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## 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.):

<b>Hard - alloy dental laboratory cutters</b>	<b>TS 9433-103-05519988-2005E</b>
<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)



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### Appendix

Date: 2017-05-19

#### List of devices.

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

<sup>1</sup> See risk classification in Medical Device Directive, annex IX





## Appendix

500 103 137 366 010	500.104.001.133.031	500.104.011.190.040
500 103 137 366 015	500.104.001.133.040	500.104.109.140.014
500 103 137 366 023	500.104.001.133.045	500.104.109.140.023
500 103 144 175 015	500.104.001.133.050	500.104.109.140.025
500 103 186 133 023	500.104.001.133.060	500.104.109.175.014
500 103 186 175 023	500.104.001.140.023	500.104.109.175.023
500 103 186 190 023	500.104.001.140.031	500.104.109.175.025
500 103 186 103 028	500.104.001.140.040	500.104.109.190.014
500 103 186 135 028	500.104.001.140.045	500.104.109.190.023
500 103 186 175 028	500.104.001.140.050	500.104.109.190.025
500 103 186 190 028	500.104.001.140.060	500.104.113.133.040
500 103 186 103 031	500.104.001.175.010	500.104.113.133.050
500 103 186 135 031	500.104.001.175.012	500.104.113.133.055
500 103 186 175 031	500.104.001.175.014	500.104.113.133.060
500 103 186 103 036	500.104.001.175.016	500.104.113.140.040
500 103 186 135 036	500.104.001.175.018	500.104.113.140.050
500 103 186 175 036	500.104.001.175.021	500.104.113.140.055
500 103 186 190 036	500.104.001.175.023	500.104.113.140.060
500 103 186 133 043	500.104.001.175.025	500.104.113.175.030
500 103 186 135 043	500.104.001.175.027	500.104.113.175.035
500 103 186 175 043	500.104.001.175.031	500.104.113.175.040
500 103 187 103 023	500.104.001.175.040	500.104.113.175.045
500 103 187 175 023	500.104.001.175.045	500.104.113.175.050
500 103 187 190 023	500.104.001.175.050	500.104.113.175.055
500 103 200 133 023	500.104.001.175.060	500.104.113.175.060
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500 103 200 135 028	500.104.001.190.016	500.104.113.190.045
500 103 200 175 028	500.104.001.190.018	500.104.113.190.050
500 103 200 190 028	500.104.001.190.021	500.104.113.190.055
500 103 200 103 031	500.104.001.190.023	500.104.113.190.060
500 103 200 135 031	500.104.001.190.025	500.104.113.215.045
500 103 200 175 031	500.104.001.190.027	500.104.113.215.050
500 103 200 103 036	500.104.001.190.031	500.104.113.215.055
500 103 200 135 036	500.104.001.190.040	500.104.113.215.060
500 103 200 175 036	500.104.001.190.045	500.104.113.220.045
500 103 200 190 036	500.104.001.190.050	500.104.113.220.050
500 103 200 133 043	500.104.001.190.060	500.104.113.220.055
500 103 200 135 043	500.104.011.175.014	500.104.113.220.060
500 103 200 175 043	500.104.011.175.018	500.104.113.222.050
500 103 201 103 023	500.104.011.175.031	500.104.113.222.055
500 103 201 175 023	500.104.011.175.040	500.104.113.222.060
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	500.104.011.190.014	500.104.113.224.055
	500.104.011.190.018	500.104.113.224.060
	500.104.011.190.031	500.104.114.133.015





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500.104.114.133.0215	500.104.143.133.055	500.104.144.140.023
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500.104.114.190.0215	500.104.143.175.040	500.104.186.103.031
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500.104.187.190.0215	500.104.199.175.050	500.104.200.220.040
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500.104.237.140.055	500.104.257.215.050	500.104.275.224.060
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