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: -

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2022-05-20

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

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
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Annex to EC Design-Examination Certificate

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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

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION

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Certificate History:

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

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