126-2007 Medical metallic instruments. General specifications
GOST 21241-89 Medical pincers. General technical requirements and test methods
GOST R 53519-2009 Surgical instruments. Haemostatic clamps. Technical requirements and test methods.

The conformity assessment procedure was that of Class I, rule 6 of Annex IX (reusable surgical instruments) of the Medical Device Directive.

MANUFACTURER herewith declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The product – « Set of microsurgical instruments », TITAN SURGICAL LLC., is safe under prescribed and reasonably foreseeable conditions of storage and use.

MANUFACTURER has implemented measures assuring that the « Set of microsurgical instruments », TITAN SURGICAL LLC, of the above mentioned type are safe and fulfill essential requirements of the 93/42/EEC Directive.

MANUFACTURER has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of user's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product. Listing of the microsurgical instruments in attachment

Date of issue: 24th April, 2020
Valid until: 23th April, 2023

TITAN SURGICAL LLC, Director General
Sukhorskiy Andrey



ATTACHMENT LISTING

Wide range of microsurgical reusable instruments of various shapes and sizes, providing minimally invasive and non-invasive surgeries in ophthalmic surgery. There are instruments of the following forms:

OC001	Vitreous aspirating cannula 20Ga, 41 mm
OC001.01	Vitreous aspirating cannula 19Ga, 41 mm
OC001.02	Vitreous aspirating cannula 16G, 41 mm
OC001.03	Foreign body aspirating cannula 14G, 41 mm
OC002	Anterior chamber cannula 21Ga, 38 mm
OC002.01	Anterior chamber cannula 20Ga, 38 mm
OC002.05	Anterior chamber cannula 27Ga, 38 mm
OC002.06	Anterior chamber cannula 23Ga, 38 mm
OC003	Simcoe suturing needle 25Ga, 38 mm
OC004	Simcoe micro hook 21Ga, 38 mm
OC005	Cortex aspirating cannula 23Ga, 38 mm
OC006	Cataract aspirating needle(Knife-cannula) 23Ga, 34 mm
OC007	Simcoe cortex aspirating cannula 23Ga, crv.,38mm
OC007.01	Simcoe cortex aspirating cannula 23Ga, crv.,38mm Left
OC007.02	Simcoe cortex aspirating cannula 23Ga, crv.,38mm Right
OC008	Park irrigating cannula 21Ga, angl., 38mm
OC009	Simcoe irrigating/aspirating cannula 23Ga, 38 mm, silicone tube 160 mm
OC010	Retinal cannula straight 19Ga with silicone tube,46mm
OC010.01	Retinal cannula curved 19Ga with silicone tube,44mm
OC010.02	Irrigating Cannula, Straight Blunt Tip, Polished, 44 mm, 21 GA
OC011	Posterior chamber cannula 23Ga, crv, 48 mm
OC012	Cannula 19Ga crv. with lateral port, 49 mm
OC013	Aspirating cannula for subretinal contents 21Ga, 47 mm
OC013.01	Aspirating cannula for subretinal contents 21Ga, 52 mm
OC013.02	Aspirating Cannula for Subretinal Contents, 27Ga, 52 mm
OC014	Heslin anterior chamber maintainer 23Ga,180 mm
OC014.01	Heslin anterior chamber maintainer 23Ga,180 mm
OC014.02	Anterior chamber maintainer 20Ga,180 mm
OC015	Lewicky anterior chamber maintainer 20Ga, 180 mm
OC016	Girard Anterior Chamber Maintainer 20Ga, 180 mm
OC016.01	Girard Anterior Chamber Maintainer 20Ga, 180 mm
OC016.02	Girard Anterior Chamber Maintainer 20Ga, 180 mm
OC017	Anterior chamber washout cannula 23Ga, 43 mm
OC018	Buratto lasik irrigating cannula 23Ga, 39 mm
OC020	Irrigating Cannula, Straight 21Ga, 44 mm
OC021	Irrigating Cannula, Straight 25Ga, 44 mm
OC021.01	Irrigating Lacrimal Cannulas,str, 25Ga, 60 mm
OC021.02	Irrigating Lacrimal Cannulas,str, 20Ga, 60 mm
OC021.03	Irrigating Lacrimal Cannulas,crv, 25Ga, 60 mm
OC021.04	Irrigating Lacrimal Cannulas,str, 22Ga, 60 mm
OC021.05	Irrigating Lacrimal Cannulas,str, 20Ga, 60 mm
OC021.06	Irrigating Lacrimal Cannulas,str, 23Ga, 60 mm
OC021.07	Irrigating Lacrimal Cannulas,str, 27Ga, 43 mm
OC021.08	Irrigating Lacrimal Cannulas,crv, 25Ga, 60 mm
OC022	McIntyre Anterior Chamber Maintainer, Ang., 25Ga, 38 mm
OC023	LASIK Irr. Cannula, Crv, 21Ga, one side port, 41 mm

OC023.01	LASIK Irr. Cannula, Crv, 21Ga, one front port, 41 mm
OC023.02	LASIK Irr. Cannula, Crv, 21Ga, two side port, 41 mm
OC023.03	LASIK Irr. Cannula, Crv, 21Ga, six side port, 41 mm
OC023.04	LASIK Irr. Cannula, Crv, 21Ga, six side port, 41 mm
OC023.05	LASIK Irr. Cannula, Crv, six side port, 41 mm
OC023.06	LASIK Irr. Cannula, Crv, six side port, 41 mm
OC023.07	Cannula, Stainless, right, crv, 25Ga, 41 mm
OC023.08	Cannula, Stainless, left, crv, 25Ga, 41 mm
OC023.09	Cannula, Stainless, crv, 25Ga, 41 mm
OC024	Rainin Nucleus Hydrodissector 25Ga, ang., 41 mm
OC024.01	Rainin Nucleus Hydrodissector 25Ga, crv., 41 mm
OC025	Nucleus Hydrodissector 18Gaa, crv., 51 mm
OC025.01	Nucleus Hydrodissector 19Ga, crv., 41 mm
OC026	Pearce J-shaped micro hydrodissector 25Ga, 33 mm
OC027	Cannula, Stainless, crv, 25Ga, 38 mm
OC028	Cannula, Stainless, str, 25Ga, 43 mm
OC031	Cannula, Stainless, crv, 20Ga, 25 mm
OC036	Nucleus Hydrodissector 18Gaa, crv., 53 mm
OC038	Cannula, Stainless, 25 G, crv., 40 mm
OC039	Mandrin, Stainless, 25 G, crv., 59 mm
OC040	Cannula for silicon oil, Stainless, 25 G, 40 mm
OC041.01	Cannula 27Ga str, 43 mm
OC042	Cannula 21Ga crv. side port 0,35mm, 36 mm
OC044	Cannula 23Ga ang, 62 mm
OC045	Cannula, 27Ga, stainless
VC 001	De Bakey Cannula, 48mm, 1,2mm dia, str., Ss
OC961	Cannula, aspiration and irrigation, 200mm, Ss.
OC962	Probe-cannula for contrast substance, 200mm, R/H, tips d=2.0mm, Ss.
ON003	Aspiration Handpiece For Bimanual Technique, Curved, 21Gaa, One Top Port 0.35mm
ON003.01	Aspiration Handpiece For Bimanual Technique, Curved, 22Gaa, One Top Port 0.35mm
ON003.02	Aspiration Handpiece For Bimanual Technique, Curved, rounded tip, 21Gaa, One Top Port 0.35mm
ON003.03	Aspiration Handpiece For Bimanual Technique, Curved, rounded tip, 22Gaa, One Top Port 0.35mm
ON003.04	Aspiration Handpiece For Bimanual Technique, Curved, 21Gaa, One Top Port 0.35mm
ON003.06	Aspiration Handpiece For Bimanual Technique, Curved, 21Gaa, One Top Port 0.4mm
ON003.07	Aspiration Handpiece For Bimanual Technique, Curved, 21Gaa, One Top Port 0.5mm
ON003.08	Aspiration Handpiece For Bimanual Technique, Curved, 21Gaa, One Top Port 0.25mm
ON004	Irrigation Handpiece For Bimanual Technique, Curved, 21Gaa, Two Ports on Side 0.35mm
ON004.01	Irrigation Handpiece For Bimanual Technique, Curved, 22Gaa, Two Ports on Side 0.35mm
ON004.02	Irrigation Handpiece For Bimanual Technique, Angled, 21Gaa, Spatulated Tip
ON004.03	Irrigation Handpiece For Bimanual Technique, Curved, 21Gaa, rounded tip, Two Ports on Side 0.35mm
ON004.04	Irrigation Handpiece For Bimanual Technique, Curved, 21Gaa, Two Ports on Side 0.35mm

ON004.07	Irrigation Handpiece For Bimanual Technique, Curved, 21Gaa, Two Ports on Side 0.5mm
ON005	Irrigation Handpiece For Bimanual Technique, Curved, 20Gaa, One Underside Port 0.50mm
ON005.01	Irrigation Handpiece For Bimanual Technique, Curved, 18Gaaa, One Underside Port 0.50mm
ON012	I/A Straight Tip, Stainless , 21Ga
ON012.01	I/A Simcoe Tip, Stainless , 21 Ga
ON013	I/A Thornton Tip, Stainless ,21 Ga
ON013.01	I/A Simcoe Tip, Stainless, 21 Ga
ON014	I/A Straight Tip, Stainless , 21 Ga
ON014.01	I/A Straight Tip, Stainless , 21 Ga
ON015	I/A Binkhorst Tip, Stainless , 21 Ga
ON016	I/A Simcoe Tip, Stainless , 21 Ga
ON018	I/A Simcoe Tip, stainless, 23 Ga
ON019.01	Aspiration Tip For Bimanual Technique, 21Ga
ON019.02	Aspiration Tip For Bimanual Technique, 22Ga
ON020.01	Irrigation Tip For Bimanual Technique, 21Ga
ON020.02	Irrigation Tip For Bimanual Technique, 22Ga
ON021	I/A Tip, Stainless, 23 Ga
ON021.01	I/A Tip, Stainless, 21 Ga
ON021.02	I/A Tip, Stainless
ON022	A//I Handpiece, titanium, 134mm,ss tube 1,7mm, angl 45°
ON023	A//I Handpiece, titanium, 134mm,ss tube 1,7mm, angl 90°
ON024	A//I Handpiece, titanium, 134mm,ss tube 1,7mm, angl 23°
ON025	Irrigation Handpiece For Bimanual Technique, Angled, 19Ga
ON026	Aspiration Handpiece For Bimanual Technique, Curved, 23Ga, One Top Port 0.3mm
ON027	Irrigation Handpiece For Bimanual Technique, Curved, 23Ga, Two Ports on Side 0.3mm



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**EC Declaration of Conformity
issued in accordance with EC Directive 93/42/EEC
relating to Medical Devices**

FORCEPS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Manufacturer: TITAN SURGICAL LLC.,
100, Vosstaniya Street, bldg. 177, of.2, 420095 Kazan, Republic of Tatarstan, RUSSIA

European representative: CET MSU Portugal Unipessoal Lda
Avenida dos Bons Amigos, 5, 1B, 2735-076, Agualva – Cácem, Portugal

Product name: FORCEPS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Product description: steel and titanium microsurgical non sterile reusable instruments designed for minimally invasive and non-invasive operations in ophthalmic surgery

Class I Medical Device.

Applied directives: MD Directive 93/42/EEC

Applied harmonized standards: ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2007 Medical devices — Application of risk management to medical devices
ISO 7741 : 1986 Instruments for surgery -- Scissors and shears -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Applied standards: GOST R ISO 50444-92 Medical instruments, apparatus and equipment. General specifications
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GOST 21241-89 Medical pincers. General technical requirements and test methods
GOST R 53519-2009 Surgical instruments. Haemostatic clamps. Technical requirements and test methods.

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Date of issue: 24th April, 2020

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TITAN SURGICAL LLC, Director General
Sukhorskiy Andrey



ATTACHMENT LISTING

Wide range of microsurgical reusable instruments of various shapes and sizes, providing minimally invasive and non-invasive surgeries in ophthalmic surgery. There are instruments of the following forms:

OF001	Fcps Hoskin type fixation flat 80mm str., titanium
OF001.01	Fcps Hoskin type fixation flat 80mm platf. str., titanium
OF001.02	Fcps Hoskin type fixation flat 110mm crv., titanium
OF001.03	Fcps Hoskin type fixation round 98mm str., titanium
OF002	Fcps Catalano tying round 100mm V-groove crv., titanium
OF002.01	Fcps Catalano tying round 100mm V-groove str., titanium
OF002.02	Fcps Catalano tying round 100mm V-groove crv., titanium
OF003	Fcps corneal colibri round 100x0.1 mm, titanium
OF003.01	Fcps corneal colibri round 100x0.12 mm, titanium
OF003.01S	Fcps corneal colibri round 100x0.12 mm, stainless
OF003.02	Fcps corneal colibri round 100x0.1 mm, titanium, 90 degree teeth
OF003.03	Fcps corneal colibri round 100x0.12 mm, titanium, 90 degree teeth
OF003.04S	Fcps corneal colibri flat 100x0.12 mm, stainless, 90 degree teeth
OF004	Fcps Hoskin type colibri round 90 mm, titanium
OF005	Fcps Catalano tying round 90x0.1 mm, titanium
OF005.01	Fcps dressing round 90mm str., titanium
OF006	Fcps Catalano tying round 100mm V-groove str., titanium
OF007	Fcps Girard corneal scleral colibri round 100x0.12mm, titanium
OF010	Fcps Shepard IOL holding round 122mm crv., titanium
OF010.01	Fcps Shepard IOL holding round 122mm crv. W/L, titanium
OF012	Fcps Catalano tying round 100mm V-groove ang., titanium
OF013	Fcps Bores corneal fixation 100x0.12mm, titanium
OF014	Fcps IOL implantation 100mm, titanium
OF016L	Fcps soft IOL folding&implant. round 125mm ang. W/L, titanium
OF016	Fcps soft IOL folding&implant. round 125mm ang., titanium
OF017	Fcps Jewelers flat 110mm str., titanium
OF017.01	Fcps Jewelers flat 120mm str., titanium
OF017.02	Fcps Jewelers flat 110mm platform str., titanium
OF017.03	Fcps Jewelers flat 120mm platform str., titanium
OF017.04	Fcps Jewelers flat 152mm str., titanium
OF018	Fcps Jewelers flat 110mm crv., titanium
OF018.01	Fcps Jewelers flat 110mm platform crv., titanium
OF018.02	Fcps Jewelers flat 120mm platform crv., titanium
OF019	Fcps Jewelers flat 110mm str., titanium
OF019.01	Fcps Jewelers flat 110mm platform str., titanium
OF020	Fcps Jewelers flat 110mm str., titanium
OF020.01	Fcps Jewelers flat 110mm platform str., titanium
OF020.02	Fcps Jewelers flat 110mm str.very sharp, titanium
OF022	Fcps Jameson Muscle,99mm, 4 teeth, slide lock, left
OF022.01	Fcps Jameson Muscle,100mm, 6 teeth, slide lock, left
OF022.02	Fcps Jameson Muscle,99mm, 4 teeth, slide lock, right
OF022.03	Fcps Jameson Muscle,100mm, 6 teeth, slide lock, right
OF022.04	Fcps Jameson Muscle,100mm, 6 teeth, slide lock
OF025	Fcps Utrata capsulorhexis round 105mm ang., titanium
OF025.01	Fcps Utrata capsulorhexis round 105mm ang., titanium

OF045.03	Fcps Castroviejo tying flat 105x0.6mm str., titanium
OF045.04	Fcps Castroviejo tying flat 109x0.12mm str., titanium
OF046	Fcps Castroviejo tying flat 102x0.12mm ang., titanium
OF046.01	Fcps Castroviejo tying flat 102x0.3mm ang., titanium
OF047	Fcps Castroviejo tying flat 105x0.12mm crv., titanium
OF047.01	Fcps Castroviejo tying flat 105x0.3mm crv., titanium
OF047.02	Fcps Castroviejo tying flat 105x0.5mm crv., titanium
OF048	Fcps dressing flat 105mmx8 str., titanium
OF048.01	Fcps dressing flat 105mmx8 ang., titanium
OF049	Fcps tying flat 105mmx6 str., titanium
OF050	Fcps tying flat 102mmx6 ang., titanium
OF051	Fcps tying flat 105mmx6 crv., titanium
OF053	Fcps Utrata capsulorhexis flat 102mm crv., titanium
OF053.01	Fcps Utrata capsulorhexis flat 102mm sharp crv., titanium
OF053.02	Fcps Utrata capsulorhexis flat 102mm w/groove crv., titanium
OF053.03	Fcps Utrata capsulorhexis flat 102mm, reversed, crv., titanium
OF054	Fcps Utrata capsulorhexis flat 102mm ang., titanium
OF054S	Fcps Utrata capsulorhexis flat 102mm ang., stainless
OF054.01	Fcps Utrata capsulorhexis flat 102mm sharp ang., titanium
OF054.01S	Fcps Utrata capsulorhexis flat 102mm sharp ang., stainless
OF054.02	Fcps Utrata capsulorhexis flat 102mm w/groove ang., titanium
OF054.03	Fcps Utrata capsulorhexis flat 102mm round tips ang., titanium
OF054.04	Fcps Utrata capsulorhexis flat 102mm, reversed, ang., titanium
OF057	Fcps Utrata capsulorhexis round 105mm ang., titanium
OF057.01	Fcps Utrata capsulorhexis round 105mm sharp ang., titanium
OF057.02	Fcps Utrata capsulorhexis round 105mm w/groove ang., titanium
OF057.03	Fcps Utrata capsulorhexis round 105mm, sharp/grasp, ang., titanium
OF058	Fcps McPherson tying flat 100mmx4 str., titanium
OF058.01	Fcps McPherson tying flat 100mmx6 str., titanium
OF059	Fcps McPherson tying flat 98mmx4 ang., titanium
OF059.01	Fcps McPherson tying flat 98mmx6 ang., titanium
OF060	Fcps McPherson tying flat 99mmx4 crv., titanium
OF060.01	Fcps McPherson tying flat 99mmx6 crv., titanium
OF060.02	Fcps McPherson tying flat 100mmx6 ., titanium
OF061	Fcps Castroviejo tying flat 100x0.12mm str., titanium
OF061.01	Fcps Castroviejo tying flat 100x0.12mm str., titanium 90 degr.
OF062	Fcps Castroviejo tying flat 98x0.12mm ang., titanium
OF063	Fcps Castroviejo tying flat 99x0.12mm crv., titanium
OF064	Fcps McPherson tying flat 74mmx4 str., titanium
OF065	Fcps Bonn tying flat 72mmx4 ang., titanium
OF066	Fcps Osher tying flat 73mmx4 crv., titanium
OF067	Fcps Bonn iris flat 74x0.063mm str., titanium
OF067S	Fcps Bonn iris flat 74x0.063mm str., stainless
OF067.01	Fcps Bonn iris flat 74x0.063mm str., titanium 90 degree teeth
OF067.01S	Fcps Bonn iris flat 74x0.063mm str., stainless 90 degree teeth
OF067.02	Fcps Bonn iris flat 74x0.12mm str., titanium
OF067.03	Fcps Bonn iris flat 74x0.12mm str., titanium 90 degree teeth
OF068	Fcps Bonn iris flat 72x0.063mm ang., titanium
OF069	Fcps Bonn iris flat 73x0.063mm crv., titanium

OF085.01	Fcps Francis chalazion flat 103x25 mm, titanium
OF085.02	Fcps Francis chalazion flat 100x20 mm, titanium
OF086	Fcps Desmarres chalazion flat 100x34 mm, titanium
OF087	Fcps Hunt chalazion flat 100x14 mm, titanium
OF088	Fcps Desmarres chalazion flat 100x12 mm, titanium
OF089	Fcps soft IOL folding round 110mm ang., titanium
OF090	Fcps Nucleus splitter flat 75mm, titanium
OF090.01	Fcps Nucleus splitter flat 75mm, titanium
OF091	Fcps McDonald IOL implantation flat 100mm, titanium
OF091.01	Fcps McDonald IOL implantation flat 95mm, stainless
OF092	Fcps Faulkner IOL holding flat 102mm ang., titanium
OF092.01	Fcps IOL holding flat 103mm ang., titanium
OF094	Fcps Shepard IOL holding flat 120mm crv., titanium
OF095	Fcps Kraft IOL holding flat 115mm crv., titanium
OF097	Fcps Cilia narrow flat 85mm, titanium
OF097.01	Fcps Cilia narrow flat 100mm, titanium
OF098	Fcps Ziegler Cilia flat 91mm, titanium
OF099	Fcps Cilia wide flat 76mm, titanium
OF100	Fcps Utrara capsulorhexis round 105mm crv., titanium
OF100.01	Fcps Utrara capsulorhexis round 105mm sharp crv., titanium
OF100.02	Fcps Utrata capsulorhexis round 105mm sharp ang., titanium
OF101	Fcps Troutman-Barraquer corneal colibri flat 75x0.12mm, titanium
OF101.01	Fcps Troutman-Barraquer corneal colibri flat 75x0.2mm, titanium
OF101.01S	Fcps Troutman-Barraquer corneal colibri flat 75x0.2mm, stainless
OF101.02	Fcps Troutman-Barraquer corneal colibri flat 75x0.12mm, stainless
OF101S	Fcps Troutman-Barraquer corneal colibri flat 75x0.12mm, stainless
OF103	Fcps IOL implantation round 100mm ang., titanium
OF103L	Fcps IOL implantation round 100mm W/I ang., titanium
OF104	Fcps Koch universal prefolder for IOL round 155mm, titanium
OF104.01	Fcps Koch universal prefolder for IOL round 162mm, titanium
OF104L	Fcps Koch universal prefolder for IOL round 155mm, with lock, titanium
OF105	Prechopper round 121mm sharp, str., titanium
OF105.01	Prechopper round 121mm sharp, str., stainless
OF106	Prechopper round 121mm wide, str., titanium
OF106.01	Prechopper round 121mm wide, str., stainless
OF107	Prechopper round 117mm sharp, ang., titanium
OF107.01	Prechopper round 121mm sharp, ang., stainless
OF108	Prechopper round 117mm wide, ang., titanium
OF108.01	Prechopper round 117mm wide, ang., stainless
OF109	Prechopper round 119mm sharp, crv., titanium
OF109.01	Prechopper round 119mm sharp, crv., stainless
OF110	Prechopper round 119mm wide, crv., titanium
OF110.01	Prechopper round 119mm wide, crv.,stainless
OF111	Prechopper round 120mm wide,,titanium
OF112	Prechop.Inamura , round,120mm, sharp, str,stainless
OF112.01	Prechop.Inamura , round,119mm,stainless
OF120	Fcps Burrato prefolder, 116 mm, titanium
OF121	Fcps IOL folding flat 110 mm, titanium
OF122	Fcps IOL implantation, flat 100 mm, titanium

OF130	Fcps Bonn flat 73x0.063mm, str., titanium
OF130.01	Fcps Bonn flat 73x0.1mm, str., titanium
OF131	Fcps tying flat 73mm, 4mm platform, 0,5mm wide, str., titanium
OF131.01	Fcps tying flat 73mm, 4mm platform, 0,5mm wide, ang., titanium
OF131.02	Fcps tying flat 73mm, 4mm platform, 0,1mm wide, str., titanium
OF131.03	Fcps tying flat 73mm, 4mm platform, 0,1mm wide, ang., titanium
OF132	Fcps flat 98x0.01mm, 45 degree, titanium
OF132.01	Fcps flat 98x0.01mm, 90 degree, titanium
OF133	Fcps tying flat 98mm, 4mm platform, 0,5mm wide, str., titanium
OF133.01	Fcps tying flat 98mm, 4mm platform, 0,5mm wide, ang., titanium
OF133.02	Fcps tying flat 98mm, 4mm platform, 0,1mm wide, str., titanium
OF133.03	Fcps tying flat 98mm, 4mm platform, 0,1mm wide, ang., titanium
OF147.02	Fcps Goldman capsulorhexis round 105mm sharp/round jaws, ang., titanium
OF147.02S	Fcps Goldman capsulorhexis round 105mm sharp/round jaws, ang., stainless
OF147.03	Fcps Goldman capsulorhexis round 105mm sharp/round jaws, ang., titanium
OF147.03S	Fcps Goldman capsulorhexis round 105mm sharp/round jaws, ang., stainless
OF147.05	Fcps Goldman capsulorhexis round 105mm sharp/round jaws, crv., titanium
OF147.05S	Fcps Goldman capsulorhexis round 105mm sharp/round jaws, crv., stainless
OF148	Fcps IOL folding round 110 mm, titanium
OF149	Fcps IOL folding, round 107 mm, titanium
OF150	Prechopper straight round 121 mm, titanium
OF150.01	Prechopper straight round 121 mm, stainless
OF151	Prechopper straight angled 117 mm, titanium
OF151.01	Prechopper straight angled 117 mm, stainless
OF152	Prechopper straight curved 119 mm, titanium
OF152.01	Prechopper straight curved 119 mm, stainless
OF153	Fcps Sieble IOL folding flat 110mm ang., titanium
OF154	Fcps Burrato IOL implantation round 105 mm, titanium
OF155	Fcps IOL folding round 110 mm, titanium
OF156	Fcps Troutman-Barraquer corneal colibri flat 75x0.1mm, titanium, 90 degr.
OF156.01	Fcps Troutman-Barraquer corneal colibri flat 75x0.12mm, titanium 90 degr.
OF156.01S	Fcps Troutman-Barraquer corneal colibri flat 75x0.12mm, stainless 90 degr.
OF156.02	Fcps Troutman-Barraquer corneal colibri flat 75x0.2mm, titanium 90 degr.
OF156.03	Fcps Troutman-Barraquer corneal colibri flat 75x0.4mm, titanium 90 degr.
OF157	Fcps Castroviejo tying flat 105x0.12mm str., titanium 90 degree teeth
OF157.01	Fcps Castroviejo tying flat 105x0.3mm str., titanium 90 degree teeth
OF157.02	Fcps Castroviejo tying flat 105x0.5mm str., titanium 90 degree teeth
OF159	Fcps IOL implantation, flat 110 mm, titanium
OF160	Fcps tying round 103mm V-groove str., titanium
OF160.01	Fcps tying round 103mm V-groove ang., titanium
OF160.02	Fcps tying round 103mm V-groove crv., titanium
OF161	Fcps tying round with holes V-groove 104mm str., titanium
OF161.01	Fcps tying round with holes V-groove 102mm ang., titanium
OF161.02	Fcps tying round with holes V-groove 102mm crv., titanium
OF162	Fcps Utrara capsulorhexis round with holes 107mm sharp str., titanium
OF162.01	Fcps Utrara capsulorhexis round with holes 104mm sharp ang., titanium
OF162.02	Fcps Utrara capsulorhexis round with holes 104mm sharp crv., titanium
OF163	Fcps Maumenee corneal colibri round with holes 104x0.1mm, titanium
OF163.01	Fcps Maumenee corneal round 122x0.12mm, titanium



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**EC Declaration of Conformity
issued in accordance with EC Directive 93/42/EEC
relating to Medical Devices**

NEEDLE HOLDERS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Manufacturer: TITAN SURGICAL LLC.,
100, Vosstaniya Street, bldg. 177, of.2, 420095 Kazan, Republic of Tatarstan, RUSSIA

European representative: CET MSU Portugal Unipessoal Lda
Avenida dos Bons Amigos, 5, 1B, 2735-076, Agualva – Cácia, Portugal

Product name: NEEDLE HOLDERS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Product description: steel and titanium microsurgical non sterile reusable instruments designed for minimally invasive and non-invasive operations in ophthalmic surgery

Class I Medical Device.

Applied directives: MD Directive 93/42/EEC

Applied harmonized standards: ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2007 Medical devices — Application of risk management to medical devices
ISO 7741: 1986 Instruments for surgery -- Scissors and shears -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Applied standards: GOST R ISO 50444-92 Medical instruments, apparatus and equipment. General specifications
GOST 19126-2007 Medical metallic instruments. General specifications
GOST 21241-89 Medical pincers. General technical requirements and test methods
GOST R 53519-2009 Surgical instruments. Haemostatic clamps. Technical requirements and test methods.

The conformity assessment procedure was that of Class I, rule 6 of Annex IX (reusable surgical instruments) of the Medical Device Directive.

