



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**

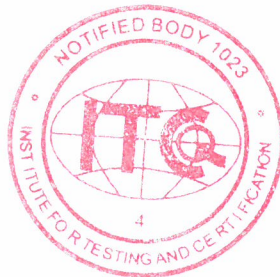
**on in vitro diagnostic medical devices, Annex IV excluding (4, 6)**

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:** 2022-04-28  
**Valid until:** 2025-05-26  
**First Issued:** 2011-01-24  
**Revision:** k



Date: 2022-04-28

A handwritten signature in blue ink, appearing to read 'Jiri Heš'.

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



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

**Annex to EC Certificate No. 11 0040 QS/NB**  
issued for manufacturer:

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

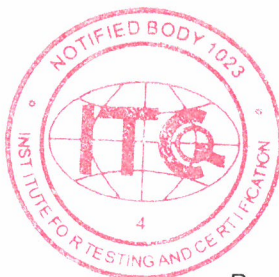
**Name:** **AmpliSens® CMV-FEP PCR kit**

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 30798



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**3a Novogireevskaya Street, Moscow 111123, Russia**

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

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 30798

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

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 61348

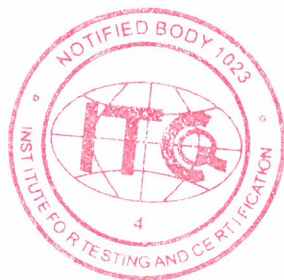
**Name:** **AmpliSens® CMV-screen/monitor-FRT PCR  
kit**

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 30798



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**Name: AmpliSens® EBV / CMV / HHV6-screen-FRT  
PCR kit**

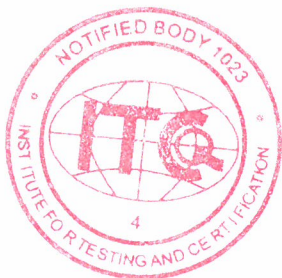
**Trade name(s): -**  
**Model(s): variant FRT-100 F**  
**Classification: List B**  
**GMDN: 61348**

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

**Trade name(s): -**  
**Model(s): variant FEP (0.2-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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**Federal Budget Institute of Science “Central Research Institute for  
Epidemiology”  
3a Novogireevskaya Street, Moscow 111123, Russia**

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

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 50409

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

**Trade name(s):** -

**Model(s):** 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 (0.2 ml tubes)

**Classification:** List B

**GMDN:** 50409



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

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 50409

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

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 50409

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

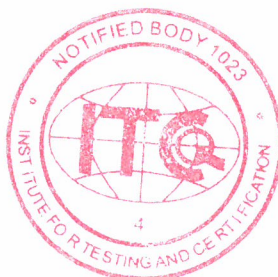
**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 50409

Date: 2022-04-28  
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**Name:** **AmpliSens® *N.gonorrhoeae* / *C.trachomatis* /  
*M.genitalium*-MULTIPRIME-FRT PCR kit**

**Trade name(s):** -

**Model(s):** 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

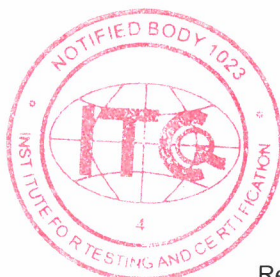
**Name:** **AmpliSens® *Mycoplasma pneumoniae* /  
*Chlamydomphila pneumoniae*-FEP PCR kit**

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 58957



Date: 2022-04-28  
Revision: k

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issued for manufacturer:

**Federal Budget Institute of Science “Central Research Institute for  
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3a Novogireevskaya Street, Moscow 11123, Russia**

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

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 58957

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

**Trade name(s):** -

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

**Classification:** List B

**GMDN:** 61144

### **Facility(ies):**

Federal Budget Institute of Science “Central Research Institute for Epidemiology”  
3a Novogireevskaya Street, Moscow 11123, Russia

Date: 2022-04-28  
Revision: k



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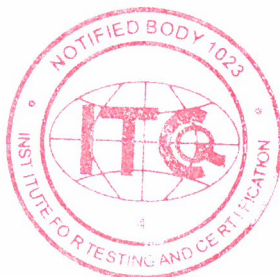
issued for manufacturer:

**Federal Budget Institute of Science “Central Research Institute for  
Epidemiology”  
3a Novogireevskaya Street, Moscow 111123, Russia**

### 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
i	2019-05-09	813600859	Product shelf life extension
j	2021-04-27	813601045	Re-certification process

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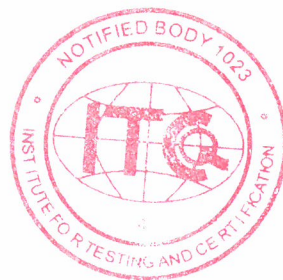
Notified Body 1023  
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**3a Novogireevskaya Street, Moscow 111123, Russia**

Revision	Date	Reference Number	Action
k	2022-04-28	813601141	Extension of the certificate validity regarding to REGULATION (EU) 2022/112 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, dated 25 <sup>th</sup> January 2022



Date: 2022-04-28  
Revision: k

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FEDERAL SERVICE FOR SUPERVISION OF CONSUMER RIGHTS PROTECTION AND HUMAN WELFARE

FEDERAL BUDGET INSTITUTE OF SCIENCE  
«CENTRAL RESEARCH INSTITUTE FOR EPIDEMIOLOGY»

111123, Moscow, 3A Novogireevskaya street, Tel.: +7 495 974 96 42, Fax: +7 495 305 54 23,  
e-mail: obtk@pcr.ru



**EC DECLARATION OF CONFORMITY**

Directive 98/79/EC of the European Parliament and of the Council of 27<sup>th</sup> of October 1998 on  
*In Vitro* Diagnostic Medical Devices

Federal Budget Institute of Science "Central Research Institute for Epidemiology" hereby under own responsibility declares that the products covered by the declaration conform with Essential Requirements listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation is retained under the premises of the manufacturer.

The quality management system meets the requirements of the standard EN ISO 13485 "Medical devices – Quality management systems – Requirements for regulatory purposes" and is certified by Institute for testing and certification, Inc. (certificate No. 21 0023 SJ, valid until 26.04.2024).

<b>Manufacturer:</b>	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
<b>Authorized Representative:</b>	Ecoli Dx, s.r.o. Purkyňova 74/2 Praha 1, 110 00 Czech Republic Tel: +420 325 209 912 Cell: +420 739 802 523 E-mail: ecoli@ecoli.sk
<b>Product Name:</b>	Annex for this Declaration
<b>Description:</b>	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents or HLA B*5701 DNA in human specimens
<b>Classification:</b>	Article 9, paragraph 3 of EC Council Directive 98/79/EC on <i>in Vitro</i> Diagnostic Devices Annex II List B IVDs (According to EC Declaration of Conformity List)
<b>Conformity Assessment Route:</b>	Annex IV (IVDD) Full QA System
<b>Notified Body:</b>	Institute for testing and certification, Inc. třída Tomáše Bati 299 Louky, 763 02 Zlín, Czech Republic E-mail: itc@itczlin.cz Notified Body No. 1023
<b>EC Certificate:</b>	No. 11 0040 QS/NB revision k, valid until 2025-05-26
<b>Place, Date of Issue:</b>	Zlín, Czech Republic, 2022-04-28

