



Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Certificate - Full Quality Assurance System No. 11 0040 QS/NB

The quality system of manufacturer

### **Federal Budget Institute of Science “Central Research Institute for Epidemiology”**

3A Novogireevskaya Street, Moscow 111123, Russia

has been certified as meeting the requirements of

### **Directive 98/79/EC**

**on in vitro diagnostic medical devices, Annex IV excluding (4, 6)**

for the following product category(ies):

### **AmpliSens® PCR kits**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to Annex IV (Section 4) is required.

**Valid from:** 2018-10-31  
**Valid until:** 2021-06-16  
**First Issued:** 2011-01-24  
**Revision:** h



Date: 2018-10-31

Mgr. Jiří Heš  
Representative of the Notified Body No. 1023



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## Annex to EC Certificate No. 11 0040 QS/NB

issued for manufacturer:

**Federal Budget Institute of Science "Central Research Institute  
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**3A Novogireevskaya Street, Moscow 111123, Russia**

### Product(s):

**Name:** **AmpliSens® Rubella virus-FRT PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT-50 F

**Classification:** List B

**GMDN:** 30793

**Name:** **AmpliSens® Toxoplasma gondii-FRT PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT-50 F

**Classification:** List B

**GMDN:** 52428

**Name:** **AmpliSens® CMV-FEP PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5-ml tubes), variant FEP (0.2-ml tubes)

**Classification:** List B

**GMDN:** 30798

**Name:** **AmpliSens® CMV-FRT PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT, variant FRT-100 F

**Classification:** List B

**GMDN:** 30798

Date: 2018-10-31

Revision: h



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**Name:** **AmpliSens® HSV / CMV-MULTIPRIME-FEP  
PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5-ml tubes), variant FEP (0.2-ml tubes)

**Classification:** List B

**GMDN:** 61348

**Name:** **AmpliSens® HSV / CMV-MULTIPRIME-FRT  
PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT, variant FRT-100 F

**Classification:** List B

**GMDN:** 61348

**Name:** **AmpliSens® CMV-screen/monitor-FRT PCR  
kit**

**Trade name(s):** -

**Model(s):** variant FRT-100 F

**Classification:** List B

**GMDN:** 30798

Date: 2018-10-31  
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**Name:** **AmpliSens® EBV / CMV / HHV6-screen-FRT  
PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT-100 F

**Classification:** List B

**GMDN:** 61348

**Name:** **AmpliSens® Chlamydia trachomatis-FEP  
PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5-ml tubes), variant FEP (0.2-ml tubes)

**Classification:** List B

**GMDN:** 30677

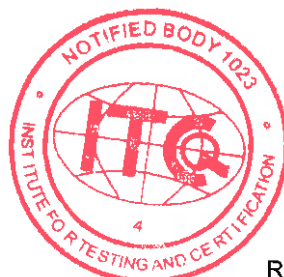
**Name:** **AmpliSens® Chlamydia trachomatis-FRT  
PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT, variant FRT-100 F

**Classification:** List B

**GMDN:** 30677



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**Name: AmpliSens® C.trachomatis / Ureaplasma-  
MULTIPRIME-FEP PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5 ml tubes), variant FEP (0.2 ml tubes)

**Classification:** List B

**GMDN:** 50409

**Name: AmpliSens® C.trachomatis / M.genitalium  
MULTIPRIME-FEP PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5 ml tubes), variant FEP (0.2 ml tubes)

**Classification:** List B

**GMDN:** 50409

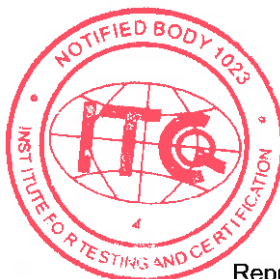
**Name: AmpliSens® C.trachomatis / Ureaplasma /  
M.genitalium-MULTIPRIME-FEP PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5 ml tubes), variant FEP (0.2 ml tubes)

**Classification:** List B

**GMDN:** 50409



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**Name:** **AmpliSens® C.trachomatis / Ureaplasma /  
M.genitalium-MULTIPRIME-FRT PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT, variant FRT-100 F

**Classification:** List B

**GMDN:** 50409

**Name:** **AmpliSens® C.trachomatis / Ureaplasma / M.  
hominis-MULTIPRIME-FEP PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5 ml tubes), variant FEP (0.2 ml tubes)

