

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

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

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: / **Centrifuge Tube**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

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

Suzhou, 201.05.26

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

CE

General Manager

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

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: / **Eppendorf Tube**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

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

Suzhou, 201.05.26

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

CE

General Manager

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



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

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: / **Filtered Pipette Tips**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

(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
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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: / **Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /**
Conformity assessment procedure: / **EG Annex III (expect point 6) of IVDD 98/79/EC**
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Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

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

Suzhou, 2022.01.01

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

CE

General Manager

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



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Nom et adresse du fabricant: / **Suzhou, 215021, Jiangsu, China**
Nome e indirizzo del fabbricante:

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: / **Gilson Pipette Tips**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
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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.

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

Suzhou, 201.05.26

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

CE

General Manager

Name und Funktion / Name and function /
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Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Microscope Cover Glass**
the medical device: /
le dispositif médical: /
il dispositivo medico:

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Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

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

Suzhou, 201.05.26

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

CE

General Manager

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

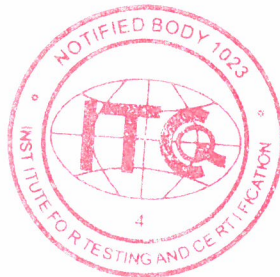
on in vitro diagnostic medical devices, Annex IV excluding (4, 6)

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



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

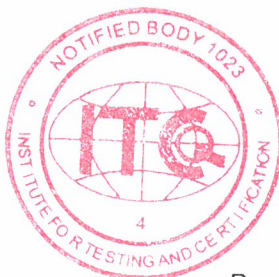
Name: **AmpliSens® CMV-FEP PCR kit**

Trade name(s): -

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

Classification: List B

GMDN: 30798



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

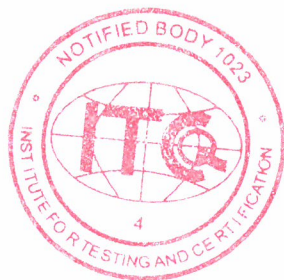
Name: **AmpliSens® CMV-screen/monitor-FRT PCR
kit**

Trade name(s): -

Model(s): variant FRT-100 F

Classification: List B

GMDN: 30798



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**

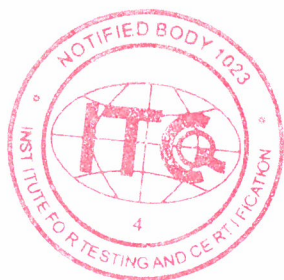
Trade name(s): -
Model(s): variant FRT-100 F
Classification: List B
GMDN: 61348

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



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



Date: 2022-04-28
Revision: k

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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**

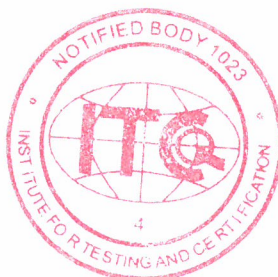
Trade name(s): -

Model(s): variant FRT-100 F

Classification: List B

GMDN: 50409

Date: 2022-04-28
Revision: k



Mgr. Jiří Heš
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Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
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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

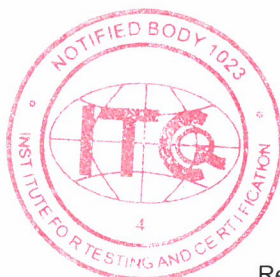
Name: **AmpliSens[®] *Mycoplasma pneumoniae* /
Chlamydomphila pneumoniae-FEP PCR kit**

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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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 11123, Russia**

Name: **AmpliSens® *Mycoplasma pneumoniae* /
Chlamydomonas 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



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

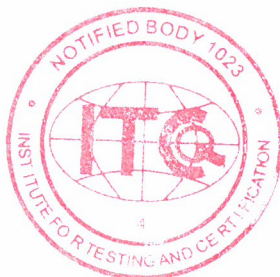
issued for manufacturer:

**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



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



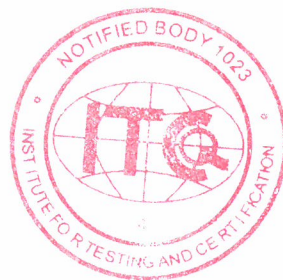
Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

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 25 th January 2022



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



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: ecolli@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 <i>in Vitro</i> 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. třída Tomáše Bati 299 Louky, 763 02 Zlín, 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:	Zlín, Czech Republic, 2022-04-28

Signed

Full name: Vasily 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 / HHV6-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



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 <i>in Vitro</i> Diagnostic Devices
Conformity Assessment Route:	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.	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-IL28B-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® HHV6-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® HHV8-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® <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

№№	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® <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



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



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Date of the first certification awarding: 20. 05. 2015


Ing. Pavel Vaněk
Head of Certification Body