Signed

Full name: Vasily G. Akimkin  
Title: Director

Valid from 2022-04-28

Valid until 2025-05-26



NoNo	Description	Model(s)
1.	<b>AmpliSens® Rubella virus-FRT</b> PCR kit	variant FRT-50 F
2.	<b>AmpliSens® Toxoplasma gondii-FRT</b> PCR kit	variant FRT-50 F
3.	<b>AmpliSens® CMV-FEP</b> PCR kit	variant FEP (0.2-ml tubes)
4.	<b>AmpliSens® CMV-FRT</b> PCR kit	variant FRT-100 F
5.	<b>AmpliSens® HSV / CMV-MULTIPRIME-FRT</b> PCR kit	variant FRT-100 F
6.	<b>AmpliSens® CMV-screen/monitor-FRT</b> PCR kit	variant FRT-100 F
7.	<b>AmpliSens® EBV / CMV / HHV6-screen-FRT</b> PCR kit	variant FRT-100 F
8.	<b>AmpliSens® Chlamydia trachomatis-FEP</b> PCR kit	variant FEP (0.2-ml tubes)
9.	<b>AmpliSens® Chlamydia trachomatis-FRT</b> PCR kit	variant FRT variant FRT-100 F
10.	<b>AmpliSens® C.trachomatis / Ureaplasma / M.genitalium-MULTIPRIME-FEP</b> PCR kit	variant FEP (0.2-ml tubes)
11.	<b>AmpliSens® C.trachomatis / Ureaplasma / M.genitalium-MULTIPRIME-FRT</b> PCR kit	variant FRT-100 F
12.	<b>AmpliSens® C.trachomatis / Ureaplasma / M.hominis-MULTIPRIME-FEP</b> PCR kit	variant FEP (0.2-ml tubes)
13.	<b>AmpliSens® C.trachomatis / Ureaplasma / M.hominis-MULTIPRIME-FRT</b> PCR kit	variant FRT-100 F
14.	<b>AmpliSens® C.trachomatis / Ureaplasma / M.genitalium / M.hominis-MULTIPRIME-FRT</b> PCR kit	variant FRT-100 F
15.	<b>AmpliSens® N.gonorrhoeae / C.trachomatis / M.genitalium / T.vaginalis-MULTIPRIME-FRT</b> PCR kit	variant FRT-100 F
16.	<b>AmpliSens® N.gonorrhoeae / C.trachomatis / M.genitalium-MULTIPRIME-FRT</b> PCR kit	variant FRT-100 F
17.	<b>AmpliSens® Genoscreen HLA B*5701-FRT</b> PCR kit	variant FRT
18.	<b>AmpliSens® Mycoplasma pneumoniae / Chlamydophila pneumoniae-FEP</b> PCR kit	variant FEP (0.2-ml tubes)
19.	<b>AmpliSens® Mycoplasma pneumoniae / Chlamydophila pneumoniae-FRT</b> PCR kit	variant FRT-100 F
20.	<b>AmpliSens® T.vaginalis / N.gonorrhoeae / C.trachomatis-MULTIPRIME-FRT</b> PCR kit	variant FRT-100 F



**EC DECLARATION OF CONFORMITY**  
Directive 98/79/EC of the European Parliament and of the Council of 27<sup>th</sup> of October 1998 on  
In Vitro Diagnostic Medical Devices

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<b>Manufacturer:</b>	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
<b>Authorised Representative:</b>	Ecoli Dx, s.r.o Purkyňova 74/2 Praha 1, 110 00 Czech Republic Tel: +420 325 209 912 Cell: +420 739 802 523 Email: ecoli@ecoli.sk
<b>Product Name:</b>	Annex for this Declaration
<b>Description:</b>	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents
<b>Classification:</b>	Article 9, paragraph 1 of EC Council Directive 98/79/EC on <i>in Vitro</i> Diagnostic Devices
<b>Conformity Assessment Route:</b>	Annex III (IVDD)

