

US FDA Establishment Registration & Device Listing

HSN COMPANY LTD. 79-23 B-205, 92, Dalseocheon-ro Seo-gu, Daegu Gwangyeoksi, 41706, KOREA, REPUBLIC OF has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration.

The registration will be valid through Dec 31, 2021. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2022 with instructions on how and when to re-register.

Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Date of Initial Registration: Jun 5, 2020

Establishment Information

Company Name: HSN COMPANY LTD.
Address: B-205, 92, Dalseocheon-ro
Seo-gu, Daegu Gwangyeoksi, 41706, KOREA, REPUBLIC OF
Contact Person: JUNHO LEE
Registration Number: 3017216464
Date of Registration Status: FY 2021

Device Listing

Listing Number	Product Code(s)	Device Name(s)	Activities
D407036	OEA	Non-surgical isolation gown	Manufacturer
D413431	MSH	Respirator, Surgical	Manufacturer
D413430	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer

This document has been issued by Intertek Testing Korea to transmit FDA registration information to the client. United States Food and Drug Administration does not issue any certificate of registration for registered facilities.

This document will not to be considered as product approval.



Listing Number:	D407036
Product Code:	OEA
Device:	Non-surgical isolation gown
Classification:	Class 1
Product Name:	HSND-0022 HSND-0011

Listing Number:	D413431
Product Code:	MSH
Device:	Respirator, Surgical
Classification:	Class 2
Product Name:	PureN nano filter mask KF94 (Model : HSNK-001)

Listing Number:	D413430
Product Code:	LYU
Device:	ACCESSORY, SURGICAL APPAREL
Classification:	Class 1
Product Name:	PureN nano filter mask KF94 (Model : HSNK-001)

