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: 2022-05-20
Valid until: 2025-05-26
First Issued: 2011-01-24
Revision: m

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION 4

Date: 2022-05-20

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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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*-FRT PCR kit**
Trade name(s):	-
Model(s):	variant FRT, variant FRT-100 F
Classification:	List B
GMDN:	30677
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

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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

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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 / Chlamydophila pneumoniae*-FEP PCR kit**
Trade name(s):	-
Model(s):	variant FEP (0.2 ml tubes)
Classification:	List B
GMDN:	58957

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Name:	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila 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
Name:	**AmpliSens® *HCV*-Monitor-L PCR kit**
Trade name(s):	-
Model(s):	variant FRT-L
Classification:	List A
GMDN:	48374

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Name:	**AmpliSens® *HBV*-Monitor-L PCR kit**
Trade name(s):	-
Model(s):	variant FRT-L
Classification:	List A
GMDN:	48307

Facility(ies):

Federal Budget Institute of Science "Central Research Institute for Epidemiology"
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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
i	2019-05-09	813600859	Product shelf life extension
j	2021-04-27	813601045	Re-certification process

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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 25th January 2022
l	2022-05-20	833600365	Product scope reduction
m	2022-05-20	813601116	Certification– List A IVD PCR kits

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