Signed \_\_\_\_\_

Full name: Vasiliy G. Akimkin  
Title: Director



Valid from 25.05.2022

№№	Description	Product Code (for reference only)
1.	AmpliSens® All bacto-screen-FRT PCR kit	H-2631-1-CE H-2632-1-4-CE
2.	AmpliSens® All-screen-FRT PCR kit	R-B45(RG,iQ)-CE
3.	AmpliSens® All viro-screen-FRT PCR kit	H-2761-1-CE
4.	AmpliSens® ARVI-screen-FRT PCR kit	R-V57-100-F(RG,iQ,Dt)-CE
5.	AmpliSens® Ascariidosis-FRT PCR kit	H-1971-1-CE
6.	AmpliSens® <i>Bacillus anthracis</i> -FRT PCR kit	R-B41(RG)-CE
7.	AmpliSens® <i>Bordetella</i> multi-FRT PCR kit	R-B84-100-F(RG,iQ,Dt)-CE
8.	AmpliSens® <i>Borrelia burgdorferi sensu lato</i> -FRT PCR kit	R-B37(RG)-CE
9.	AmpliSens® <i>Borrelia miyamotoi</i> -FRT PCR kit	H-2791-1-CE H-2792-1-4-CE
10.	AmpliSens® BRCA1-FRT PCR kit	S-3901-1-CE
11.	AmpliSens® <i>Brucella</i> spp.-FRT PCR kit	R-B10(RG)-CE
12.	AmpliSens® <i>C.albicans</i> / <i>C.glabrata</i> / <i>C.krusei</i> -MULTIPRIME-FRT PCR kit	R-F3-F(RG,iQ)-CE
13.	AmpliSens® <i>Candida albicans</i> -FEP PCR kit	F1-100-R0,2-FEP-CE
14.	AmpliSens® <i>Candida albicans</i> -FRT PCR kit	R-F1-F(RG,iQ)-CE
15.	AmpliSens® CCHFV-FRT PCR Kit	R-V22-50-F(RG,iQ,Mx,Dt)-CE
16.	AmpliSens® <i>Corynebacterium diphtheriae</i> / tox-genes-FRT PCR kit	H-2842-1-CE H-2843-1-4-CE
17.	AmpliSens® Cov-Bat-FRT PCR kit	H-2242-1-CE
18.	AmpliSens® COVID-19-FL PCR kit	H-4094-1-1-CE
19.	AmpliSens® <i>Coxiella burnetii</i> -FRT PCR kit	R-B85-50-F(RG,iQ,Mx,Dt)-CE
20.	AmpliSens® <i>Cryptococcus neoformans</i> -FRT PCR kit	R-F4-F(RG,iQ)-CE
21.	AmpliSens® Dengue virus type-FRT PCR kit	R-V63(RG,CFX)-CE
22.	AmpliSens® Dengue virus-FRT PCR kit	H-2391-1-CE H-2392-1-4-CE
23.	AmpliSens® EBOV Zaire-FRT PCR kit	R-V69-50-F-CE
24.	AmpliSens® EBV-screen/monitor-FRT PCR kit	R-V9-100-S(RG,iQ,Mx)-CE
25.	AmpliSens® Enterovirus 71-FRT PCR kit	R-V64-F-CE
26.	AmpliSens® Enterovirus-FRT PCR kit	R-V16(RG)-CE
27.	AmpliSens® Enterovirus / Parechovirus-FRT PCR kit	H-3751-1-2-CE
28.	AmpliSens® ESBL CTX-M-FRT PCR kit	HN-3571-1-CE
29.	AmpliSens® Escherichioses-FRT PCR kit	R-B62(RG,iQ)-CE
30.	AmpliSens® F2/F5-SNP-FRT PCR kit	S-3451-1-CE S-3452-1-4-CE
31.	AmpliSens® FiloA-screen-FRT PCR kit	H-2781-1-4-CE
32.	AmpliSens® Florocenosis / Aerobes-FRT PCR kit	R-B88-100-FT-CE
33.	AmpliSens® Florocenosis / Bacterial vaginosis-FRT PCR kit	R-B74-100-FT(RG)-CE
34.	AmpliSens® Florocenosis / <i>Candida</i> -FRT PCR kit	R-F5-100-FT(RG,CFX)-CE
35.	AmpliSens® Florocenosis / <i>Mycoplasma</i> -FRT PCR kit	R-B75-100-FT(RG,iQ,Mx)-CE
36.	AmpliSens® <i>Giardia lamblia</i> -FRT PCR kit	H-2821-1-CE H-2822-1-4-CE

№№	Description	Product Code (for reference only)
37.	<b>AmpliSens® Gardnerella vaginalis-FEP</b> PCR kit	B7-100-R0,2-FEP-CE
38.	<b>AmpliSens® Gardnerella vaginalis-FRT</b> PCR kit	R-B7-F(RG,iQ)-CE
39.	<b>AmpliSens® Genoscreen-IL28B-FRT</b> PCR kit	R-O5-100-F(RG,iQ,Dt,CFX)-CE
40.	<b>AmpliSens® HAV-FRT</b> PCR kit	R-V4(RG,iQ)-CE
41.	<b>AmpliSens® Helicobacter pylori-FRT</b> PCR kit	R-B9(RG,iQ)-CE H-2831-1-CE H-2832-1-4-CE
42.	<b>AmpliSens® Hemochromatosis-FRT</b> PCR kit	S-2451-1-CE S-2452-1-4-CE
43.	<b>AmpliSens® HGV-FRT</b> PCR kit	R-V2-50-F(RG,iQ,Mx,Dt)-CE
44.	<b>AmpliSens® HHV6-screen-titre-FRT</b> PCR kit	R-V10-T(RG,iQ,Mx)-CE
45.	<b>AmpliSens® HHV7-screen/monitor-FRT</b> PCR kit	H-2431-1-1-CE
46.	<b>AmpliSens® HHV8-screen/monitor-FRT</b> PCR kit	H-3581-1-1-CE H-3582-1-14-CE
47.	<b>AmpliSens® HPV 16/18-FRT</b> PCR kit	R-V12-100-CE R-V12-F-CE R-V12(RG,iQ,Mx)-CE
48.	<b>AmpliSens® HPV 6/11-FRT</b> PCR kit	R-V11-100-CE R-V11-Mod(RG,iQ,Mx)-CE R-V11(RG,iQ,Mx)-CE
49.	<b>AmpliSens® HPV HCR genotype-FRT</b> PCR kit	R-V25(RG,iQ,Mx)-CE
50.	<b>AmpliSens® HPV HCR genotype-titre-FRT</b> PCR kit	R-V67-F-CE H-2261-1-13-CE
51.	<b>AmpliSens® HPV HCR screen-EPh</b> PCR kit	V31-100F-CE
52.	<b>AmpliSens® HPV HCR screen-FEP</b> PCR kit	V31-3x-FEP-CE V31-FEP-CE
53.	<b>AmpliSens® HPV HCR screen-titre-14-FRT</b> PCR kit	H-2311-1-13-CE
54.	<b>AmpliSens® HPV HCR screen-titre-FRT</b> PCR kit	R-V31-T-2x(RG,iQ,SC)-CE R-V31-T-4x(RG,iQ,Mx)-CE R-V31-F-CE
55.	<b>AmpliSens® HSV I, II-FRT</b> PCR kit	R-V8-F(RG,iQ)-CE
56.	<b>AmpliSens® HSV-typing-FEP</b> PCR kit	V38-100-R0,2-FEP-CE
57.	<b>AmpliSens® HSV-typing-FRT</b> PCR kit	R-V38-F(RG,iQ)-CE
58.	<b>AmpliSens® Human enterovirus-FEP</b> PCR kit	H-2771-2-2-CE H-2772-2-CE
59.	<b>AmpliSens® Human enterovirus-FRT</b> PCR kit	H-2771-1-2-CE H-2773-1-CE H-2773-1-4-CE
60.	<b>AmpliSens® Influenza virus A/H1-swine-FEP</b> PCR kit	V55-50-R0,2-FEP-CE
61.	<b>AmpliSens® Influenza virus A/H1-swine-FRT</b> PCR kit	R-V55(RG)-CE R-V55-F(SC)-CE
62.	<b>AmpliSens® Influenza virus A-type-FRT</b> PCR kit	R-V54-100-F(RG,iQ,Dt,SC)-CE
63.	<b>AmpliSens® Influenza virus A-type-H5, H7, H9-FRT</b> PCR kit	R-V66-F-CE
64.	<b>AmpliSens® Influenza virus A H5N1-FRT</b> PCR kit	R-V33(SC)-CE
65.	<b>AmpliSens® Influenza virus A/B-FRT</b> PCR kit	R-V36-100-F-Mod(RG,iQ,Dt,CFX,SC)-CE
66.	<b>AmpliSens® Influenza virus B-type-FRT</b> PCR kit	H-3991-1-23-CE H-3992-1-3-CE
67.	<b>AmpliSens® JCV-BKV screen-monitor-FRT</b> PCR kit	H-2441-1-1-CE

№№	Description	Product Code (for reference only)
68.	AmpliSens® <i>Legionella pneumophila</i> -FEP PCR kit	B50-R0,2-FEP-CE
69.	AmpliSens® <i>Legionella pneumophila</i> -FRT PCR kit	R-B50(RG)-CE
70.	AmpliSens® <i>Leptospira</i> -FRT PCR kit	R-B49(RG,iQ)-CE
71.	AmpliSens® Leucosis Quantum <i>M-bcr</i> -FRT PCR kit	TR-O1(RG,iQ,Mx,A)-CE
72.	AmpliSens® <i>Listeria monocytogenes</i> -screen/monitor-FRT PCR kit	H-2161-1-1-CE
73.	AmpliSens® MDR A.b.-OXA-FRT PCR kit	HN-3871-1-CE HN-3872-1-4-CE
74.	AmpliSens® MDR KPC/OXA-48-FRT PCR kit	R-C2(RG,CFX)-CE
75.	AmpliSens® MDR MBL-FRT PCR kit	R-C1(RG,CFX)-CE
76.	AmpliSens® MDR MCR-1-FRT PCR kit	HN-4171-1-CE HN-4172-1-4-CE
77.	AmpliSens® MDR VRE-FRT PCR kit	HN-3891-1-CE HN-3892-1-4-CE
78.	AmpliSens® <i>MRSA</i> -screen-titre-FRT PCR kit	R-B78-100-FT(RG,iQ)-CE
79.	AmpliSens® <i>MTC</i> -diff-FRT PCR kit	R-B80(RG,iQ,Dt,SC)-CE
80.	AmpliSens® <i>MTC</i> -MDR-FRT PCR kit	H-3611-1-CE H-3612-1-4-CE
81.	AmpliSens® <i>MTC</i> -FEP PCR kit	B57-FEP-CE
82.	AmpliSens® <i>MTC</i> -FRT PCR kit	R-B57(RG,iQ,SC,Dt)-CE
83.	AmpliSens® <i>MTHFR</i> -SNP-FRT PCR kit	S-3721-1-CE S-3722-1-4-CE
84.	AmpliSens® <i>Mycoplasma genitalium</i> -FEP PCR kit	B4-100-R0,2-FEP-CE
85.	AmpliSens® <i>Mycoplasma genitalium</i> -FRT PCR kit	R-B4(RG)-CE R-B4-F(RG,iQ)-CE
86.	AmpliSens® <i>Mycoplasma hominis</i> -FEP PCR kit	B3-100-R0,2-FEP-CE
87.	AmpliSens® <i>Mycoplasma hominis</i> -FRT PCR kit	R-B3(RG)-CE R-B3-F(RG,iQ)-CE
88.	AmpliSens® <i>M.genitalium</i> -ML/FQ-Resist-FRT PCR kit	H-3971-1-CE
89.	AmpliSens® <i>N.meningitidis</i> / <i>H.influenzae</i> / <i>S.pneumonia</i> -FRT PCR kit	R-B25(RG,iQ)-CE
90.	AmpliSens® <i>Neisseria gonorrhoeae</i> -screen-FEP PCR kit	B51-100-R0,2-FEP-CE
91.	AmpliSens® <i>Neisseria gonorrhoeae</i> -screen-FRT PCR kit	R-B51(RG)-CE R-B51-F(RG,iQ)-CE
92.	AmpliSens® NmABCW-FRT PCR kit	H-3861-1-3-CE
93.	AmpliSens® <i>Norovirus</i> GI / GII-FRT PCR kit	H-2751-1-3-CE
94.	AmpliSens® <i>Parvovirus</i> B19-FRT PCR kit	R-V49(RG,iQ,Mx)-CE
95.	AmpliSens <i>Plasmodium</i> spp. / <i>P.falciparum</i> / <i>P.vivax</i> -FRT PCR kit	H-3981-1-CE H-3982-1-4-CE
96.	AmpliSens® <i>Pneumocystis jirovecii</i> ( <i>carinii</i> )-FRT PCR kit	R-F2-Mod(RG,iQ,Mx)-CE
97.	AmpliSens® Pneumo-quantum-FRT PCR kit	H-2811-1-1-CE H-2812-1-14-CE
98.	AmpliSens® <i>Poliovirus</i> -FRT PCR kit	R-V58(RG,iQ)-CE
99.	BRCA-screen kit	S-1619-6-CE
100.	PEERO-prep reagent kit for sample preparation	K15-1611-40-CE
101.	AmpliSens® Pyroscreen PHARMA-screen-Imatinib kit	S-16121-6-CE