**Classification:** List B

**GMDN:** 50409

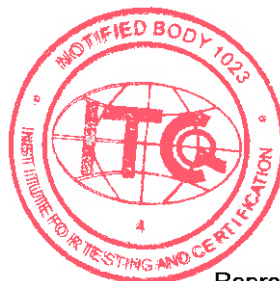
**Name:** **AmpliSens® C.trachomatis / Ureaplasma /  
M.hominis-MULTIPRIME-FRT PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT, variant FRT-100 F

**Classification:** List B

**GMDN:** 50409



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**Name:** **AmpliSens® C.trachomatis / Ureaplasma /  
M.genitalium / M.hominis-MULTIPRIME-FRT  
PCR kit**

**Trade name(s):** -  
**Model(s):** variant FRT, variant FRT-100 F  
**Classification:** List B  
**GMDN:** 50409

**Name:** **AmpliSens® N.gonorrhoeae / C.trachomatis /  
M.genitalium / T.vaginalis-MULTIPRIME-FRT  
PCR kit**

**Trade name(s):** -  
**Model(s):** variant FRT, variant FRT-100 F  
**Classification:** List B  
**GMDN:** 50409

**Name:** **AmpliSens® N.gonorrhoeae / C.trachomatis /  
M.genitalium-MULTIPRIME-FEP PCR kit**

**Trade name(s):** -  
**Model(s):** variant FEP (0.5 ml tubes), variant FEP (0.2 ml tubes)  
**Classification:** List B  
**GMDN:** 50409

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**Name:** **AmpliSens® N.gonorrhoeae / C.trachomatis /  
M.genitalium-MULTIPRIME-FRT PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT, variant FRT-100 F

**Classification:** List B

**GMDN:** 50409

**Name:** **AmpliSens® Genoscreen HLA B\*5701-FRT  
PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT

**Classification:** List B

**GMDN:** 56403

**Name:** **AmpliSens® Mycoplasma pneumoniae /  
Chlamydomphila pneumoniae-FEP PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5 ml tubes), variant FEP (0.2 ml tubes)

**Classification:** List B

**GMDN:** 58957

Date: 2018-10-31

Revision: h



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**Name: AmpliSens® Mycoplasma pneumoniae /  
Chlamydophila pneumoniae-FRT PCR kit**

**Trade name(s):** -

**Model(s):** variant FRT, variant FRT-100 F

**Classification:** List B

**GMDN:** 58957

**Name: AmpliSens® T.vaginalis / N.gonorrhoeae /  
C.trachomatis-MULTIPRIME-FEP PCR kit**

**Trade name(s):** -

**Model(s):** variant FEP (0.5 ml tubes), variant FEP (0.2 ml tubes)

**Classification:** List B

**GMDN:** 61144

**Name: AmpliSens® T.vaginalis / N.gonorrhoeae /  
C.trachomatis-MULTIPRIME-FRT PCR kit**

**Trade name(s):** -

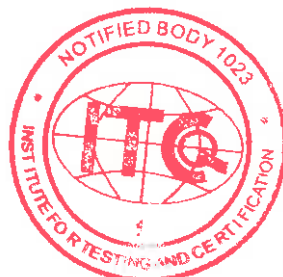
**Model(s):** variant FRT, variant FRT-100 F

**Classification:** List B

**GMDN:** 61144

Date: 2018-10-31

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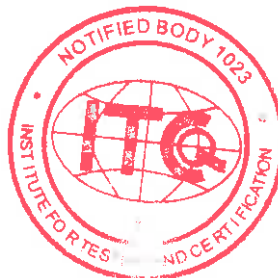
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**Facility(ies):**

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**Certificate History:**

Revision	Date	Reference Number	Action
	2011-01-24	813600111	Certification
a	2011-07-21	813600161	Change of manufacturer name
b	2012-02-13	343601304	Product scope extension
c	2014-05-13	343602568	Product scope extension
d	2016-01-15	813600504a	Prolongation of certificate validity
e	2016-06-17	813600504	Re-certification process
f	2016-08-29	343603690	Change of manufacturer facility address
g	2017-11-30	343603888	Changes of product compositions, packaging and quality system documentation
h	2018-10-31	813600754	Change of product labelling, shelf life extension and quality system documentation



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