MANUFACTURER herewith declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The product – « Set of microsurgical instruments », TITAN SURGICAL LLC., is safe under prescribed and reasonably foreseeable conditions of storage and use.

MANUFACTURER has implemented measures assuring that the « Set of microsurgical instruments », TITAN SURGICAL LLC, of the above mentioned type are safe and fulfill essential requirements of the 93/42/EEC Directive.

MANUFACTURER has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of user's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product. Listing of the microsurgical instruments in attachment

Date of issue: 24th April, 2020

Valid until: 23th April, 2023

TITAN SURGICAL LLC., Director General
Sukhorskiy Andrey



ATTACHMENT LISTING

Wide range of microsurgical reusable instruments of various shapes and sizes, providing minimally invasive and non-invasive surgeries in ophthalmic surgery. There are instruments of the following forms:

OH001	NdleHold.-Sciss. round 140x3.5/7.5mm str. stainless
OH002	NdleHold.-Sciss. round 140x3.5/7.5mm crv. stainless
OH002L	NdleHold.-Sciss. round 140x3.5/7.5mm L crv. Titanium
OH003	NdleHold.-Sciss. round 135x2.5/6.5mm crv. stainless
OH005	Ndle Hold. Kalt flat 135x10,5mm str., titanium
OH005.01	Ndle Hold. Kalt flat 135x10,5mm crv., titanium
OH006	Ndle Hold. Tennant round 135x11mm crv., titanium
OH006L	Ndle Hold. Tennant round 135x11mm L crv., titanium
OH006U	Ndle Hold. Tennant round 135x11mm UL crv., titanium
OH007	Ndle Hold. Cohan round 100x7.5mm crv., titanium
OH007.01	Ndle Hold. Cohan round 100x7.5mm str., titanium
OH007.01L	Ndle Hold. Cohan round 100x7.5mm L str., titanium
OH007.01U	Ndle Hold. Cohan round 100x7.5mm UL str., titanium
OH007L	Ndle Hold. Cohan round 100x7.5mm L crv., titanium
OH007U	Ndle Hold. Cohan round 100x7.5mm UL crv., titanium
OH008	Ndle Hold. Barraquer round 100x8.5mm crv., titanium
OH008.01	Ndle Hold. Barraquer round 100x8.5mm str., titanium
OH008.01L	Ndle Hold. Barraquer round 100x8.5mm L str., titanium
OH008.01U	Ndle Hold. Barraquer round 100x8.5mm UL str., titanium
OH008L	Ndle Hold. Barraquer round 100x8.5mm L crv., titanium
OH008U	Ndle Hold. Barraquer round 100x8.5mm UL crv., titanium
OH009	Ndle Hold. Castroviejo round 125x11mm crv., titanium
OH009L	Ndle Hold. Castroviejo round 125x11mm L crv., titanium
OH009U	Ndle Hold. Castroviejo round 125x11mm UL crv., titanium
OH010	Ndle Hold. Castroviejo round 125x11mm str., titanium
OH010U	Ndle Hold. Castroviejo round 125x11mm UL str., titanium
OH011	Ndle Hold. Barraquer round 125x7.5mm crv., titanium
OH011U	Ndle Hold. Barraquer round 125x7.5mm UL crv., titanium
OH012	Ndle Hold. Castroviejo round 125x7.5mm str., titanium
OH012U	Ndle Hold. Castroviejo round 125x7.5mm str., titanium, Univ lock
✓ OH013	Ndle Hold. Barraquer round 125x9.5mm crv., titanium
OH013L	Ndle Hold. Barraquer round 125x9.5mm W/L crv., titanium
OH013U	Ndle Hold. Barraquer round 125x9.5mm UL crv., titanium
OH014	Ndle Hold. Tennant round 135x11mm crv., titanium
OH015	Ndle Hold. Barraquer round 100x9.5mm crv., titanium
OH015.01	Ndle Hold. Barraquer round 100x9.5mm str., titanium
OH015L	Ndle Hold. Barraquer round 100x9.5mm L crv., titanium
OH015U	Ndle Hold. Barraquer round 100x9.5mm UL crv., titanium
OH016	Ndle Hold. Bechert-Sinskey round 100x7.5mm str., titanium
OH016U	Ndle Hold. Bechert-Sinskey round 100x7.5mm UL str., titanium
OH017	Ndle Hold. Bechert-Sinskey round 125x8mm str., titanium
OH018	Ndle Hold. Bechert-Sinskey round 125x8mm str., titanium
OH019	Ndle Hold. McPherson round 125x10.5mm crv., titanium
OH019L	Ndle Hold. McPherson round 125x10.5mm L crv., titanium
OH019U	Ndle Hold. McPherson round 125x10.5mm UL crv., titanium
OH020	Ndle Hold. Barraquer round 125x9.5mm crv., titanium
OH020.01	Ndle Hold. Barraquer round 125x9.5mm str., titanium



«Titan Surgical» LLC.

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**EC Declaration of Conformity
issued in accordance with EC Directive 93/42/EEC
relating to Medical Devices**

SCISSORS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Manufacturer: TITAN SURGICAL LLC.,
100, Vosstaniya Street, bldg. 177, of.2, 420095 Kazan, Republic of Tatarstan, RUSSIA

European representative: CET MSU Portugal Unipessoal Lda
Avenida dos Bons Amigos, 5, 1B, 2735-076, Agualva – Cácerem, Portugal

Product name: SCISSORS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Product description: steel and titanium microsurgical non sterile reusable instruments designed for minimally invasive and non-invasive operations in ophthalmic surgery

Class I Medical Device.

Applied directives: MD Directive 93/42/EEC

Applied harmonized standards: ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2007 Medical devices — Application of risk management to medical devices
ISO 7741: 1986 Instruments for surgery -- Scissors and shears -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Applied standards: GOST R ISO 50444-92 Medical instruments, apparatus and equipment. General specifications
GOST 19126-2007 Medical metallic instruments. General specifications
GOST 21241-89 Medical pincers. General technical requirements and test methods
GOST R 53519-2009 Surgical instruments. Haemostatic clamps. Technical requirements and test methods.

The conformity assessment procedure was that of Class I, rule 6 of Annex IX (reusable surgical instruments) of the Medical Device Directive.

MANUFACTURER herewith declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The product – « Set of microsurgical instruments », TITAN SURGICAL LLC., is safe under prescribed and reasonably foreseeable conditions of storage and use.

MANUFACTURER has implemented measures assuring that the « Set of microsurgical instruments », TITAN SURGICAL LLC, of the above mentioned type are safe and fulfill essential requirements of the 93/42/EEC Directive.