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102.	AmpliSens® Pyroscreen PHARMA-screen-transport kit	S-16119-6-CE
103.	AmpliSens® Pyroscreen PHARMA-screen-Warfarin kit	S-16120-6-CE
104.	AmpliSens® <i>Rickettsia conorii</i> -FRT PCR kit	H-2741-1-CE H-2742-1-4-CE
105.	AmpliSens® <i>Rickettsia</i> spp. SFG-FRT PCR kit	H-3741-1-CE H-3742-1-4-CE
106.	AmpliSens® Rotavirus / Norovirus / Astrovirus-FRT PCR kit	R-V40(RG,iQ)-CE
107.	AmpliSens® SARS-CoV-2-IT reagent kit	H-4121-10-CE
108.	AmpliSens® SARS-CoV-2-N501Y-IT reagent kit	H-4161-10-CE
109.	AmpliSens® <i>Shigella</i> spp. and <i>EIEC</i> / <i>Salmonella</i> spp. / <i>Campylobacter</i> spp.-FRT PCR kit	R-B44(RG,iQ)-CE
110.	AmpliSens® <i>Streptococcus agalactiae</i> -screen-titre-FRT PCR kit	R-B77-100-FT(RG,iQ)-CE
111.	AmpliSens® <i>Streptococcus pyogenes</i> -screen/monitor-FRT PCR kit	H-2171-1-1-CE H-2172-1-14-CE
112.	AmpliSens® <i>T.vaginalis</i> / <i>N.gonorrhoeae</i> -MULTIPRIME-FRT PCR kit	R-B65-F(RG,iQ)-CE
113.	AmpliSens® TBE-FRT PCR kit	R-V52(RG)-CE
114.	AmpliSens® TBEV, <i>B.burgdorferi</i> sl, <i>A.phagocytophilum</i> , <i>E.chaffeensis</i> / <i>E.muris</i> -FRT PCR kit	R-V59(RG,iQ,Mx,Dt)-CE
115.	AmpliSens® <i>Treponema pallidum</i> -FRT PCR kit	R-B20-F(RG,iQ)-CE
116.	AmpliSens® <i>Trichomonas vaginalis</i> -EPH PCR kit	B6-100-R0,2-CE
117.	AmpliSens® <i>Trichomonas vaginalis</i> -FEP PCR kit	B6-100-R0,2-FEP-CE
118.	AmpliSens® <i>Trichomonas vaginalis</i> -FRT PCR kit	R-B6-F(RG,iQ)-CE
119.	AmpliSens® <i>U.parvum</i> / <i>U.urealyticum</i> -FEP PCR kit	B19-100-R0,2-FEP-CE
120.	AmpliSens® <i>U.parvum</i> / <i>U.urealyticum</i> -FRT PCR kit	R-B19(RG)-CE R-B19-F(RG,iQ)-CE
121.	AmpliSens® <i>Ureaplasma</i> spp.-FRT PCR kit	R-B2(RG)-CE R-B2-F(RG,iQ)-CE
122.	AmpliSens® <i>Ureaplasma</i> spp.-screen-titre-FRT PCR kit	R-B2-100-FT(RG,iQ,Mx)-CE
123.	AmpliSens® <i>Vibrio cholerae</i> -FRT PCR kit	R-B53(RG)-CE
124.	AmpliSens® VZV-FRT PCR kit	R-V61-50-F(RG)-CE
125.	AmpliSens® WNV-FRT PCR kit	R-V53(RG,iQ,Mx)-CE
126.	AmpliSens® Yellow fever virus-FRT PCR kit	H-2461-1-CE H-2462-1-4-CE
127.	AmpliSens® <i>Yersinia enterocolitica</i> / <i>Y.pseudotuberculosis</i> -FRT PCR kit	R-B64(RG,iQ)-CE
128.	AmpliSens® <i>Yersinia pestis</i> -FRT PCR kit	R-B79(RG,iQ,Dt)-CE
129.	AmpliSens® Zika virus-FRT PCR kit	H-2411-1-CE

Signed \_\_\_\_\_

Full name: Vasiliy Akimkin  
Title: Director

