



1st KAPAL  
**On-Air**  
*on the 30<sup>th</sup> of April 2020*

# PPEs 등록/인증 관련

**Sang Tae Park Ph.D**

Executive Director, KAPAL

*(CEO of Coree LLC, a family company of Hanmi Science)*

# Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices

## • Personal Protective Equipment EUAs

- Mask/Respirator: 의료 목적 사용 위한 미국 마스크 규격 >N95 (NIOSH)

- 부족 상황: 4월초(4/3)에 Non-NIOSH Mask 위한 FDA EUA 발표
  - 총 6개국의 기준 인정(한국, 일본, 브라질, 유럽, 호주, 멕시코): 수출 가능한 상태 아님
    - 중국과 정치적 대립으로 중국 제외 > 2일 뒤에 다시 추가됨

- 요구 사항

- 4개의 해외 인증중 하나 필요: CE, ARTG(호주), Health Canada, PMDA(Japan)
- Criteria 1 or 2 기준 자료: 제조사, 제품번호, 판매허가, 품질허가/승인서, 제품설명/사진(영어)

- EUA Process

- 요청 자료를 [CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov](mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov) 로 제출
- 추가 자료 요청 가능: 중국제품 EUA 등록시에 제품 품질 허가 회사의 등록 및 해외 추가 인증 자료 요청해 옴
- 기간: 신청 시기 영향이 많은 것으로 파악 (초기 제품은 1주일 이내)
- 등록 제품은 FDA EUA site에 Appendix A로 게시되며, 별도의 허가 레터 발송(제조사, 수입자 등 관련 내용 포함)

# 기타 PPEs?

- Class I 제품: Exempt (등록 필요 없음)
  - 대상 제품: surgical suits/caps/dress/helmet/shoe cover/shoes
  - Face shield 같은 제품도 여기 포함
- Class II 제품: 등록 필요
  - 대상 제품: Surgical gown/toga/isolation gown/hood
  - Nitrile Glove: 등록 필요. But, PMN없이 가능(COVID-19 대응)

# 등록과 인증?

기준에 따른 상품 등록과 인증은 다름

1/1



**CERTIFICATE OF FDA REGISTRATION**

Registration Number :

Establishment Name :

Establishment Address :

Owner/Operator Number:

Device Name : MASK, SCAVENGING (Protective Mask)

Product Code : KHA

Device Listing Number : D378043

This certificate only affirms the above stated Establishment has completed the FDA Registration and Device Listing with the US Food & Drug Administration for FY 2020. This certificate issued by Jeston is just to present the registration result on this certificate. Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." Within the expiration date of this certificate Jeston may confirm the validity of this certificate upon request, unless terminated after issuance of this certificate. Jeston makes no other representations or warranties, nor does this certificate make any warranties or representations to any person or entity other than the named certificate holder, for whose sole benefit it is issued, Jeston assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a third-party certificate of registration. Jeston is not affiliated with the U.S. Food and Drug Administration.

This registration having been verified as effective within the following date by Jeston.  
Registration Expiration Date : 2020-12-31

*Kaiwin Guan*  
Kaiwin Guan  
Certification Service Manager



Ningbo Jeston Certification Service Co., Ltd.  
Tel: +86 574 8737 7879 E-Mail:jeston@nbjeston.com Http://www.nbjeston.com

## Example

- 중국산 KN95 마스크 등록증 (FDA)
- KHA 상품 코드에 등록된 것
- EUA 통한 Non-NIOSH mask 인증 아님

<b>Jurisdiction<sup>7</sup></b>	<b>Performance Standard</b>	<b>Acceptable product classifications</b>	<b>Standards/ Guidance Documents</b>	<b>Protection Factor <math>\geq 10</math></b>
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1 <sup>st</sup>	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES