Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 0040 QS/NB/d

Issued in compliance with the Directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on in vitro diagnostic medical devices as amended, which is implemented by the Czech Government Order No. 56/2015 (Collection of Laws). This certifies that the products – in vitro diagnostic medical devices according to Annex II, List B of the Directive 98/79/EC

AmpliSens® PCR Kits

(For detailed specification refer to Annex of this Certificate)

Authorised European representative

Ecoli s.r.o.
Studenohorská 12, 841 03 Bratislava, Slovak Republic

Manufacturer

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

3A Novogireevskaya Street, Moscow 111123, Russia

are manufactured under conditions fulfilling the quality system requirements of Annex IV, Section 3.2. of the Directive 98/79/EC.

The Notified Body No. 1023 has performed an audit of the above products quality system. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Reports No. 813600111/2011, No. 813600161/2011, No. 343601304/2012, No. 343602568/2014 and No. 813600504a/2016, which are enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **23rd July 2016** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each in vitro diagnostic medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Issued in Zlín, on 15th January 2016
Replaces the withdrawn EC Certificate No. 11 0040 QS/NB/c issued on 13th May 2014

Annex to EC Certificate
No. 11 0040 QS/NB/d

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List of the medical devices covered by this EC Certificate:

№	Product Code	Description
1.	R-V24-S(RG,iQ,Mx)-CE	"AmpliSens® *Rubella virus*-FRT" PCR kit
2.	R-P1(RG,iQ,Mx)-CE	"AmpliSens® *Toxoplasma gondii*-FRT" PCR kit
3.	V7-100-R0,5-FEP-CE V7-100-R0,2-FEP-CE	"AmpliSens® *CMV*-FEP" PCR kit
4.	R-V7(RG)-CE R-V7(iQ)-CE R-V7-F(RG,iQ)-CE	"AmpliSens® *CMV*-FRT" PCR kit
5.	V60-100-R0,5-FEP-CE V60-100-R0,2-FEP-CE	"AmpliSens® *HSV* / *CMV*-MULTIPRIME-FEP" PCR kit
6.	R-V60(RG)-CE R-V60(iQ)-CE R-V60-F(RG,iQ)-CE	"AmpliSens® *HSV* / *CMV*-MULTIPRIME-FRT" PCR kit
7.	R-V7-100-S(RG,iQ,Mx)-CE	"AmpliSens® *CMV*-screen/monitor-FRT" PCR kit
8.	R-V48(RG,iQ,Mx)-CE	"AmpliSens® *EBV* / *CMV* / *HHV*6-screen-FRT" PCR kit
9.	B1-100-R0,5-FEP-CE B1-100-R0,2-FEP-CE	"AmpliSens® *Chlamydia trachomatis*-FEP" PCR kit
10.	R-B1(RG)-CE R-B1(iQ)-CE R-B1-F(RG,iQ)-CE	"AmpliSens® *Chlamydia trachomatis*-FRT" PCR kit
11.	B47-100-R0,5-FEP-CE B47-100-R0,2-FEP-CE	"AmpliSens® *C.trachomatis* / *Ureaplasma*-MULTIPRIME-FEP" PCR kit
12.	B66-100-R0,5-FEP-CE B66-100-R0,2-FEP-CE	"AmpliSens® *C.trachomatis* / *M.genitalium*-MULTIPRIME-FEP" PCR kit

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List of the medical devices covered by this EC Certificate:

№	Product Code	Description
13.	B46-100-R0,5-FEP-CE B46-100-R0,2-FEP-CE	"AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium*-MULTIPRIME-FEP" PCR kit
14.	R-B46(iQ)-CE R-B46(RG)-CE R-B46-F(RG,iQ)-CE	"AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium*-MULTIPRIME-FRT" PCR kit
15.	B43-100-R0,5-FEP-CE B43-100-R0,2-FEP-CE	"AmpliSens® *C.trachomatis / Ureaplasma / M.hominis*-MULTIPRIME-FEP" PCR kit
16.	R-B43(iQ)-CE R-B43(RG)-CE R-B43-F(RG,iQ)-CE	"AmpliSens® *C.trachomatis / Ureaplasma / M.hominis*-MULTIPRIME-FRT" PCR kit
17.	R-B60(RG)-CE R-B60-F(RG)-CE	"AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium / M.hominis*-MULTIPRIME-FRT" PCR kit
18.	R-B61(RG)-CE R-B61-F(RG)-CE	"AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium / T.vaginalis*-MULTIPRIME-FRT" PCR kit
19.	B67-100-R0,5-FEP-CE B67-100-R0,2-FEP-CE	"AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium*-MULTIPRIME-FEP" PCR kit
20.	R-B67(RG)-CE R-B67(iQ)-CE R-B67-F(RG,iQ)-CE	"AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium*-MULTIPRIME-FRT" PCR kit
21.	R-O2(RG,iQ)-CE	"AmpliSens® Genoscreen HLA B*5701-FRT" PCR kit

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List of the medical devices covered by this EC Certificate:

№	Product Code	Description
22.	B42-Mod-50-R0,2-FEP-CE B42-Mod-50-R0,5-FEP-CE B42-50-R0,2-FEP-CE B42-50-R0,5-FEP-CE	„AmpliSens® Mycoplasma pneumoniae / Chlamydophila pneumoniae-FEP" PCR kit
23.	R-B42-100-F-CE R-B42-4x(RG)-CE R-B42-4x(iQ)-CE	„AmpliSens® Mycoplasma pneumoniae / Chlamydophila pneumoniae-FRT" PCR kit
24.	R-B83(RG)-CE R-B83(iQ)-CE R-B83-F(RG,iQ)-CE	„AmpliSens® T.vaginalis / N.gonorrhoeae / C.trachomatis-MULTIPRIME-FRT" PCR kit
25.	B83-100-R0,5-FEP-CE B83-100-R0,2-FEP-CE	„AmpliSens® T.vaginalis / N.gonorrhoeae / C.trachomatis-MULTIPRIME-FEP" PCR kit

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