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## СЕРТИФИКАТ №. CERTIFICATE N. 9124.KMIP

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

# АКЦИОНЕРНОЕ ОБЩЕСТВО «КАЗАНСКИЙ МЕДИКО-ИНСТРУМЕНТАЛЬНЫЙ ЗАВОД»

РОССИЙСКАЯ ФЕДЕРАЦИЯ, РЕСПУБЛИКА ТАТАРСТАН, 420021, Г. КАЗАНЬ, УЛ. САЛИХА САЙДАШЕВА, Д. 12

### JSC KMIZ

12, SALIKH SAIDASHEV STR., KAZAN, 420021, THE REPUBLIC OF TATARSTAN, 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 и производство медицинских изделий (вращающихся стоматологических изделий, эндоканальных стоматологических изделий, игл хирургических, микрохирургических и стоматологических изделий, стоматологических наконечников и микромоторов) Design and manufacture of medical devices (dental rotating devices, dental endodontic devices, surgical needles, microsurgical and dental devices, dental handpieces and micromotors)

Дальнейшие разъяснения относительно применимости требований ISO 13485:2016 могут быть получены от организации Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

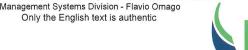
> ИСПОЛЬЗОВАНИЕ И СРОК ДЕЙСТВИЯ СЕРТИФИКАТА ДОЛЖНЫ УДОВЛЕТВОРЯТЬ ТРЕБОВАНИЯМ ПРАВИЛ ПО СЕРТИФИКАЦИИ СИСТЕМ МЕНЕДЖМЕНТА THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

ДАТА: ПЕРВИЧНАЯ СЕРТИФИКАЦИЯ DATE: FIRST CERTIFICATION 2017-01-19

ДАТА ВЫПУСКА **CURRENT ISSUE** 2020-01-16

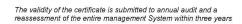
СРОК ДЕЙСТВИЯ 2023-01-18

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## ANNEX CERTIFICATE n. 9124.KMIP-1 ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ №

**UNITS** at the following addresses: ПОДРАЗДЕЛЕНИЯ по следующим адресам:

Акционерное общество «Казанский медико-инструментальный завод» Российская Федерация, Республика Татарстан, 420021, г. Казань, ул. Салиха Сайдашева, д.12

#### JSC KMIZ

12, Salikh Saidashev str., Kazan, 420021, the Republic of Tatarstan, Russian Federation

ДЛЯ СЛЕДУЮЩЕЙ ОБЛАСТИ ДЕЯТЕЛЬНОСТИ FOR THE FOLLOWING ACTIVITIES

Разработка и производство медицинских изделий (вращающихся стоматологических изделий, эндоканальных стоматологических изделий, игл хирургических)

Design and manufacture of medical devices (dental rotating devices, dental endodontic devices, surgical needles)

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH OPERATIVE UNIT OF KAZAN MEDICAL INSTRUMENTS PLANT JOINT STOCK COMPANY

FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9124.KMIP

DATE: ДАТА:

FIRST CERTIFICATION ПЕРВИЧНАЯ СЕРТИФИКАЦИЯ

2017-01-19

**CURRENT ISSUE** ДАТА ВЫПУСКА

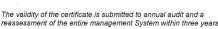
2020-01-16

**EXPIRY** СРОК ДЕЙСТВИЯ 2023-01-18

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# ANNEX CERTIFICATE n. 9124.KMIP-2 ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ №



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UNITS at the following addresses: ПОДРАЗДЕЛЕНИЯ по следующим адресам:

Общество с ограниченной ответственностью «Микрохирургические инструменты»

Российская Федерация, Республика Татарстан, 420021, г. Казань, ул. Салиха Сайдашева, д.12

Microsurgical Instruments Co., Ltd.

12, Salikh Saidashev str., Kazan, 420021, the Republic of Tatarstan, Russian Federation

FOR THE FOLLOWING ACTIVITIES ДЛЯ СЛЕДУЮЩЕЙ ОБЛАСТИ ДЕЯТЕЛЬНОСТИ

Разработка и производство медицинских изделий (микрохирургических и стоматологических изделий)

Design and manufacture of medical devices (microsurgical and dental devices)

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH OPERATIVE UNIT OF KAZAN MEDICAL INSTRUMENTS PLANT JOINT STOCK COMPANY

FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9124.KMIP

DATE: ДАТА:

FIRST CERTIFICATION ПЕРВИЧНАЯ СЕРТИФИКАЦИЯ

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2020-01-16

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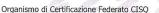
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The validity of the certificate is submitted to annual audit and a









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## ANNEX CERTIFICATE n. 9124.KMIP-3 ПРИЛОЖЕНИЕ К СЕРТИФИКАТУ №

UNITS at the following addresses: ПОДРАЗДЕЛЕНИЯ по следующим адресам:

Общество с ограниченной ответственностью «Турбодента»

Российская Федерация, Республика Татарстан, 420021, г. Казань, ул. Салиха Сайдашева, д.12

Turbodenta Co., Ltd. 12, Salikh Saidashev str., Kazan, 420021, the Republic of Tatarstan, Russian Federation

FOR THE FOLLOWING ACTIVITIES ДЛЯ СЛЕДУЮЩЕЙ ОБЛАСТИ ДЕЯТЕЛЬНОСТИ

Разработка и производство медицинских изделий (стоматологических наконечников и микромоторов)

Design and manufacture of medical devices (dental handpieces and micromotors)

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH OPERATIVE UNIT OF KAZAN MEDICAL INSTRUMENTS PLANT JOINT STOCK COMPANY

FOR THE VALIDITY PLEASE REFER TO CSQ CERTIFICATE N. 9124.KMIP

DATE: ДАТА: FIRST CERTIFICATION

ПЕРВИЧНАЯ СЕРТИФИКАЦИЯ

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2023-01-18

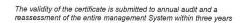
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THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

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

## JSC KMIZ

12, SALIKH SAIDASHEV STR., KAZAN, 420021, THE REPUBLIC OF TATARSTAN, RUSSIAN FEDERATION

Microsurgical Instruments Co., Ltd. 12, Salikh Saidashev str., Kazan, 420021, the Republic of Tatarstan, Russian Federation

**Turbodenta Co., Ltd.** 12, Salikh Saidashev str., Kazan, 420021, the Republic of Tatarstan, Russian Federation

has implemented and maintains a

Quality Management System

for the following scope:

Design and manufacture of medical devices (dental rotating devices, dental endodontic devices, surgical needles, microsurgical and dental devices, dental handpieces and micromotors)

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: **2020 - 01 - 16**Expires on: **2023 - 01 - 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 - 109545

THE KITERIATICHAL CERTIFICATION NETWORK

Alex Stoichitoiu President of IQNET CISQ

Ing. Claudio Provetti President of CISO

IQNet Partners\*:

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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.