 Kazan Medical Instruments Plant	<i>Declaration of Conformity</i>	DoC2014 vs. 02
		TF 22
		Page: 1 of 3

DECLARATION OF CONFORMITY

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

2) **European authorized representative**: CEpartner4U BV,
 Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
 (on product labels printed as:
 CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

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

Surgical needles	TS 9432-097-05519988-2002	<i>see appendix</i>
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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	2008-04-30
EN ISO 14971:2012	2012-08-30
EN 1041:2008	2009-02 19
EN ISO 10993-11:2009	2009-12-02
EN ISO 17664:2004	2005-09-30
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
 Registration nr. NL-CA002-2013-29240

KAZAN, RUSSIA 2014-07-07

(Place & date of issue)

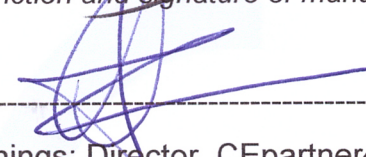


 Shakirov Noor Khamzinovich,
 Director-General of KMIP JSC
 (name; function and signature of manufacturer)

Maarn, NL; 2014-07-07

(Место и дата выдачи)

год-месяц-день)




 Ton Pennings; Director, CEpartner4U BV
 (ФИО; должность и подпись уполномоченного представителя)



Esdoornlaan13
 3951 DB Maarn NL
 tel: +31 (0)343 442 524
www.cepartner4u.nl

Declaration form: Standard ISO/IEC 17050-1:2010

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Appendix

Date: 2014-07-07

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-compliance
Surgical needles	see page 3	Class I / Rule 6	2013-10-01

¹ See risk classification in Medical Device Directive, annex IX



Appendix

0A1-0,7x18	3A1-0,9x36	4B1-1,1x30
0A1-0,8x22;	3A1-1,0x45	4B1-1,1x50
1B2-1,8x108	3A1-1,1x50	4B1-1,2x35
0A1-0,6x22	3A1-1,2x60	4B1-1,2x55
0A1-0,6x30	3A1-1,3x70	4B1-1,3x40
0A1-0,6x36	3A1-1,4x75	4B1-1,3x65
0A1-0,7x45	3A1-1,8x90	4B1-1,4x75
0A1-0,7x55	3B1-0,6x20	4B1-1,5x50
0A1-0,8x65	3B1-0,7x28	4B1-1,8x60
0A1-0,8x75	3B1-1,1x36	4B1-1,8x70
3A1-0,6x20	3B1-1,1x50	4B1-2,0x90
3A1-0,6x36	3B1-1,2x55	5A1-0,9x22
3A1-0,7x45	3B1-1,2x60	5A1-1,1x30
3A1-0,8x32	3B1-1,3x70	5A1-1,2x36
3A1-0,8x65	3B1-1,5x85	5A1-1,3x50
4A1-0,6x20	4A1-0,9x22	5A1-1,4x60
4A1-0,6x30	4A1-0,9x36	5B1-0,9x22
4A1-0,6x36	4A1-1,0x45	5B1-1,0x25
4A1-0,7x25	4A1-1,1x30	5B1-1,1x30
4A1-0,7x45	4A1-1,2x35	5B1-1,2x36
4A1-0,7x50	4A1-1,2x60	5B1-1,3x50
4A1-0,7x55	4A1-1,3x40	5B1-1,4x60
4A1-0,8x32	4A1-1,4x75	
4A1-0,8x65	4A1-1,5x50	
2B1-0,6x20	4A1-1,8x70	
2B1-0,8x32	4B1-0,7x28	
2B1-0,9x40	4B1-0,9x22	
3B2-0,6x30	4B1-0,9x36	
4B1-0,6x20	4B1-1,0x25	
4B1-0,6x30	4B1-1,0x45	