DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
TPHA Microtitre plate kit	043100A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.

_____
Eddy Velthuis
Technical Director

Digitally signed by Ceaicovschi Tudor
Date: 2024.01.12 11:16:47 EET
Reason: MoldSign Signature
Location: Moldova

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom
Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
RPR Carbon kit	044150A 044500A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.

_____

Eddy Velthuis
Technical Director

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD** **Unit 602, International Center, No.535, Shenxu Road,** **Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Centrifuge Tube**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD** **(Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /** **EG Annex III (expect point 6) of IVDD 98/79/EC** **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE** **Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

General Manager

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Eppendorf Tube**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

General Manager

BOEN HEALTHCARE CO.,LTD 苏州博恩贸易有限公司 3205011038530

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Filtered Pipette Tips**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	

CE

Suzhou, 2022.01.01

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Gilson Pipette Tips**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	

CE

Suzhou, 201.05.26

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data	Name und Funktion / Name and function / Nom et fonction / Nome e funzione

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Microscope Cover Glass**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-04-28

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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-04-28
Revision: k

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

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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-04-28
Revision: k

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

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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-04-28
Revision: k

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

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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-04-28
Revision: k

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

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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-04-28
Revision: k

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

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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 4

Date: 2022-04-28
Revision: k

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

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

Facility(ies):

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

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-04-28
Revision: k

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

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

Date: 2022-04-28
Revision: k

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION

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

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

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-04-28
Revision: k

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

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

CE

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27th 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).

Manufacturer:	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
Authorized Representative:	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
Product Name:	Annex for this Declaration
Description:	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents or HLA B*5701 DNA in human specimens
Classification:	Article 9, paragraph 3 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices Annex II List B IVDs (According to EC Declaration of Conformity List)
Conformity Assessment Route:	Annex IV (IVDD) Full QA System
Notified Body:	Institute for testing and certification, Inc. třida Tomáše Bati 299 Louky, 763 02 Zlin, Czech Republic E-mail: itc@itczlin.cz Notified Body No. 1023
EC Certificate:	No. 11 0040 QS/NB revision k, valid until 2025-05-26
Place, Date of Issue:	Zlin, Czech Republic, 2022-04-28

Signed _____

Full name: Vasiliy G. Akimkin
Title: Director

Valid from 2022-04-28

Valid until 2025-05-26

№№	Description	Model(s)
1.	**AmpliSens® *Rubella virus*-FRT** PCR kit	variant FRT-50 F
2.	**AmpliSens® *Toxoplasma gondii*-FRT** PCR kit	variant FRT-50 F
3.	**AmpliSens® *CMV*-FEP** PCR kit	variant FEP (0.2-ml tubes)
4.	**AmpliSens® *CMV*-FRT** PCR kit	variant FRT-100 F
5.	**AmpliSens® *HSV* / *CMV*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
6.	**AmpliSens® *CMV*-screen/monitor-FRT** PCR kit	variant FRT-100 F
7.	**AmpliSens® *EBV* / *CMV* / *HHV*6-screen-FRT** PCR kit	variant FRT-100 F
8.	**AmpliSens® *Chlamydia trachomatis*-FEP** PCR kit	variant FEP (0.2-ml tubes)
9.	**AmpliSens® *Chlamydia trachomatis*-FRT** PCR kit	variant FRT variant FRT-100 F
10.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.genitalium*-MULTIPRIME-FEP** PCR kit	variant FEP (0.2-ml tubes)
11.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.genitalium*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
12.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.hominis*-MULTIPRIME-FEP** PCR kit	variant FEP (0.2-ml tubes)
13.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.hominis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
14.	**AmpliSens® *C.trachomatis* / *Ureaplasma* / *M.genitalium* / *M.hominis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
15.	**AmpliSens® *N.gonorrhoeae* / *C.trachomatis* / *M.genitalium* / *T.vaginalis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
16.	**AmpliSens® *N.gonorrhoeae* / *C.trachomatis* / *M.genitalium*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F
17.	**AmpliSens® Genoscreen HLA B*5701-FRT** PCR kit	variant FRT
18.	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila pneumoniae*-FEP** PCR kit	variant FEP (0.2-ml tubes)
19.	**AmpliSens® *Mycoplasma pneumoniae* / *Chlamydophila pneumoniae*-FRT** PCR kit	variant FRT-100 F
20.	**AmpliSens® *T.vaginalis* / *N.gonorrhoeae* / *C.trachomatis*-MULTIPRIME-FRT** PCR kit	variant FRT-100 F

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

CE

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27th 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).

Manufacturer:	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
Authorised Representative:	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
Product Name:	Annex for this Declaration
Description:	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents
Classification:	Article 9, paragraph 1 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices
Conformity Assessment Route:	Annex III (IVDD)

Signed _____ Valid from 25.05.2022

Full name: Vasiliy G. Akimkin
Title: Director

№№	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® Ascaridosis-FRT** PCR kit	H-1971-1-CE
6.	**AmpliSens® *Bacillus anthracis*-FRT** PCR kit	R-B41(RG)-CE
7.	**AmpliSens® *Bordetella* multi-FRT** PCR kit	R-B84-100-F(RG,iQ,Dt)-CE
8.	**AmpliSens® *Borrelia burgdorferi sensu lato*-FRT** PCR kit	R-B37(RG)-CE
9.	**AmpliSens® *Borrelia miyamotoi*-FRT** PCR kit	H-2791-1-CE H-2792-1-4-CE
10.	**AmpliSens® BRCA1-FRT** PCR kit	S-3901-1-CE
11.	**AmpliSens® *Brucella* spp.-FRT** PCR kit	R-B10(RG)-CE
12.	**AmpliSens® *C.albicans* / *C.glabrata* / *C.krusei*-MULTIPRIME-FRT** PCR kit	R-F3-F(RG,iQ)-CE
13.	**AmpliSens® *Candida albicans*-FEP** PCR kit	F1-100-R0,2-FEP-CE
14.	**AmpliSens® *Candida albicans*-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® *Corynebacterium diphtheriae* / 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® *Coxiella burnetii*-FRT** PCR kit	R-B85-50-F(RG,iQ,Mx,Dt)-CE
20.	**AmpliSens® *Cryptococcus neoformans*-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 / *Candida*-FRT** PCR kit	R-F5-100-FT(RG,CFX)-CE
35.	**AmpliSens® Florocenosis / *Mycoplasma*-FRT** PCR kit	R-B75-100-FT(RG,iQ,Mx)-CE
36.	**AmpliSens® *Giardia lamblia*-FRT** PCR kit	H-2821-1-CE H-2822-1-4-CE

№№	Description	Product Code (for reference only)
37.	**AmpliSens® *Gardnerella vaginalis*-FEP** PCR kit	B7-100-R0,2-FEP-CE
38.	**AmpliSens® *Gardnerella vaginalis*-FRT** PCR kit	R-B7-F(RG,iQ)-CE
39.	**AmpliSens® Genoscreen-*IL*28B-FRT** PCR kit	R-O5-100-F(RG,iQ,Dt,CFX)-CE
40.	**AmpliSens® *HAV*-FRT** PCR kit	R-V4(RG,iQ)-CE
41.	**AmpliSens® *Helicobacter pylori*-FRT** PCR kit	R-B9(RG,iQ)-CE H-2831-1-CE H-2832-1-4-CE
42.	**AmpliSens® Hemochromatosis-FRT** PCR kit	S-2451-1-CE S-2452-1-4-CE
43.	**AmpliSens® *HGV*-FRT** PCR kit	R-V2-50-F(RG,iQ,Mx,Dt)-CE
44.	**AmpliSens® *HHV*6-screen-titre-FRT** PCR kit	R-V10-T(RG,iQ,Mx)-CE
45.	**AmpliSens® *HHV7*-screen/monitor-FRT** PCR kit	H-2431-1-1-CE
46.	**AmpliSens® *HHV*8-screen/monitor-FRT** PCR kit	H-3581-1-1-CE H-3582-1-14-CE
47.	**AmpliSens® *HPV* 16/18-FRT** PCR kit	R-V12-100-CE R-V12-F-CE R-V12(RG,iQ,Mx)-CE
48.	**AmpliSens® *HPV* 6/11-FRT** PCR kit	R-V11-100-CE R-V11-Mod(RG,iQ,Mx)-CE R-V11(RG,iQ,Mx)-CE
49.	**AmpliSens® *HPV* HCR genotype-FRT** PCR kit	R-V25(RG,iQ,Mx)-CE
50.	**AmpliSens® *HPV* HCR genotype-titre-FRT** PCR kit	R-V67-F-CE H-2261-1-13-CE
51.	**AmpliSens® *HPV* HCR screen-EPh** PCR kit	V31-100F-CE
52.	**AmpliSens® *HPV* HCR screen-FEP** PCR kit	V31-3x-FEP-CE V31-FEP-CE
53.	**AmpliSens® *HPV* HCR screen-titre-14-FRT** PCR kit	H-2311-1-13-CE
54.	**AmpliSens® *HPV* HCR screen-titre-FRT** PCR kit	R-V31-T-2x(RG,iQ,SC)-CE R-V31-T-4x(RG,iQ,Mx)-CE R-V31-F-CE
55.	**AmpliSens® *HSV* I, II-FRT** PCR kit	R-V8-F(RG,iQ)-CE
56.	**AmpliSens® *HSV*-typing-FEP** PCR kit	V38-100-R0,2-FEP-CE
57.	**AmpliSens® *HSV*-typing-FRT** PCR kit	R-V38-F(RG,iQ)-CE
58.	**AmpliSens® *Human enterovirus*-FEP** PCR kit	H-2771-2-2-CE H-2772-2-CE
59.	**AmpliSens® *Human enterovirus*-FRT** PCR kit	H-2771-1-2-CE H-2773-1-CE H-2773-1-4-CE
60.	**AmpliSens® *Influenza virus* A/H1-swine-FEP** PCR kit	V55-50-R0,2-FEP-CE
61.	**AmpliSens® *Influenza virus* A/H1-swine-FRT** PCR kit	R-V55(RG)-CE R-V55-F(SC)-CE
62.	**AmpliSens® *Influenza virus* A-type-FRT** PCR kit	R-V54-100-F(RG,iQ,Dt,SC)-CE
63.	**AmpliSens® *Influenza virus* A-type-H5, H7, H9-FRT** PCR kit	R-V66-F-CE
64.	**AmpliSens® *Influenza virus* A H5N1-FRT** PCR kit	R-V33(SC)-CE
65.	**AmpliSens® *Influenza virus* A/B-FRT** PCR kit	R-V36-100-F-Mod(RG,iQ,Dt, CFX,SC)-CE
66.	**AmpliSens® *Influenza virus* B-type-FRT** PCR kit	H-3991-1-23-CE H-3992-1-3-CE
67.	**AmpliSens® *JCV-BKV* screen-monitor-FRT** PCR kit	H-2441-1-1-CE

№№	Description	Product Code (for reference only)
68.	**AmpliSens® *Legionella pneumophila*-FEP** PCR kit	B50-R0,2-FEP-CE
69.	**AmpliSens® *Legionella pneumophila*-FRT** PCR kit	R-B50(RG)-CE
70.	**AmpliSens® *Leptospira*-FRT** PCR kit	R-B49(RG,iQ)-CE
71.	**AmpliSens® Leucosis Quantum *M-bcr*-FRT** PCR kit	TR-O1(RG,iQ,Mx,A)-CE
72.	**AmpliSens® *Listeria monocytogenes*-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® *MRSA*-screen-titre-FRT** PCR kit	R-B78-100-FT(RG,iQ)-CE
79.	**AmpliSens® *MTC*-diff-FRT** PCR kit	R-B80(RG,iQ,Dt,SC)-CE
80.	**AmpliSens® MTC-MDR-FRT** PCR kit	H-3611-1-CE H-3612-1-4-CE
81.	**AmpliSens® *MTC*-FEP** PCR kit	B57-FEP-CE
82.	**AmpliSens® *MTC*-FRT** PCR kit	R-B57(RG,iQ,SC,Dt)-CE
83.	**AmpliSens® MTHFR-SNP-FRT** PCR kit	S-3721-1-CE S-3722-1-4-CE
84.	**AmpliSens® *Mycoplasma genitalium*-FEP** PCR kit	B4-100-R0,2-FEP-CE
85.	**AmpliSens® *Mycoplasma genitalium*-FRT** PCR kit	R-B4(RG)-CE R-B4-F(RG,iQ)-CE
86.	**AmpliSens® *Mycoplasma hominis*-FEP** PCR kit	B3-100-R0,2-FEP-CE
87.	**AmpliSens® *Mycoplasma hominis*-FRT** PCR kit	R-B3(RG)-CE R-B3-F(RG,iQ)-CE
88.	**AmpliSens® *M.genitalium*-ML/FQ-Resist-FRT** PCR kit	H-3971-1-CE
89.	**AmpliSens® *N.meningitidis* / *H.influenzae* / *S.pneumonia*-FRT** PCR kit	R-B25(RG,iQ)-CE
90.	**AmpliSens® *Neisseria gonorrhoeae*-screen-FEP** PCR kit	B51-100-R0,2-FEP-CE
91.	**AmpliSens® *Neisseria gonorrhoeae*-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® *Norovirus* GI / GII-FRT** PCR kit	H-2751-1-3-CE
94.	**AmpliSens® *Parvovirus* B19-FRT** PCR kit	R-V49(RG,iQ,Mx)-CE
95.	**AmpliSens *Plasmodium* spp. / *P.falciparum* / *P.vivax*-FRT** PCR kit	H-3981-1-CE H-3982-1-4-CE
96.	**AmpliSens® *Pneumocystis jirovecii* (*carinii*)-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® *Poliovirus*-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

