



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

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

***"RUMEX Instruments" Ltd.***

*34, Sibirsky tract Str., building 4, 420029, Kazan, Republic of Tatarstan, Russia  
has implemented and maintains a*

***Quality Management System***

*for the following scope:*

**design, manufacture, sale of medical surgical and  
microsurgical instruments for ophthalmic,  
cardiological and general surgery**

*which fulfils the requirements of the following standard:*

## ISO 13485:2016


**Issued on: 14<sup>th</sup> January, 2019**

**Expires on: 14<sup>th</sup> January, 2022**

*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-19.0010.026**



  
**Alex Stoichitoiu**  
**President of IQNet**

  
**Arkady Vladimirtsev,**  
**Director General of**  
**Russian Register**



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## ***ANNEX 1 to IQNet Certificate***

***Number RU-19.0010.026***

### ***Certification scope of the management system of "RUMEX Instruments" Ltd.***

1. Product / service: design, manufacture, sale of medical surgical and microsurgical instruments for ophthalmic, cardiological and general surgery.
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



  
*Alex Stoichitoiu*  
 President of IQNet

  
*Arkady Vladimirtsev,*  
 Director General of  
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