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Important Note: This whitepaper is provided as general guidance on the importation of medical devices into the United States. This whitepaper is not, in and of itself, legal advice. The specific facts of any particular transaction may result in a different outcome of treatment of the product. Providing this whitepaper does not result in an attorney-client relationship. If you have questions or need legal advice, please contact a Barnes, Richardson & Colburn attorney.

The spread of COVID-19 in the United States has prompted an urgent need for the supply of medical devices (most prominently, personal protective equipment (PPE) and ventilators) to keep up with the corresponding increase in demand from the healthcare sector. Despite this demand, uncertainty remains due to the fluid regulatory framework which currently applies to imports of medical devices to the United States to deal with the COVID-19 Public Health Emergency. Due to the technical nature of the determinations which must be made in relation to the admissibility of medical products into the United States, and the often changing requirements during the current period, it is strongly advised that all exporters and importers consult with a customs attorney and an experienced customs broker/freight forwarder prior to shipment of such products.

We address below some of the most important features of the U.S. system. We will summarize the export of medical devices to the United States both during the regular course of business, and, as presently modified, to maximize supply during the COVID-19 Public Health Emergency.

1. U.S. Customs and Border Protection (CBP) – The First Entry Point for All Imports

U.S. Customs and Border Protection (CBP) regulates and facilitates the movement of carriers, goods between the United States and other nations. CBP enforces the regulations of many "Partner Government Agencies" (PGA's) at the border. Among these agencies is the Food and Drug Agency (FDA) which has jurisdiction over medical devices.

On behalf of PGA's, including FDA, CBP may prohibit entry of goods; limit entry to certain ports; restrict routing, storage, or use; or require treatment, labeling, or processing as a condition of release. In addition, CBP may demand that articles released from the entry process be redelivered into CBP custody. The agency also has authority to issue substantial penalties, liquidated damages and to seize and forfeit imported articles.

2. Regulation of Medical Devices by the Food and Drug Administration (FDA)

2.1 Foods, Drugs, Cosmetics (and Medical Devices)

Imports of medical devices into the United States are governed by provisions of the Federal Food, Drug, and Cosmetic Act (FD&CA), which is administered by the FDA. Imported products regulated by the FDA are subject to inspection by CBP and/or FDA. Shipments found not to comply with its laws and regulations are subject to refusal, although at the FDA's discretion, an importer may be permitted to bring a nonconforming importation into compliance if it is possible to do so. Shipments that cannot be brought into compliance must be destroyed or re-exported.

2.2 Bringing Medical Devices to Market in the Regular Course of Business

The FDA defines a medical device as any "instrument, apparatus, implement [or] machine…intended for the diagnosis of diseases or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man." The FDA groups medical devices into three broad classes: Class I, II, or III depending on the device's risk, invasiveness, and impact on the patient's overall health. The FDA has classified over 1,700 distinct types of medical devices.

2.2.1 Class I, II and II Medical Devices

<u>Class I Medical Devices</u>

Class I devices are those which are "not intended for use in supporting or sustaining life or of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury." These are the most common Class of devices regulated by the FDA, constituting 47 percent of approved devices.

Class I devices are the fastest and easiest to bring to market since they present the lowest amount of risk to the patient and are rarely critical to life-sustaining care. The majority of Class I devices are exempt from FDA requirements for Premarket Notification (510(k)) and Premarket Approval (PMA). Class I devices are not exempt from FDA General Controls, which apply to Class I, II, and III Medical Devices.

Examples of Class I Medical Devices: Electric Toothbrush; Tongue Depressor; Oxygen Mask; Reusable Surgical Scalpel; Bandages; Hospital Beds

<u>Class II Medical Devices</u>

Class II covers "devices for which general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device." Class II devices are more complicated than Class I devices and present a higher category of risk and may, for instance, include devices which come into contact with a patient's cardiovascular system or internal organs, and diagnostic tools.

Most Class II devices are approved through the Premarket Notification (510(k)) process. In addition to the General Controls applicable to Class I devices, Class II devices are subject to Special Controls which vary according to device (i.e. special labeling requirements, patient registries, premarket data requirements, device performance standards). The FDA released an exemption list in early 2018 which exempts over 800 generic Class I and II medical devices from the 510(k) process.

Examples of Class II Medical Devices: Catheters; Blood Pressure Cuffs; Syringes; Blood Transfusion Kits; Contact Lenses; **N95 Face Masks**; Surgical Masks; Surgical Gloves; Absorbable Sutures

Class III Medical Devices

Class III devices are those which "usually sustain or support life, are implanted or present a potential unreasonable risk of illness or injury." Less than 10 percent of the medical devices regulated by the FDA fall into Class III. This classification is generally extended to permanent implants, smart medical devices, and life support systems.

