 Kazan Medical Instruments Plant	Declaration of Conformity	DoC 2017 vs. 01
		TF 20
		Page:1 of 2

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.):

Barbed Broaches	TS 9434-083-05519988-2002	see appendix
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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 1041:2008	2009-02 19
EN 1639:2009	2010-07-07
EN ISO 10993-11:2009	2009-12-02
EN ISO 17665-1:2006	2006-11-15

5) Additional information (conformity procedure, Notified Body, CE certificate, 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))



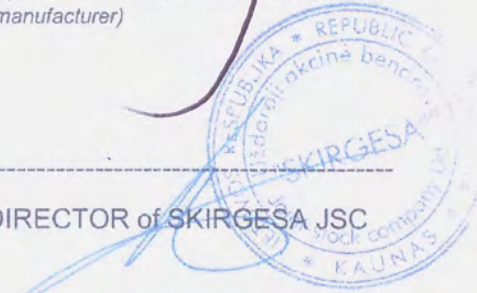
Shakirov Nur Khamzinovich, Director-General of KMIP JSC


(Name, function and signature of manufacturer)

KAUNAS, LITHUANIA, 2017-05-19

(Place & date of issue (yyyy-mm-dd))

SKIRMANTAS AKELIS, DIRECTOR of SKIRGESA JSC



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(name; function and signature of authorized representative)

Appendix

Date: 2017-05-19

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-compliance
Barbed Broaches length of 50 mm and 30 mm	340.600.909.202.020 340.600.909.202.025 340.600.909.202.030 340.600.909.202.035 340.600.909.202.040 340.600.909.202.050 340.600.909.202.060	Class I / Rule 5	2013-10-01
Barbed Broaches with attached handle, length of 35 mm	340.640.909.202.020 340.640.909.202.025 340.640.909.202.030 340.640.909.202.035 340.640.909.202.040 340.640.909.202.050 340.640.909.202.060	Class I / Rule 5	2013-10-01

¹ See risk classification in Medical Device Directive, annex IX