

"Titan Surgical" LLC

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EC DECLARATION OF CONFORMITY

Manufacturer's Name

"Titan Surgical" LLC

and Address

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

 ${\sf CA,PD,PR,PT,RE,VD,VE,VF,VH,VL,VS,VZ,ZT,OB,OC,OCT,OD,OE,OF,OG,OH,OJ,}$

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 Sulmorskiy

General Director

ИНН 658119529 э