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

Digitally signed by Ceaicovschi Tudor
Date: 2022.12.20 13:03:31 EET
Reason: MoldSign Signature
Location: Moldova

NOTIFIED BODY 1023 ITC 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

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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® *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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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

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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® *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

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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

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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® *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

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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 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

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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 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
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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

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

Ing. Pavel Vaněk
Head of Certification Body

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

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L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

SGQ N° 023A
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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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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

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DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

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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“. /

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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
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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)**

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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“. /

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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. /

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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**

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das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Microscope Slide**
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:	**Non Vacuum Blood 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:	**Serological Pipette**
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

LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

otorga el certificado número

grants the certificate no.

2013 11 0039 EN

según la norma

in accordance with the standard

UNE-EN ISO 13485: 2018

(EN ISO 13485: 2016 & ISO 13485: 2016)

Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios

Medical devices – Quality management systems - Requirements for regulatory purposes

a la empresa

to the company

Dia.Pro Diagnostic Bioprobes S.r.l.

Sede social y de fabricación/ *Headquarters and manufacturing facility*

Via G. Carducci, 27-20099-Sesto San Giovanni-Milano-Italy

Para las siguientes actividades / *For the following activities:*

Diseño, desarrollo y producción de reactivos y productos reactivos, calibradores y materiales de control para inmunoquímica, microbiología, inmunología infecciosa y técnicas de biología molecular.

Diseño, desarrollo, producción y servicio técnico de instrumentos y software para diagnóstico *in vitro*.

Design, development and manufacturing of reagents, reagent products, calibrators and control materials for immunochemistry, microbiology, infectious immunology and molecular biology techniques.

Design and development, management of production and technical servicing of instruments and software for "in vitro" diagnostic.

Modificaciones de alcance/ *Scope modifications:*: **Ver Anexo I /** *see Annex I*
Fecha de validez/ *Date of validity:* **Desde/** *From:* **25-02-2021** **Hasta/***To:* **18-11-2023**
Certificación inicial/ *Initial certification date:* **27-11-2013**
Renovaciones / *Renewal of certification dates:* **8-03-2019; 25-02-2021**

Madrid, 23 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ANEXO I / *ANNEX I*

CERTIFICADO UNE-EN ISO 13485: 2018/ *UNE-EN ISO 13485: 2018 CERTIFICATE*

Modificaciones del alcance / *Scope modifications:*

Fecha/*Date*	**Descripción de la modificación**/ *Modification description*
18-12-2018	Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico *Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques).* *Change in the level of detail of the technological scope description.*
8-03-2019	Ampliación del ámbito tecnológico para incluir: Inmunoquímica y microbiología Instrumentos y software para diagnóstico "in vitro". Modificación del alcance para incluir la actividad de asistencia técnica para Instrumentos y software para diagnóstico "in vitro". *Extension of technological scope:* *Immunochemistry and Microbiology* *Instruments and software for "in vitro" diagnostic* *Modification of the scope to include the activity of technical servicing of instruments and software for "in vitro" diagnostic*

Madrid, 23 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

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MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE
EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*				ON nº/*NB no*
2004 05 0442 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To***	**26-05-2025**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.**
Dirección/*Address*: **Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)**
Representante autorizado ante la UE/*Authorized EU representative*: Idem

Para el producto/*For the product*:

Categoría/*Category*: **Productos sanitarios para diagnóstico "in vitro"**/ *In vitro diagnostic medical devices*
Grupo genérico/ *Generic group*: **Diagnóstico de enfermedades infecciosas** / *Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en el Anexo de este Certificado/*Specified in Annex to this Certificate*

Elaborado en/*In the facilities*:

Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy).

Fecha inicial/ *Initial date:* 10/05/2014
Fecha de prórroga anterior/ *Previous extension date:* 26/11/2018

Este certificado debe ir acompañado por certificado de examen de diseño: NO / *This certificate must be accompanied by design examination certificate*: *NO*

Este certificado es consecuencia de la auditoria del sistema completo de garantía de calidad y del examen de la documentación técnica contenida en el expediente nº 2003 05 0240, y garantiza que los productos descritos cumplen los requisitos de la Directiva./ *This certificate is issued on the full quality assurance system audit, and the examination of the technical documentation contained in dossier nº 2003 05 0240, and guarantees that the described products fulfils the requirements of the Directive.*

Madrid, 19 de mayo de 2022
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
Fecha de la firma: 19/05/2022
Puede comprobar la autenticidad del documento en la sede de la AEMPS:https://localizador.aemps.es
CSV: B 8 B Q W K 2 5 B 8

CORREO ELECTRÓNICO
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28022 MADRID
Tel.: (+34) 91 822.57.87 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2004 05 0442 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name*: **DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.**
Dirección/*Address*: **Via G. Carducci, 27. 20099 Sesto San Giovanni. Milano (Italy)**
Representante autorizado ante la UE/*Authorized EU representative*: **Idem**

Tipo de producto/ *Devices type*: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas humanas. / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/ *Classification:* Lista B del Anexo II / *List B of Annex II*

1. **Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de Inmunoabsorción enzimática (ELISA)/** *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0303; IVD 0305]**

1.1. CMV IgM

- CMV.CE (96 tests)

1.2. CMV IgG

- CMVG.CE (96 tests)

1.3. Toxo IgM

- TOXOM.CE (96 tests)

1.4. Toxo IgG

- TOXOG.CE (96 tests)

1.5. RUB IgM

- RUBM.CE (96 tests)

1.6. RUB IgG

- RUBG.CE (96 tests)
- RUBG.CE.192 (192 tests)
- RUBG.CE.480 (480 tests)

1.7. TORCH IgM

- TORCHM.CE (96 tests)

1.8. *Chlamydia Trachomatis* IgG

- CTG.CE (96 tests)

-

1.9. *Chlamydia Trachomatis* IgM

- CTM.CE (96 tests)

1.10. *Chlamydia Trachomatis* IgA

- CTA.CE (96 tests)

1.11. *Chlamydia Pneumoniae* IgG

- CPG.CE (96 tests)

1.12. *Chlamydia Pneumoniae* IgM

- CPM.CE (96 tests)

1.13. *Chlamydia Pneumoniae* IgA

- CPA.CE (96 tests)

2. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de PCR en tiempo real/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Real-Time PCR* [NANDO: IVD 0303; IVD 0305]

2.1. CMV DNA Quantitation (QT) 2nd Generation

- CMVDNAQT.2G. CE (50 tests)
- CMVDNAQT.2G.CE.25 (25 tests)
- CMVDNAQT.2G.CE.100 (100 tests)
- CMVDNAQT.2G.CE.150 (150 tests)

-

2.2. Dx CMV Assay

- 37020 (96 tests)

2.3. *Toxoplasma Gondii* DNA

- TOXODNA.CE (50 tests)
- TOXODNA.CE.25 (25 tests)
- TOXODNA.CE.100 (100 tests)
- TOXODNA.CE.150 (150 tests)

2.4. *Chlamydia Trachomatis* DNA

- CTDNA.CE (50 tests)
- CTDNA.CE.25 (25 tests)
- CTDNA.CE.100 (100 tests)
- CTDNA.CE.150 (150 tests)

2.5. PRIME MDx CMV DNA Quantitative detection kit

- 56449 (24 tests)
- 56450 (48 tests)

2.6. PRIME MDx *Toxoplasma gondii* DNA detection kit

- 5647 (24 tests)
- 5648 (48 tests)

3. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante ensayos de quimioluminiscencia (CLIA)/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Chemiluminescence Immunoassay (CLIA)* **[NANDO: IVD 0303; IVD 0305]**

3.1 DIA.CHEMILUX Cytomegalovirus IgM

- RACMVM.CE (100 tests)

3.2 DIA.CHEMILUX Cytomegalovirus IgG

- RACMVG.CE (100 tests)

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2004 05 0442 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

3.3 DIA.CHEMILUX Toxoplasma IgM

- RATOXOM.CE (100 tests)

3.4 DIA.CHEMILUX Toxoplasma IgG

- RATOXOG.CE (100 tests)

3.5 DIA.CHEMILUX Rubella IgM
- RARUBM.CE (100 tests)

3.6 DIA.CHEMILUX Rubella IgG
- RARUBG.CE (100 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 19 de mayo de 2022
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Imposta di bollo assolta

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E
DEL SERVIZIO FARMACEUTICO
UFFICIO 4 DGDMF –DISPOSITIVI MEDICO DIAGNOSTICI IN VITRO

DGDMF/4/I.5.1.e.2/2022/59

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;
VISTO il D.lgs. n .332/2000 recante attuazione della direttiva 98/79/CE;
VISTA l'istanza datata 07/04/2022 presentata dalla ditta Dia.Pro Diagnostic BioProbes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159;
CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 06 Agosto 2021;
VISTI gli atti d'ufficio;
HAVING REGARD *to 98/79/EC directive concerning the in vitro diagnostic medical-devices;*
HAVING REGARD *to legislative Decree (D.lgs.)n. 332/2000 reporting the accomplishment of 98/79/EC Directive;*
HAVING REGARD *to the request dated 07/04/2022 submitted by the company Dia.Pro Diagnostic BioProbes Srl located in Via G. Carducci 27 – 20099 Sesto San Giovanni (MI) – C.F. / P.Iva 11924660159;*
WHEREAS *this company paid the fees required by Ministerial Decree (D.M.) August 6, 2021;*
HAVING REGARD to *the official deeds;*

SI ATTESTA
IT IS ATTESTED

che la ditta, Dia.Pro Diagnostic BioProbes Srl con sede legale e sede operativa in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) Italia – C.F./P.Iva 11924660159, è il fabbricante ed ha marcato CE, come dispositivi medico - diagnostici in vitro, secondo le procedure previste dalla direttiva 98/79/CE, i seguenti prodotti:

that the Company Dia.Pro Diagnostic BioProbes Srl with registered place of business and operative site in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI), Italy – C.F./P.Iva 11924660159, is the manufacturer and affixed CE marking as in vitro diagnostisc medical devices, according to the Directive 98/79/EC, to the following products:

LINEA EPATITE / *HEPATITIS LINE*

PRODOTTO / *PRODUCT*	**CODICE / *CODE***	**TESTS N°**
HAV Ab	AVAB.CE	96
HAV IgM	AVM.CE	96
HBc Ab	BCAB.CE	96
HBc IgM	BCM.CE	96

HCV Ab Confirmation	CCONF.CE	12
HCV Ab	CVAB.CE	192
	CVAB.CE.96	96
	CVAB.CE.480	480
	CVAB.CE.960	960
	CVAB.CE.DB	192
HCV IgM	CVM.CE	96
HDV Ab	DAB.CE	96
HDV Ag	DAG.CE	96
HDV IgM	DIM.CE	96
HEV IgG	EVG.CE	96
HEV IgM	EVM.CE	96
HEV Ab Version ULTRA	EVABULTRA.CE	192
	EVABULTRA.CE.96	96
	EVABULTRA.CE.480	480
	EVABULTRA.CE.960	960
HBe Ag&Ab	HBE.CE	96
HBs Ab	SAB.CE	96
HBs Ag one version ULTRA	SAG1ULTRA.CE	192
	SAG1ULTRA.CE.96	96
	SAG1ULTRA.CE.480	480
	SAG1ULTRA.CE.960	960
	SAG1ULTRA.CE.DB	192
HBs Ag Confirmation	SCONF.CE	20
	SCONF.CE.40	40

LINEA RETROVIRUS / *RETROVIRUS LINE*

PRODOTTO / *PRODUCT*	**CODICE / *CODE***	**TESTS N°**
HTLV I&II Ab Version ULTRA	HTLVABULTRA.CE	192
	HTLVABULTRA.CE.96	96
	HTLVABULTRA.CE.480	480
	HTLVABULTRA.CE.960	960
	HTLVABULTRA.CE.DB	192
HIV Ab&Ag	IVCOMB.CE	192
	IVCOMB.CE.96	96
	IVCOMB.CE.480	480
	IVCOMB.CE.960	960
	IVCOMB.CE.DB	192

LINEA TORCH / *TORCH LINE*

PRODOTTO / *PRODUCT*	**CODICE / *CODE***	**TESTS N°**
CMV IgG	CMVG.CE	96
CMV IgM	CMVM.CE	96
HSV1 IgG	HSV1G.CE	96
HSV1 IgM	HSV1M.CE	96
HSV2 IgG	HSV2G.CE	96
HSV2 IgM	HSV2M.CE	96
HSV1&2 IgG	HSVG.CE	96
HSV1&2 IgM	HSVM.CE	96
RUB IgG	RUBG.CE	96
	RUBG.CE.192	192
	RUBG.CE.480	480
RUB IgM	RUBM.CE	96
TORCH IgM	TORCHM.CE	96
Toxo IgG	TOXOG.CE	96
Toxo IgM	TOXOM.CE	96

LINEA SEROLOGIA / *SEROLOGY LINE*

PRODOTTO / *PRODUCT*	**CODICE / *CODE***	**TESTS N°**
CagA IgA	CAGA.CE	96
CagA IgG	CAGG.CE	96
CoxB IgM	COXBM.CE	96
CoxB IgG	COXBG.CE	96
Chlamydia Pneumoniae IgA	CPA.CE	96
Chlamydia Pneumoniae IgG	CPG.CE	96
Chlamydia Pneumoniae IgM	CPM.CE	96
Chlamydia Trachomatis IgA	CTA.CE	96
Chlamydia Trachomatis IgG	CTG.CE	96
Chlamydia Trachomatis IgM	CTM.CE	96
Dengue virus IgG	DENG.CE	96
Dengue virus IgM	DENM.CE	96
Dengue virus NS1 Ag	DENS1AG.CE	96
Ea IgG	EAG.CE	96
Ea IgM	EAM.CE	96
EBNA IgG	EBNG.CE	96
EBNA IgM	EBNM.CE	96
HP IgA	HPA.CE	96
HP IgG	HPG.CE	96
HP IgM	HPM.CE	96
HP Ag	HPAG.CE	48
	HPAG.CE.96	96
Malaria Ab	MALAB.CE	192
	MALAB.CE.480	480
	MALAB.CE.96	96

	MALAB.CE.960	960
	MALAB.CE.DB	192
Measles virus IgG	MEAG.CE	96
Measles virus IgM	MEAM.CE	96
Meningitis IgG	MENG.CE	96
MTB IgG	MTBG.CE	96
SYPH IgM	SIM.CE	96
Syphilis Ab Version ULTRA	SIABULTRA.CE	192
	SIABULTRA.CE.96	96
	SIABULTRA.CE.480	480
	SIABULTRA.CE.960	960
	SIABULTRA.CE.DB	192
Syphilis Ab One Version ULTRA	SIAB1ULTRA.CE	192
	SIAB1ULTRA.CE.96	96
	SIAB1ULTRA.CE.480	480
	SIAB1ULTRA.CE.960	960
	SIAB1ULTRA.CE.DB	192
T.cruzi Ab	TCAB.CE	192
	TCAB.CE.96	96
	TCAB.CE.480	480
	TCAB.CE.960	960
	TCAB.CE.DB	192
EBV VCA IgA	VCAA.CE	96
VCA IgG	VCAG.CE	96
VCA IgM	VCAM.CE	96
West Nile Virus IgG	WNG.CE	96
West Nile Virus IgM	WNM.CE	96
Parvovirus B19 IgG	PARVOG.CE	96
Parvovirus B19 IgM	PARVOM.CE	96
ZIKV IgM	ZIKVM.CE	96
ZIKV IgG	ZIKVG.CE	96
ZIKV IgG Avidity Test	ZIKVAV.CE	48
CHIKV IgM	CHIKVM.CE	96
CHIKV IgG	CHIKVG.CE	96
TETOX IgG	TETG.CE	96
Yellow Fever Virus IgG	YFVG.CE	96

LINEA AUTOIMMUNITA' / *AUTOIMMUNITY LINE*

ANA 8 parameters profile	ANA8PRO.CE	12
ANA Screening IgG	ANAS.CE	96
IgG anti Centromere B	CENPB.CE	96
IgG anti dsDNA	DSDNA.CE	96
ENA 6 parameters profile	ENA6PRO.CE	12
ENA Screening IgG	ENAS.CE	96
IgG anti Jo-1	JO1.CE	96
IgG anti U1-snRNP 68	RNP.CE	96
IgG anti Scl-70	SCL70.CE	96

IgG anti Sm	SM.CE	96
IgG anti SSA 52 KD	SSA52.CE	96
IgG anti SSA 60 KD	SSA60.CE	96
IgG anti SSB	SSB.CE	96
Anti Thyroglobulin IgG	TG.CE	96
Anti Thyroid Peroxidase	TPO.CE	96

LINEA COVID-19 / *COVID-19 LINE*

PRODOTTO / *PRODUCT*	**CODICE / *CODE***	**TESTS N°**
COVID-19 IgG	COV19G.CE COV19G.CE.192	96 192
COVID-19 IgM	COV19M.CE COV19M.CE.192	96 192
COVID-19 IgA	COV19A.CE COV19A.CE.192	96 192
COVID-19 Spike 1&2 IgG	COV19GSPIKE.CE COV19GSPIKE.CE.192	96 192
ACE2-RBD Neutralization Assay	ACE2-RBDNEUTR.CE	96
COVID-19 IgG Confirmation	COV19CONF.CE	24
COVID-19 IgG/IgM Confirmation and Typing	COV19TY.CE	24

I suddetti prodotti, in base all'art. 4 della direttiva 98/79/CE, sono di libera circolazione e possono essere messi in commercio in Italia e in tutto il territorio dell'Unione Europea.
Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione.
The above mentioned products, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union.
This certificate is issued on the interested company's request according to the law and for exporting.

IL DIRIGENTE DELL'UFFICIO 4
THE DIRECTOR OF OFFICE 4
(Dott.ssa Antonella Colliardo)

RM/CM