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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 ADDRESSESS:

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

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

Only the English text is authentic





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# ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ № 9124.AMA3-1 150 subsidiaries all over the globe. 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 \*\* 150 subsidiaries all over the globe. ANNEX N. 9124.AMA3-2

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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

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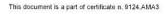
СРОК ДЕЙСТВИЯ EXPIRY

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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

- <mark>I∴Net</mark> -

Alex Stoichitoiu President of IQNET CISQ

Ing. Mario Romersi President of CISQ

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