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СЕРТИФИКАТ №.
CERTIFICATE N. 9124.AMA3

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

Общество с ограниченной ответственностью
«Ассоциация Медицины и Аналитики»

199034, Российская Федерация, Санкт-Петербург, 17-я линия В.О., д. 4-6, литер Е, помещение 1Н

«Association of Medicine and Analytics» Company Limited

4-6, Room 1N, Liter E, 17 line of Vasilievsky Island, Saint-Petersburg, 199034, Russian Federation

ПОДРАЗДЕЛЕНИЯ
ПО СЛЕДУЮЩИМ АДРЕСАМ:
UNITS
AT THE FOLLOWING ADDRESSES:

См. Приложение к сертификату с информацией по подразделениям ()*
View the annex for the units ()*

соответствует требованиям стандарта
IS IN COMPLIANCE WITH THE STANDARD
ISO 13485:2016

ДЛЯ СЛЕДУЮЩЕЙ ОБЛАСТИ ДЕЯТЕЛЬНОСТИ
FOR THE FOLLOWING ACTIVITIES

Разработка, производство и поставка комплексных тест-систем и
средств для in vivo и in vitro диагностики
*Design, manufacturing and supply of integrated test-systems and
tools for in vivo and in vitro diagnostics*

Refer to quality management system manual for details of applications to ISO 13485:2016 requirements

Ссылка на Руководство по системе менеджмента качества для уточнения деталей применения к требованиям ISO 13485:2016

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

ДАТА: ПЕРВИЧНАЯ СЕРТИФИКАЦИЯ
DATE: FIRST CERTIFICATION
2015-10-19

ДАТА ВЫПУСКА
CURRENT ISSUE
2021-09-10

СРОК ДЕЙСТВИЯ
EXPIRY DATE
2024-10-18

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Management Systems Division - Flavio Ornago

Only the English text is authentic



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SGQ N° 005 A
*Signatory of EA, IAF and ILAC
Mutual Recognition Agreements*

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

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CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale.
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ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ № 9124.AMA3-1
ANNEX N. 9124.AMA3-1



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ДЛЯ СЛЕДУЮЩЕЙ ОБЛАСТИ ДЕЯТЕЛЬНОСТИ:
Activities:

Разработка и поставка комплексных тест-систем и средств для
in vivo и in vitro диагностики

*Design and supply of integrated test-systems and tools
for in vivo and in vitro diagnostics*

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT
OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO «Association of Medicine and Analytics» Company Limited
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9124.AMA3

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ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ № 9124.AMA3-2
ANNEX N. 9124.AMA3-2

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4-6, 17 line of Vasilievsky Island, Saint-Petersburg, 199034, Russian Federation

ДЛЯ СЛЕДУЮЩЕЙ ОБЛАСТИ ДЕЯТЕЛЬНОСТИ:

Activities:

Производство комплексных тест-систем и средств для in vivo и in vitro диагностики

Manufacturing of integrated test-systems and tools for in vivo and in vitro diagnostics

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT
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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

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

ASSOCIATION OF MEDICINE AND ANALYTICS CO LTD

4-6, ROOM 1N, LITER E, 17 LINE OF VASILIEVSKY ISLAND - SAINT-PETERSBURG,
199034 RUSSIAN FEDERATION

4-6, 17 LINE OF VASILIEVSKY ISLAND - SAINT-PETERSBURG,
199034 RUSSIAN FEDERATION

has implemented and maintains a

Quality Management System

for the following scope:

***Design, manufacturing and supply of integrated test-systems and
tools for in vivo and 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 - 09 - 10

Expires on: 2024 - 10 - 18

*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 - 101226



Alex Stoichitoiu
President of IQNET



Ing. Mario Romersi
President of CISQ

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SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia