



"Titan Surgical" LLC

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2020 May, 25

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, 12 Chemin des Joncs, 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



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