



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

*CISQ/IMQ has issued an IQNet recognized certificate that the organization:*

**BIOLINK LTD.**

NIKOLAEVA STREET 13, OFFICE 205, NOVOSIBIRSK, 630090, RUSSIAN FEDERATION

*has implemented and maintains a*

*Quality Management System*

*for the following scope:*

***Design, development and production of medical devices for in vitro diagnostics***

*Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization*

*which fulfills the requirements of the following standard:*

**ISO 13485:2016**

*Issued on: 2021 - 02 - 22*

*Expires on: 2024 - 02 - 21*

*This attestation is directly linked to the IQNet Partner's original certificate  
and shall not be used as a stand-alone document*

**Registration Number: IT - 131520**



*Alex Stoichitoiu*  
**President of IQNET**



*Ing. Mario Romersi*  
**President of CISQ**

**IQNet Partners\*:**

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\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)





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CERTIFICATE N.  
СЕРТИФИКАТ № 0198.2021



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.  
IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY  
НАСТОЯЩИМ ПОДТВЕРЖДАЕМ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА, ДЕЙСТВУЮЩАЯ В

**BIOLINK LTD.**

NIKOLAEVA STREET 13, OFFICE 205, NOVOSIBIRSK, 630090, RUSSIAN FEDERATION

**ООО «БИОЛИНК»**

РОССИЙСКАЯ ФЕДЕРАЦИЯ, 630090, Г. НОВОСИБИРСК, УЛИЦА НИКОЛАЕВА, 13, ОФИС 205

ПРОИЗВОДСТВЕННЫЕ ПЛОЩАДКИ  
по следующим адресам:  
PRODUCTION UNITS  
at the following addresses:

NIKOLAEVA STREET 13, OFFICE 205, NOVOSIBIRSK, 630090, RUSSIAN FEDERATION

РОССИЙСКАЯ ФЕДЕРАЦИЯ, 630090, Г. НОВОСИБИРСК, УЛИЦА НИКОЛАЕВА, 13, ОФИС 205

IS IN COMPLIANCE WITH THE STANDARD / СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ СТАНДАРТА

**ISO 13485:2016**

FOR THE FOLLOWING ACTIVITIES / ДЛЯ СЛЕДУЮЩЕЙ ОБЛАСТИ ДЕЯТЕЛЬНОСТИ

Design, development and production of medical devices for in vitro diagnostics

Проектирование, разработка и производство медицинских изделий для диагностики in vitro

Refer to quality management system manual for details of applications to ISO 13485:2016 requirements  
В руководстве системы менеджмента качества организации уточнены детали применения требований ISO 13485:2016

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS  
OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS  
ИСПОЛЬЗОВАНИЕ И СРОК ДЕЙСТВИЯ СЕРТИФИКАТА ДОЛЖНЫ УДОВЛЕТВОРЯТЬ  
ТРЕБОВАНИЯМ ПРАВИЛ ПО СЕРТИФИКАЦИИ СИСТЕМ МЕНЕДЖМЕНТА

DATE: FIRST CERTIFICATION  
ДАТА: ПЕРВИЧНАЯ СЕРТИФИКАЦИЯ  
2021-02-22

CURRENT ISSUE  
ДАТА ВЫПУСКА  
2021-02-22

EXPIRY  
СРОК ДЕЙСТВИЯ  
2024-02-21

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY  
Management Systems Division - Flavio Orago  
Only the English text is authentic



www.cisq.com



SGQ N° 005 A  
Membro degli Accordi di Mutuo  
Riconoscimento EA, IAF e ILAC  
Signatory of EA, IAF and ILAC  
Mutual Recognition Agreements

The validity of the certificate is submitted to annual audit and a reassessment  
off the entire management System within three years

Organismo di Certificazione Federato CISQ  
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CISQ è la Federazione Italiana di Organismi di  
Certificazione dei sistemi di gestione aziendale.  
CISQ is the Italian Federation of management  
system Certification Bodies.