



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

## EC Design-Examination Certificate

### No. 22 0195 CN/NB

issued for manufacturer

### **Federal Budget Institute of Science “Central Research Institute for Epidemiology”**

3a Novogireevskaya Street, Moscow 111123, Russia

in accordance with requirements of

### **Directive 98/79/EC**

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

for the following product category(ies):

### **AmpliSens® PCR kits**

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with IVDD Annex IV, Section 4. The design of the devices conforms to the requirements of this Directive. For placing on the market of List A devices covered by this certificate, an EC Certificate according to the Annex IV (excluding sections 4 and 6) is required.

**Valid from:** 2022-05-20  
**Valid until:** 2025-05-26  
**First Issued:** 2022-05-20  
**Revision:** -



Date: 2022-05-20

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



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## Annex to EC Design-Examination Certificate

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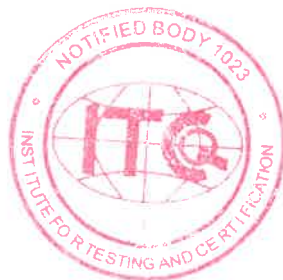
issued for manufacturer:

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

### Product:

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

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



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Revision: -

  
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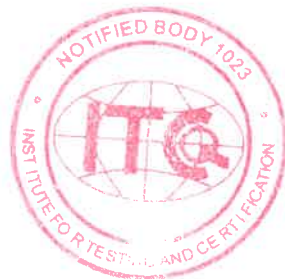
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#### Certificate History:

Revision	Date	Reference Number	Action
-	2022-05-20	813601116	Certification



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