MANUFACTURER has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of user's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product. Listing of the microsurgical instruments in attachment

Date of issue: 24th April, 2020

Valid until: 23th April, 2023

TITAN SURGICAL LLC., Director General
Sukhorskiy Andrey



ATTACHMENT LISTING

Wide range of microsurgical reusable instruments of various shapes and sizes, providing minimally invasive and non-invasive surgeries in ophthalmic surgery. There are instruments of the following forms:

OS001	Sciss. Westcott curved, flat 120x16.5mm blunt, stainless
OS001.01	Sciss. Westcott curved, flat 117x13mm blunt, stainless
OS002	Sciss. Castroviejo round 105x9 mm crv., sharp, stainless
OS003	Sciss. Vannas flat 115x9mm str., sharp, stainless
OS004	Sciss. Vannas flat 115x9mm crv., sharp, stainless
OS004.01	Sciss. Vannas flat 115x9mm crv., sharp, titanium
OS005	Sciss. Vannas flat 115x9mm ang., sharp, stainless
OS006	Sciss. Noyes flat 105x12mm str., sharp, stainless
OS006.01	Sciss. Noyes flat 105x12mm str. sharp/blunt, stainless
OS006.02	Sciss. Noyes flat 105x12mm str., blunt, stainless
OS007	Sciss. Castroviejo flat 100x8 mm crv., sharp, stainless
OS007.02	Sciss. Castroviejo round 105x8 mm crv, sharp, stainless
OS008	Sciss. Vannas flat 84x9.5mm str., sharp, stainless
OS008.01	Sciss. Vannas flat 80x5.5mm str., sharp stainless
OS009	Sciss. Vannas flat 84x9.5mm crv., sharp stainless
OS009.01	Sciss. Vannas flat 80x5.5mm crv., sharp stainless
OS009.02	Sciss. Vannas flat 86x12mm crv., sharp stainless
OS010	Sciss. Vannas flat 81x9.5mm ang., sharp, stainless
OS010.01	Sciss. Vannas flat 80x5.5mm ang., sharp, stainless
OS011	Sciss. Vannas flat 81x9.5mm ang., sharp, stainless
OS011.01	Sciss. Vannas flat 80x5.5mm ang., sharp, stainless
OS012	Sciss. Castroviejo Universal flat 105x14mm crv., blunt, stainless
OS012.01	Sciss. Castroviejo Universal flat 105x14mm str., sharp, stainless
OS013	Sciss. Conjunctival round 108x11mm crv., blunt, stainless
OS014	Sciss. Conjunctival flat 100x11.5mm crv., sharp, stainless
OS014T	Sciss. Conjunctival flat 100x11.5mm crv., sharp, titanium
OS014.01	Sciss. Conjunctival flat 100x11.5mm str., sharp, stainless
OS014.01T	Sciss. Conjunctival flat 100x11.5mm str., sharp, titanium
OS015	Sciss. Anterior Capsulotomy round 82x10mm ang., sharp, stainless
OS015.01	Sciss. Anterior Capsulotomy round 90x15,5mm crv., sharp, stainless
OS016	Sciss. Vannas round 84x8.5mm crv., sharp, stainless
OS016.01	Sciss. Vannas round 80x6mm crv., sharp, stainless
OS016.02	Sciss. Vannas round 80x6mm str., sharp, stainless
OS016.03	Sciss. Vannas round 87x12mm crv., blunt, stainless
OS017	Sciss. Katzin round 100x7mm R. crv., sharp, stainless
OS017.01	Sciss. Katzin round 100x7mm L. crv., sharp, stainless
OS018	Sciss. Castroviejo Universal round 110x13.5mm crv., blunt, stainless
OS018.02	Sciss. Castroviejo Universal flat 110x13.5mm crv., blunt, stainless
OS018.03	Sciss. Castroviejo Universal round 110x11mm crv., blunt, stainless
OS019	Sciss. Troutman-Castroviejo flat 105x9.5mm R. crv., blunt, stainless
OS020	Sciss. Troutman-Castroviejo flat 105x9.5mm L. crv., blunt, stainless
OS021	Sciss. Anterior Capsulotomy flat 90x10mm ang., sharp, stainless
OS021.01	Sciss. Anterior Capsulotomy flat 90x10mm crv., sharp, stainless
OS022	Sciss. Vannas flat 90x8.5mm crv., sharp, stainless
OS023	Sciss. Tenotomy flat 105x12mm str., blunt, stainless
OS023.01	Sciss. Tenotomy flat 115x13mm crv., blunt, stainless
OS024	Sciss. Castroviejo flat 100x10.5mm R. crv., blunt, stainless
OS024.01	Sciss. Castroviejo flat 100x11mm R. crv., blunt, titanium
OS025	Sciss. Castroviejo flat 100x10.5mm L. crv., blunt, stainless
OS025.01	Sciss. Castroviejo flat 100x11mm L. crv., blunt, titanium
OS026	Sciss. Vannas flat 90x10mm ang., sharp, stainless
OS026.01	Sciss. Vannas flat 95x15mm crv., blunt, stainless
OS026.02	Sciss. Vannas flat 90x10mm ang., sharp, titanium
OS027	Sciss. Vannas double action 106x6mm str., sharp stainless-titanium
OS027.01	Sciss. Vannas double action 106x6mm crv., sharp, stainless-titanium
OS027.02	Sciss. Vannas double action 105x5,5mm ang., sharp, stainless-titanium
OS028	Sciss. Castroviejo flat 105x11mm R. crv., blunt, stainless
OS028.01	Sciss. Castroviejo flat 105x11mm L. crv., blunt, stainless

OS029	Sciss. Anterior Capsulotomy flat 98x6,5mm ang., stainless
OS039	Sciss. Westcott curved, round 120x16mm blunt, stainless
OS039.01	Sciss. Westcott curved, flat 120x16mm blunt, stainless
OS041	Sciss. Vannas round 84x8.5mm crv.,sharp, titanium
OS042	Sciss. Castroviejo flat corneal 100x8mm crv., sharp,titanium
OS043	Sciss. Castroviejo Universal round 110x13.5mm crv., blunt,titanium
OS044	Sciss. Vannas flat 84x9.5mm crv., sharp,titanium
OS044.01	Sciss. Vannas flat 81x6mm str., sharp,titanium
OS045	Sciss. Castroviejo flat 94x7mm crv.,sharp, stainless-titanium
OS045.01	Sciss. Castroviejo flat 94x7mm blunt crv., stainless-titanium
OS046	Sciss. Troutman-Castroviejo flat 104x9.5mm R. crv., blunt,titanium
OS046.01	Sciss. Troutman-Castroviejo flat 104x9.5mm L. crv., blunt,titanium
OS046.02	Sciss. Troutman-Castroviejo flat 102x6.5mm R. crv., blunt,stainless/titanium
OS046.03	Sciss. Troutman-Castroviejo flat 102x6.5mm L. crv., blunt,stainless/titanium
OS047	Sciss. Castroviejo flat 104x11mm R. crv., blunt,titanium
OS047.01	Sciss. Castroviejo flat 104x11mm L. crv., blunt,titanium
OS047.02	Sciss. Castroviejo flat 103x7mm L. crv., blunt,stainless/titanium
OS047.03	Sciss. Castroviejo flat 103x7mm R. crv., blunt,stainless/titanium
OS048	Sciss. Vannas round with holes 104x8.5mm crv.,sharp, st.-titanium
OS049	Sciss. Vannas flat 80x5.2mm sharp crv., stainless-titanium
OS049.01	Sciss. Vannas flat 80x5.2mm blunt crv., stainless-titanium
OS049.02	Sciss. Vannas flat 80x5.2mm sharp str., stainless-titanium
OS051	Sciss. Westcott curved, flat 120x16.5mm blunt, stainless-titanium
OS051.01	Sciss. Westcott curved, flat 120x16.5mm sharp, stainless-titanium
OS052	Sciss. Anterior Capsulotomy round 82x10mm ang., stainless-titanium
OS053	Sciss. Westcott curved, flat 120x17mm blunt, stainless-titanium
OS054	Sciss. Westcott curved, round 120x16,5mm blunt, stainless-titanium
OS054.01	Sciss. Westcott str.round 120x17mm blunt, stainless-titanium
OS054.02	Sciss. Westcott curved, round 120x17mm blunt, stainless
OS055	Sciss. Westcott straight, flat 120x17mm sharp, stainless-titanium
OS056	Sciss. Westcott curved, flat 120x16.5mm sharp, stainless-titanium
OS056.01s	Sciss. Westcott curved, flat 117x12.5mm sharp, stainless
OS056.02s	Sciss. Westcott curved, flat 140x16.5mm sharp, stainless
OS056.03s	Sciss. Westcott curved, flat 120x15.8mm sharp, stainless
OS056s	Sciss. Westcott curved, flat 120x16.5mm sharp, stainless
OS058	Sciss. muscle angled, flat 108x11.5mm R, blunt,stainless-titanium
OS059	Sciss. muscle angled, flat 108x11.5mm L, blunt,stainless-titanium
OS060	Sciss. for plastic serrated crv, flat 140x20.5mm, blunt,stainless-titanium
OS061	Sciss. Castroviejo Univer. round 110x13mm crv., blunt,stainless-titanium
OS062	Sciss. str, flat 108x9.7mm,sharp, stainless
OS062.01	Sciss. crv, flat 108x9.7mm, sharp,stainless
OS063	Sciss. Westcott curved, round 120x16.5mm, titanium
OS063.01	Sciss. Westcott curved, round 90x17mm, titanium
OS064	Sciss. ang, round 112x11.5mm, blunt,stainless-titanium
OS065	Sciss. Westcott curved, flat 110x20mm blunt, stainless
OS066	Sciss. Vannas straight, flat 110x7,2mm sharp stainless-titanium
OS067	Sciss. Westcott curved, flat 110x12mm sharp, stainless-titanium
OS068	Sciss. Vannas str., flat 110x6,5mm sharp stainless
OS068.01	Sciss. Vannas crv., flat 110x6,5mm sharp stainless
OS069	Sciss. Westcott curved, flat 114x20,5mm, stainless
OS070	Sciss. Noyes flat 99x10mm str.,very sharp, stainless
OS070.01	Sciss. Noyes flat 99x10mm str.,sharp, stainless
OS071	Sciss. crv, flat 90x9.5mm,blunt, stainless
OS072	Sciss. Westc/Stitch curved, flat 120x16mm sharp, stainless
OS072.01	Sciss. Westc/Stitch curved, flat 120x16mm blunt, stainless
OS072.02	Sciss. Westc/Stitch curved, flat 100x14mm blunt, stainless
OS 073	Sciss. Westc/Stitch curved, flat 120x21mm sharp, stainless
OS 074	Sciss. Westcott curved, flat 140mm,blades 22mm sharp , stainless
OS075	Sciss. Angl to side flat 102x8,7mm, blunt,stainless
OS076	Sciss. Vannas flat with hole 96 x8,8 mm crv.,sharp titanium
OS076.01	Sciss. Vannas flat with hole 96 x8 mm crv.,sharp st/titanium



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**EC Declaration of Conformity
issued in accordance with EC Directive 93/42/EEC
relating to Medical Devices**

CHOPPERS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Manufacturer: TITAN SURGICAL LLC.,
100, Vosstaniya Street, bldg. 177, of.2, 420095 Kazan, Republic of Tatarstan, RUSSIA

European representative: CET MSU Portugal Unipessoal Lda
Avenida dos Bons Amigos, 5, 1B, 2735-076, Agualva – Cácer, Portugal

Product name: CHOPPERS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Product description: steel and titanium microsurgical non sterile reusable instruments designed for minimally invasive and non-invasive operations in ophthalmic surgery

Class I Medical Device.

Applied directives: MD Directive 93/42/EEC

Applied harmonized standards: ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2007 Medical devices — Application of risk management to medical devices
ISO 7741: 1986 Instruments for surgery -- Scissors and shears -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Applied standards: GOST R ISO 50444-92 Medical instruments, apparatus and equipment. General specifications
GOST 19126-2007 Medical metallic instruments. General specifications
GOST 21241-89 Medical pincers. General technical requirements and test methods
GOST R 53519-2009 Surgical instruments. Haemostatic clamps. Technical requirements and test methods.

The conformity assessment procedure was that of Class I, rule 6 of Annex IX (reusable surgical instruments) of the Medical Device Directive.

MANUFACTURER herewith declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The product – « Set of microsurgical instruments », TITAN SURGICAL LLC., is safe under prescribed and reasonably foreseeable conditions of storage and use.

MANUFACTURER has implemented measures assuring that the « Set of microsurgical instruments », TITAN SURGICAL LLC, of the above mentioned type are safe and fulfill essential requirements of the 93/42/EEC Directive.

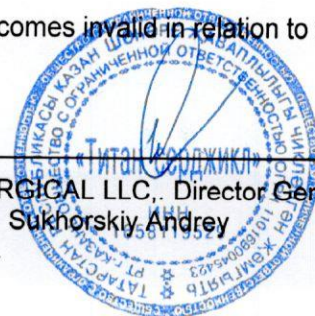
MANUFACTURER has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of user's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product. Listing of the microsurgical instruments in attachment

Date of issue: 24th April, 2020

Valid until: 23th April, 2023

TITAN SURGICAL LLC., Director General
Sukhorskiy Andrey



ATTACHMENT LISTING

Wide range of microsurgical reusable instruments of various shapes and sizes, providing minimally invasive and non-invasive surgeries in ophthalmic surgery. There are instruments of the following forms:

