



www.imq.it

CISQ is a member of



THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

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.

СЕРТИФИКАТ №.
CERTIFICATE N. 9120.AMA2

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 9001:2015

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

*Ссылка на Руководство по интегрированной системе менеджмента для уточнения
деталей применения к требованиям ISO 9001:2015*

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

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
2018-10-03

СРОК ДЕЙСТВИЯ
EXPIRY DATE
2021-10-19

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

Validity termination date for standard transition deadline: 2018-09-15
Transition and renewal decision date: 2018-10-03



SGQ № 005 A

*Signatory of EA, IAF and ILAC
Mutual Recognition Agreements*

IAF: 19

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



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

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



www.imq.it

CISQ is a member of



THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

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.

ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ № 9120.AMA2-1 ANNEX N. 9120.AMA2-1

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

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

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. 9120.AMA2

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

ДАТА ВЫПУСКА
CURRENT ISSUE
2018-10-03

СРОК ДЕЙСТВИЯ
EXPIRY
2021-10-19

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

Validity termination date for standard transition deadline: 2018-09-15
Transition and renewal decision date: 2018-10-03



www.cisq.com

Organismo di Certificazione Federato CISQ
www.imq.it

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



SGQ N° 005 A

Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

This document is a part of certificate n. 9120.AMA2

IAF: 19

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



www.imq.it

CISQ is a member of



THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

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.

ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ № 9120.AMA2-2 ANNEX N. 9120.AMA2-2

199034, Российская Федерация, Санкт-Петербург, 17-я линия В.О., д.4-6
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
Manufacture 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. 9120.AMA2

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

ДАТА ВЫПУСКА
CURRENT ISSUE
2018-10-03

СРОК ДЕЙСТВИЯ
EXPIRY
2021-10-19

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

Validity termination date for standard transition deadline: 2018-09-15
Transition and renewal decision date: 2018-10-03



SGQ N° 005 A

Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

This document is a part of certificate n. 9120.AMA2

IAF: 19

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



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

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



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

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: 2018 - 10 - 03

Expires on: 2021 - 10 - 19

*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 - 101225



*Alex Stoichitoiu
President of IQNET*



*Ing. Claudio Provetti
President of CISQ*

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.



www.imq.it



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.

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, manufacture 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 2018-10-03	СРОК ДЕЙСТВИЯ EXPIRY DATE 2021-10-19
---	---	--

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ormago

Only the English text is authentic



www.cisq.com



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

Organismo di Certificazione Federato CISQ
www.imq.it

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



www.imq.it

CISQ is a member of



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.

ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ № 9124.AMA3-1 ANNEX N. 9124.AMA3-1

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

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

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

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

ДАТА ВЫПУСКА
CURRENT ISSUE
2018-10-03

СРОК ДЕЙСТВИЯ
EXPIRY
2021-10-19

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

This document is a part of certificate n. 9124.AMA3

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



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

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



www.imq.it

CISQ is a member of



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.

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

199034, Российская Федерация, Санкт-Петербург, 17-я линия В.О., д.4-6

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

Manufacture 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

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

ДАТА ВЫПУСКА
CURRENT ISSUE
2018-10-03

СРОК ДЕЙСТВИЯ
EXPIRY
2021-10-19

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



www.cisq.com



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

This document is a part of certificate n. 9124.AMA3

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

Organismo di Certificazione Federato CISQ
www.imq.it

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



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, manufacture 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: 2018 - 09 - 17

Expires on: 2021 - 09 - 19

*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. Claudio Provetti
President of CISQ

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE Mexico PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.