Digitally signed by Latîşev Anastasia
Date: 2022.07.29 15:24:46 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV AUSTRIA

CERTIFICATE OF CONFORMITY

Certificate - No.: 19-IS-0988-TAT-22-LVD-EMC-3204

Applicant	:	INOVIA Yenilikçi Elektronik Teknolojileri San. Tic. Ltd. Şti. Oruçreis Mh. Giyimkent 7. Sk. No 115/A Esenler / İstanbul, TURKEY
Equipment	:	Real-Time PCR
Type/Model(s)	:	# RealGen series (RealGen-2X/-5X), XG series, GenX series #
Assessment Performed	:	Assesses for compliance with Annex-I Principal Elements of the Safety Objectives for Electrical Equipment Designed For Use Within Certain Voltage Limits of the Low Voltage Directive 2014/35/EU and Annex-I Essential Requirements of the Electromagnetic Compatibility Directive 2014/30/EU.
Standard(s) / Certification Basis	:	2014/35/EU Low Voltage Directive 2014/30/EU Electromagnetic Compatibility Directive EN 61010-1:2010, EN 61010-2-010:2014 EN 61000-6-2:2005/AC:2005, EN 61000-6-4:2007/A1:2011 EN 61000-6-3:2007/A1:2011/AC:2012 EN 61000-3-3:2013

This Certificate of Conformity is issued on a voluntary basis according to 2014/35/EU Low Voltage Directive & 2014/30/EU Electromagnetic Compatibility Directive. It conforms that the equipment complies with Annex-I requirements of the directives. It refers only to the sample and its technical file submitted for conformity assessment.

In addition, Novel Coronavirus(2019-nCoV) RT-PCR Detection Kit test reports are seen on technical file. (See Annex-I)

Reference Test Report No	:	KD-200401007E
Issue Date	:	24.01.2022
Expiry Date	:	23.01.2023

TÜV AUSTRIA TURK LTD. TÜV AUSTRIA

For and on behalf of
TÜV AUSTRIA TURK Belgelendirme
Eğitim ve Gözetim Hizmetleri Ltd.Şti.
Ali Osman ÖZVEREN

CE

After preparation of the necessary technical documentation as well as the declaration of conformity the required CE marking can be affixed on the product. Other relevant directives have to be observed.

This Certificate of Conformity has been granted to the applicant based on the results of testing performed by the applicant/manufacturer or an accepted laboratory and the consequent review of the test report by TÜV AUSTRIA TURK. Revisions to the referenced certification basis or any change of the design, materials, components or processing may require the repetition of all or some of the qualification tests in order for the test report and therefore this associated certificate to remain valid. To fulfill the obligations laid down in Annex II of 2014/30/EU EMC & Annex III of 2014/35/EU LVD for serial production is under responsibility of the manufacturer.

TÜV AUSTRIA TURK

Çamlık Mah. İkbal Cad.
Dinç Sk. No:28 PK:34774
Ümraniye / ISTANBUL
E-mail: infoturkey@tuv.at

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书 | 인증서

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ANNEX-I OF CERTIFICATE NO: 19-IS-0998-TAT-22-LVD-EMC-3204

	Catalogue reference number	Commercial Name	Generic Device Name
1	INOQPCRDK-1	INOVIALAB 2019-nCov qPCR	Novel Coronavirus (2019-nCov) RT-PCR Detection Kit
2	INOQPCRDK-2	INOVIALAB FluA/FluB 2019-nCov qPCR	FluA/FluB/2019-nCov RT-PCR Detection Kit
3	INOQPCRIAK-1	INOVIALAB 2019-nCov Rapid	Novel Coronavirus (2019-nCov) Real-Time Isothermal Amplification Kit
4	INO-RSV-Rapid	INOVIALAB RSV Rapid	Novel Coronavirus (2019-nCoV) Real-Time Isothermal Amplification Kit
5	INOCPMP-Rapid	INOVIALAB CP/MP Rapid	Chlamdia pneumoniae /Mycoplasma pneumonia Real-Time Isothermal Amplification Kit
6	INONCOVIgM/IgG-Rapid	INOVIALAB 2019-nCov IgM/IgG Rapid	Novel Coronavirus (2019-nCov) IgM/IgG test kit

TÜV AUSTRIA TURK LTD. STI. TÜV AUSTRIA TAT-1

For and on behalf of
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Eğitim ve Gözetim Hizmetleri Ltd.Şti.
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