# 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 | *see appendix* |

**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 ----------
Shakirov Noor Khamzinovich,
Director-General of KMIP JSC
*(Place & date of issue)* *(name; function and signature of manufacturer)*

Maarn, NL; 2014-07-07 ----------
Ton Pennings; Director, CEpartner4U BV
*(Место и дата выдачи год-месяц-день)* *(ФИО; должность и подпись уполномоченного представителя)*

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