OK001	Knife Sato 120mm, t/h
OK002	Knife Lens Crushing 120mm, t/h
OK002.01	Knife Lens Crushing 120mm, t/h
OK003	Cystotome ang. 120mm, t/h
OK003.01	Cystotome ang. 120mm, t/h
OK003.02	Cystotome ang. 120mm, t/h
OK003.03	Cystotome ang. 120mm, t/h
OK004	Knife Drisdale Lens Crushing 120mm ang., t/h
OK005	Knife Drisdale Lens Crushing 120mm crv., t/h
OK005.01	Scraper 120mm crv., t/h
OK010	Phacochoopper ang. 1.5mm 120mm, titanium
OK010.01	Phacochoopper ang. 1.3mm 120mm, titanium
OK010.02	Phacochoopper ang. 1.0mm 120mm, titanium
OK010.02S	Phacochoopper ang. 1.0mm 120mm, stainless
OK011	Spud Golf Club 120mm, t/h
OK012	Spud Foreign Body 120mm, t/h
OK013	Spud Davis Foreign Body 120mm, t/h
OK014	Spud Foreign Body 120mm, t/h
OK019	Phacochoopper angled large, 110 mm, t/h
OK019.01	Phacochoopper angled large, 110 mm, t/h
OK019S	Phacochoopper angled large, 110 mm, stainless
OK020	Phacochoopper angled large, 110 mm, t/h
OK021	Phacochoopper Daniel-Walkow angled large, 110 mm, t/h
OK021.01	Phacochoopper angled large, 110 mm, t/h
OK022	Hook and phacochoopper, 120 mm t/h
OK022.01	Hook and phacochoopper, 120 mm t/h
OK023	Rosen Phacochoopper universal, 110 mm 1,0mm t/h
OK023.01	Rosen Phacochoopper universal, 110 mm 0,9mm t/h
OK023.02	Rosen Phacochoopper universal, 110 mm 0,6mm t/h
OK025	Suarez sprader, 115mm, titanium
OK026	Nichamin chopper, 115mm, titanium
OK026.01	Knife for crushing the nuclear, 112mm, t/h
OK027	Seibel nucleus chopper/trident splitter 134mm, t/h
OK028	Seibel chopper 110mm, ball 0,5mm t/h
OK028.01	Seibel chopper 110mm,ball 0,45mm t/h
OK030	Phaco splitter 112mm, t/h
OK032	Hokey epithelium removal knife for PRK 120mm, t/h
OK034	Chang Chopper, Double-Ended, Right Handed Doctor, 129mm, t/h
OK034.01	Chang Chopper, Double-Ended, Left Handed Doctor, 129mm, t/h
OK034.02	Chang Chopper, Right Handed Doctor, 125mm, t/h
OK034.03	Chang Chopper, Left Handed Doctor, 125mm, t/h
OK035	Phaconit Quick Chopper, 116mm, t/h
OK035.01	Phaconit Quick Chopper, 107mm, t/h
OK035.02	Quick Chopper, ang.,107mm, t/h
OK035.03	Quick Chopper, ang.,111mm, t/h
OK035.04	Quick Chopper, ang.,107mm, t/h



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**EC Declaration of Conformity
issued in accordance with EC Directive 93/42/EEC
relating to Medical Devices**

SPATULAS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Manufacturer: TITAN SURGICAL LLC.,
100, Vosstaniya Street, bldg. 177, of.2, 420095 Kazan, Republic of Tatarstan, RUSSIA

European representative: CET MSU Portugal Unipessoal Lda
Avenida dos Bons Amigos, 5, 1B, 2735-076, Agualva – Cácem, Portugal

Product name: SPATULAS OPHTHALMOLOGICAL REUSABLE NON-STERILE

Product description: steel and titanium microsurgical non sterile reusable instruments designed for minimally invasive and non-invasive operations in ophthalmic surgery

Class I Medical Device.

Applied directives: MD Directive 93/42/EEC

Applied harmonized standards: ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2007 Medical devices — Application of risk management to medical devices
ISO 7741: 1986 Instruments for surgery -- Scissors and shears -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods. EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Applied standards: GOST R ISO 50444-92 Medical instruments, apparatus and equipment. General specifications
GOST 19126-2007 Medical metallic instruments. General specifications
GOST 21241-89 Medical pincers. General technical requirements and test methods
GOST R 53519-2009 Surgical instruments. Haemostatic clamps. Technical requirements and test methods.

The conformity assessment procedure was that of Class I, rule 6 of Annex IX (reusable surgical instruments) of the Medical Device Directive.

MANUFACTURER herewith declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The product – « Set of microsurgical instruments », TITAN SURGICAL LLC., is safe under prescribed and reasonably foreseeable conditions of storage and use.

MANUFACTURER has implemented measures assuring that the « Set of microsurgical instruments », TITAN SURGICAL LLC, of the above mentioned type are safe and fulfill essential requirements of the 93/42/EEC Directive.

MANUFACTURER has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of user's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

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ATTACHMENT LISTING

Wide range of microsurgical reusable instruments of various shapes and sizes, providing minimally invasive and non-invasive surgeries in ophthalmic surgery. There are instruments of the following forms:



OT001	Spatula 120x0.5mm, t/h
OT001.01	Spatula 120x1.0mm, t/h
OT001.02	Spatula 120x1.5mm, t/h
OT001.03	Barraquer cyclodialysis spatula, 120mm, ang. 90°, 0.5 x 15mm rounded blade, smoothly pointed tip, t/h
OT001.04	Dementiev PRL Microspatula 90mm stainless
OT001.05	Spatula 120x0.5mm, t/h
OT001.07	Spatula 121x2,0mm, t/h
OT001.08	Spatula 120x1.5mm, t/h
OT002	Hirshman Iris Lens Spatula, 13mm Angled Tip, 120mm t/h
OT003	Spatula Double 130x0.5/1.0mm, t/h
OT004	Spatula Kimura Platinum 150x4mm
OT005	Spatula Barraquer Cyclodialysis 120x0.25mm ang., t/h
OT005.01	Spatula Barraquer Cyclodialysis 120x0.5mm ang., t/h
OT005.02	Spatula Barraquer Cyclodialysis 120x0.75mm ang., t/h
OT005.03	Spatula Barraquer Cyclodialysis 120x1.00mm ang., t/h
OT005.04	Spatula Barraquer Cyclodialysis 120x7,5mm ang., titanium
OT005.05	Spatula Barraquer Cyclodialysis 120mm ang., titanium
OT005.06	Spatula Barraquer Cyclodialysis 112x0.45mm ang., t/h
OT005.07	Spatula Barraquer Cyclodialysis 116x0,5mm ang., t/h
OT006	Spatula Castroviejo Double 153x0.25/0.5mm, t/h
OT006.01	Spatula Castroviejo Double 153x0.5/0.75mm, t/h
OT006.02	Spatula Castroviejo Double 153x0.75/1,0mm, t/h
OT007	Spatula Castroviejo Double 132x0.4/0.5mm, t/h
OT007.01	Spatula Castroviejo Double 132x0.4/0.5mm, titanium
OT008	Lindstrom LASIK / PRK spatula, 140 mm
OT009	Koch nucleus spatula, 111 mm, tip 0,5mm, t/h
OT009.01	Koch nucleus spatula, 111 mm, tip 0,6mm, t/h
OT009.02	Koch nucleus spatula, 111 mm, tip 0,5mm, t/h
OT009.03	Koch nucleus spatula, 111 mm, tip 0,6mm, t/h
OT010	Koch nucleus spatula/Hook Sinskey, 109 mm t/h
OT011	Tenzel double-ended Periosteal Elevator 192mm t/h
OT011.02	Double-ended Elevator 200mm t/h
OT012	Spatula/hook Sinskey 110mm, t/h
OT013	Spatula/nucleus rotator 126mm, t/h
OT014	Paton double-ended spatula and spoon 153mm, t/h
OT015	Castroviejo Cyclodialysis Spatula 115mm/ t/h
OT015.01	Castroviejo Cyclodialysis Spatula 121mm/ t/h
OT016	Spatula with 2 teeth 0,5mm 141mm t/h
OT017	Phaco spatula 109mm, t/h
OT017.01	Phaco spatula 109mm, titanium
OT018.01	Eye Spatula, 109mm, tip 0.6 x 0.4 mm wide t/h
OT019	Bahamond Flap LASIK Spatula 116mm t/h
OT020	Bahamond Retreatment LASIK Spatula 116mm t/h
OT021	Bahamon LASIK Flap, Double Spatula 111mm t/h
OT022	LASEK Detaching Spatula 111mm t/h