№№	Description	Product Code (for reference only)
102.	**AmpliSens® Pyroscreen PHARMA-screen-transport kit**	S-16119-6-CE
103.	**AmpliSens® Pyroscreen PHARMA-screen-Warfarin kit**	S-16120-6-CE
104.	**AmpliSens® *Rickettsia conorii*-FRT** PCR kit	H-2741-1-CE H-2742-1-4-CE
105.	**AmpliSens® *Rickettsia* 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® *Shigella* spp. and *EIEC* / *Salmonella* spp. / *Campylobacter* spp.-FRT** PCR kit	R-B44(RG,iQ)-CE
110.	**AmpliSens® *Streptococcus agalactiae*-screen-titre-FRT** PCR kit	R-B77-100-FT(RG,iQ)-CE
111.	**AmpliSens® *Streptococcus pyogenes*-screen/monitor-FRT** PCR kit	H-2171-1-1-CE H-2172-1-14-CE
112.	**AmpliSens® *T.vaginalis* / *N.gonorrhoeae*-MULTIPRIME-FRT** PCR kit	R-B65-F(RG,iQ)-CE
113.	**AmpliSens® TBE-FRT** PCR kit	R-V52(RG)-CE
114.	**AmpliSens® *TBEV*, *B.burgdorferi sl*, *A.phagocytophilum*, *E.chaffeensis* / *E.muris*-FRT** PCR kit	R-V59(RG,iQ,Mx,Dt)-CE
115.	**AmpliSens® *Treponema pallidum*-FRT** PCR kit	R-B20-F(RG,iQ)-CE
116.	**AmpliSens® *Trichomonas vaginalis*-EPh** PCR kit	B6-100-R0,2-CE
117.	**AmpliSens® *Trichomonas vaginalis*-FEP** PCR kit	B6-100-R0,2-FEP-CE
118.	**AmpliSens® *Trichomonas vaginalis*-FRT** PCR kit	R-B6-F(RG,iQ)-CE
119.	**AmpliSens® *U.parvum* / *U.urealyticum*-FEP** PCR kit	B19-100-R0,2-FEP-CE
120.	**AmpliSens® *U.parvum* / *U.urealyticum*-FRT** PCR kit	R-B19(RG)-CE R-B19-F(RG,iQ)-CE
121.	**AmpliSens® *Ureaplasma* spp.-FRT** PCR kit	R-B2(RG)-CE R-B2-F(RG,iQ)-CE
122.	**AmpliSens® *Ureaplasma* spp.-screen-titre-FRT** PCR kit	R-B2-100-FT(RG,iQ,Mx)-CE
123.	**AmpliSens® *Vibrio cholerae*-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® *Yersinia enterocolitica* / *Y.pseudotuberculosis*-FRT** PCR kit	R-B64(RG,iQ)-CE
128.	**AmpliSens® *Yersinia pestis*-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

Management Systems Certification Body
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
www.itczlin.cz

CERTIFICATE

No. 21 0023 SJ

We confirm on the basis of a performed audit that company

Federal Budget Institute of Science "Central Research Institute for Epidemiology"

3a, Novogireevskaya str., 111123 Moscow, Russian Federation
Company VAT No.: 7720024671

has implemented and documented a functional quality management system in compliance with the requirements of the standard

EN ISO 13485:2016

Covering the following activities:

Design and development, manufacturing and final control of *in vitro* diagnostic medical devices

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233404948/2021. The Certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo.
During use of the Certificate the Certificate Holder undertakes to follow the Rules of Use of the Certificate. This document is publicly available on www.itczlin.cz

S 3002

Date of Issue: 27. 04. 2021
Valid until: 26. 04. 2024

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Ing. Pavel Vaněk
Head of Certification Body