

DECLARATION OF CONFORMITY

1) Manufacturer: KAZAN MEDICAL INSTRUMENTS PLANT JSC (KMIP JSC)
Address: No.12, Salikh Saidashev str., Kazan, 420021, Republic of Tatarstan, RUSSIA

2) European authorized representative: SKIRGESA JSC
Address: ENERGETIKU STR.8, LT-52461, KAUNAS, LITHUANIA
On product labels printed as:
 SKIRGESA JSC, ENERGETIKU STR.8, LT-52461, KAUNAS, LITHUANIA
 FAX. +370 37458161, E-mail: info@skirgesa.lt

3) Product(s) (name, type or model/batch number, etc.):

Hard - alloy dental laboratory cutters TS 9433-103-05519988-2005E <i>see appendix</i>

4) The product(s) described above is in conformity with:

DIRECTIVES

General Applicable Directive:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 june 1993 Concerning medical device (MDD93/42/EEC)

Document No.	Edition / Date of issue
BS EN 62366	2008-04-30
EN ISO 14971:2012	2012-08-30
EN 1639:2009	2010-07-07
EN 1041:2008	2009-02 19
EN ISO 17664:2004	2005-09-30
EN ISO 17665-1:2006	2006-11-15

5) Additional information (conformity procedure, Registration nr., etc.):

Conformity assessment procedure for CE marking: Medical Device Directive, Annex VII

KAZAN, RUSSIA, 2017-05-19
 (Place & date of issue (yyyy-mm-dd))




Shakirov Nur-Khamzinovich, Director-General of KMIP JSC
 (name; function and signature of manufacturer)

KAUNAS, LITHUANIA, 2017-05-19
 (Place & date of issue (yyyy-mm-dd))

SKIRMANTAS AKELIS, DIRECTOR of SKIRGESA JSC
 (name; function and signature of authorized representative)



 Kazan Medical Instruments Plant	Declaration of Conformity	DoC 2017 vs. 01 TF 4
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Appendix

Date: 2017-05-19

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-marking
Hard - alloy dental laboratory cutters	see page 3-6	Class I / Rule1	2006-07-17

¹ See risk classification in Medical Device Directive, annex IX

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

KAZAN MEDICAL INSTRUMENTS PLANT
JOINT STOCK COMPANY

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

соответствует требованиям стандарта
IS IN COMPLIANCE WITH THE STANDARD

EN ISO 13485:2012

для следующей области деятельности
FOR THE FOLLOWING ACTIVITIES

Разработка и производство вращающихся стоматологических инструментов;
эндоканальных стоматологических инструментов; микрохирургических
инструментов; стоматологических наконечников и микромоторов
*Design and manufacture of dental rotating tools, dental endodontic instruments,
microsurgical instruments, dental handpieces and micromotors*

Дальнейшие разъяснения относительно применимости требований EN ISO 13485:2012 могут быть получены от организации
Further clarifications regarding the applicability of EN ISO 13485:2012 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	ДАТА ВЫПУСКА CURRENT ISSUE	СРОК ДЕЙСТВИЯ EXPIRY DATE
2017-01-19	2017-01-19	2020-01-18

Организация обязана пройти процесс сертификации в соответствии с (требованиями)
ISO 13485:2016 до 28.02.2019; в противном случае срок действия данного сертификата истекает
The Organization shall obtain the certification according to ISO 13485:2016
within 2019/02/28; otherwise the validity of this certificate will expire

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

Only the English text is authentic

CISQ è la Federazione Italiana di
Organismi di Certificazione dei
sistemi di gestione aziendale.

CISQ is the Italian Federation
of management system
Certification Bodies.