OHC
OSANG HEALTHCARE

Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si,
Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 0411 Fax: 82 031 460 0401
Website: www.osanghc.com

FSN Ref: OS-FSN-20200619-01

Date: June 19, 2020

Field Safety Notice
GeneFinder™ COVID-19 Plus RealAmp Kit

To all customers and Distributors:

Contact details of local representative
ELITechGroup SpA
Corso Svizzera 185, Torino (Italy)
Sergio Fazari
s.fazari@elitechgroup.com - +39 011 976 191

Information on Affected Devices
Device Type(s):
GeneFinder ™ COVID-19 PLUS RealAmp Kit is used for detection of COVID-19 (COVID-19) virus through reverse Transcription and Real-Time Polymerase Chain Reaction from RNA extracted from Respiratory specimens such as Alveolar lavage fluid, throat swab, sputum. This product can qualitatively detect COVID-19 using Polymerase Chain Reaction.

Commercial name(s):
GeneFinder COVID-19PlusRealAmp Kit

Primary clinical purpose of device(s):
Qualitatively detection of COVID-19 virus using Polymerase Chain Reaction

Device Model/Catalogue/part number(s): IFMR-45

Affected serial or lot number range:
2004-R45-18; 2004-R45-25; 2004-R45-26; 2004-R45-49

Reason for Field Safety Corrective Action (FSCA)
Description of the product problem:
The phenomenon was associated with the appearance of a high background signal with the amplification reaction of the "N gene".

Hazard giving rise to the FSCA:
This background signal, higher than normal, if exceeds the detection threshold and if the amplification graphs are NOT checked, may be interpreted as a positive result.

Probability of problem arising:
Due to the immediate mitigation of raising the detection threshold, enforced on all the instruments, the probability of other problems is very low.

Background on Issue:
ELITechGroup SpA, distributor of the product "GeneFinder™ COVID-19 Plus RealAmp Kit" - ref. IFMR-45 (produced by OSANG Healthcare Co., Ltd. - South Korea) has received some customer reports related to this product.

OHC
OSANG HEALTHCARE

Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si,
Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 0411 Fax: 82 031 460 0401
Website: www.osanghc.com

FSN Ref: OS-FSN-20200619-01

Type of Action to mitigate the risk
Action To Be Taken by the User:

☒ Identify Device

☒ Other

For Applied Biosystems 7500/7500 Fast Dx, CFX96 (Bio-Rad) users and for the analysis of the tests performed by the products belonging to the production batches involved, it is recommended to change the threshold values as shown below

Before

Target	Threshold		Baseline	
	ABI	CFX96	Start	End
RdRp gene	30,000	300	3	15
N gene	30,000	300	3	15
E gene	30,000	300	3	15
IC	10,000	100	3	15

After

Target	Threshold		Baseline	
	ABI	CFX96	Start	End
RdRp gene	30,000	300	3	15
N gene	**100,000**	**1,000**	3	15
E gene	30,000	300	3	15
IC	10,000	100	3	15

For ELITe InGenius users
A new Assay Protocol has been developed by OSANG Healthcare Co. Ltd. which raises the detection threshold to avoid interference from any non-specific/background signals. Based on internal verification, the sensitivity is not affected by this change.

In addition to the above measures, any user of the "GeneFinder™ COVID-19 Plus RealAmp Kit" product is recommended to check the fluorescence diagram provided by the instrument before validating the final test results.

Action Being Taken by the Manufacturer:

☐ Product Removal
☐ Software upgrade
☐ Other
☒ On-site device modification/inspection
☐ IFU or labelling change
☐ None

The new Assay Protocol is currently being installed on ELITe InGenius platforms.

General Information
This is a new FSN and no further advice or information are expected for the time being.

Manufacturer information:
OSANGHealthcareCo., Ltd.
Anyangcheondong-ro, Dongan-gu, 132
Anyang-si,Gyeonggi-do – 14040
Min Sun Kim
mskim@osanghc.com - +82-31-460-0411

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

OHC
OSANG HEALTHCARE

Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si,
Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 0411 Fax: 82 031 460 0401
Website: www.osanghc.com

FSN Ref: OS-FSN-20200619-01

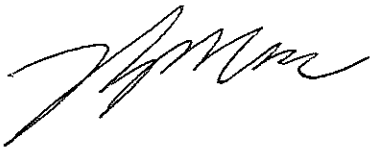
Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Name/Signature MANUFACTURER OSANG Healthcare Co., Ltd. Quality Management Director Ik-Hyeon Kim	
Name/Signature LOCAL RAPRESENTATIVE ELITechGroup SpA Quality Management Director Sergio Fazari