



Ministry of Food and Drug Safety

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Certificate of Free Sales

No. of Certificate : 20200123282
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 product(s) is(are) permitted to be freely sold in domestic and overseas markets.

○ Applicant (=Product-license holder)

(This certificate shall not be issued to others than the product-license holder)

- Name : Asan Pharmaceutical CO., LTD.

- Address : 122-26, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, Korea

- Registered No : Manufacturer IVD-4806

No. and date of product-license, comments	Classification
IVD- 20-1490 / SEP. 29. 2020	IVD reagents for extracting nucleic acids [1]

※ Attached, if necessary (approved product information)

Model(Export Name) Medical Device Accessories Manufacturer/Legal manufacturer
 Combined/Composite medical device

○ Do the facilities and operations conform to KGMP as recommended by the Ministry of Food and Drug Safety?

Yes No

Issued date : OCT. 06. 2020 (Certificate No.20200123282)

Certified by

Director of Medical Devices Policy Division
Department of Medical Device Safety Bureau Ministry
of Food and Drug Safety

This medical device is approved by National Institute of Medical Device Safety Information(NIDS) established under Article 42 of Medical Device Act.

Attachment

Product License No. : IVD- 20-1490 (SEP. 29, 2020)

Classification : IVD reagents for extracting nucleic acids

Model(Export Name)

· ASANPREP™ Viral Nucleic Acid Purification Kit

