

5.1.2e

Document Number : OEOK-LKTS-SNI7-L7OE

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No. of Certificate : 20200039982

Date : 2020/04/09

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in overseas markets.

Manufacturer (Registered No. : 1620)

IONE BIO Inc.

#604, Daeryung Techno Tower 5-cha, 632, Seobusaet-gil, Geumcheon-gu, Seoul

Product-License No.	Classification
20-271	IVD reagents for infectious disease marker (Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', Infectious agents with moderate infectivity), nucleic acid test: [3]

※Attached : List of Product Classification and Model

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National Institute of Food and Drug Safety
Evaluation
Ministry of Food and Drug Safety

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

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Classification :

IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease,
Legally designated infectious pathogens other than 'high risk pathogens', Infectious
agents with moderate infectivity), nucleic acid test

Model(Export Name)

· CoV19-iLAMP