



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, 2022*

*Expires on: 14<sup>th</sup> January, 2025*

*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-22.0015.026**



*Alex Stoichitoiu  
President of IQNet*

*Arkady Vladimirtsev,  
Director General of  
Russian Register*



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

***Number RU-22.0015.026***

### ***Certification scope of 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 equipment
3. Exclusions from the processes of product realization: 7.5.3, 7.5.5, 7.5.7, 7.5.9.2, 8.2.6 (in terms of implantable medical devices).



  
*Alex Stoichitoiu*  
*President of IQNet*

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



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