Due to the level of risk associated with Class III devices, they are subject to all FDA General Controls and the FDA Premarket Approval (PMA) process, with certain limited exemptions for substantially equivalent products which qualify for the relatively less rigorous Premarket Notification (510(k)) process

Examples of Class III Medical Devices: Breast implants; Pacemakers; Defibrillators; High-frequency ventilators; Cochlear implants; Fetal blood sampling monitors; Implanted prosthetics

2.2.2. Regulatory Framework Applicable to Class I, II and II Medical Devices

General Controls

General Controls provide the FDA with the means of regulating medical devices to ensure their safety and effectiveness. General Controls apply to all medical devices and include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices.

Premarket Notification (510(k))

The Premarket Notification process requires that medical device manufacturers or exporters register and notify the FDA at least 90 days in advance of either: 1) bringing into commercial distribution a new medical device for the first time; 2) reintroducing a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. This change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use. During this 90-day period, the FDA will determine whether the new medical device is substantially equivalent to a device already placed into one of the three classification categories, and otherwise does not raise different questions of safety and effectiveness.

Premarket Approval (PMA)

Premarket Approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and is the most stringent type of device marketing application required by FDA. The review of a premarket approval application (PMA) includes administrative and limited scientific review by FDA staff to determine completeness; in-depth scientific, regulatory, and Quality System review; review and recommendation by the appropriate advisory committee; and final deliberations, documentation, and notification of the FDA decision.

Devices which are determined by the FDA to not be substantially equivalent to devices already classified as Class I or II are "new" devices and fall automatically into Class III. Before such devices can be

marketed, they must have an approved premarket approval application or be reclassified into Class I or Class II.

Current Good Manufacturing Practices (cGMP)

All devices regulated by the FDA are subject to current Good Manufacturing Practice (cGMP) requirements for registration, labeling, and quality. cGMPs ensure that products are produced using proper design protocols, strong quality management systems, quality raw materials, robust operating procedures, systems to detect product quality deviations, and reliable and well-maintained testing and production facilities. The cGMP requirements are designed to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls, and to encourage innovative approaches to achieve higher quality through continual improvement.

2.3 Bringing Medical Devices to Market During a Public Health Emergency (Ex. COVID-19)

2.3.1 Imports Made Pursuant to an Emergency Use Authorization

What is an Emergency Use Authorization (EUA)?

The FDA Commissioner is empowered to authorize the emergency use (EUA) of an a) unapproved medical product; or b) an unapproved use of an approved medical product, under certain circumstances. This authorization can be activated when:

> 1) the Secretary of the U.S. Department of Health and Human Services has issued a declaration of an emergency justifying authorization of the emergency use provision;
>
> 2) the Commissioner determines that the known and potential benefits of the product to be used to diagnose, prevent or treat the disease or condition identified by the emergency declaration, outweighs the known and potential risks associated with the products;
>
> 3) the Commissioner determines that no adequate, approved and available alternative exists to the emergency use of the product.

In facilitating the distribution and use of the class of products covered by the EUA, the FDA may:

- Extend the expiration date of an eligible FDA-approved product and establish appropriate conditions relating to such extensions, such as appropriate storage, sampling, and labeling;
- Waive otherwise-applicable cGMP standards (e.g. storage and handling), General Control and registration and listing requirements to accommodate emergency response needs;
- Allow emergency dispensing of the product without requiring an individual prescription, and by responders who may not otherwise be licensed to dispense or administer the product;
- Permit the Centers for Disease Control and Prevention (CDC) to create and issue “emergency use instructions” (EUI) concerning the FDA-approved conditions of use for eligible products;

EUAs Issued by FDA for Import of Certain Medical Devices During COVID-19 Public Health Emergency

The FDA has thus far (as of 4/8/2020) issued EUAs concerning the import and distribution of two classes of medical devices: respirators and ventilators. The EUAs waive applicable cGMPs, including the quality

system requirements under 21 C.F.R. § 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized respirators that are used in accordance with this EUA. Other detailed "Conditions of Authorization" pertaining to manufacturers and importers apply and are included in Section IV of the EUAs.

2.3.1.1. Face Masks and Respirators

Imported, Non-NIOSH-Approved Disposable Facepiece Respirators (March 28, 2020)

The FDA issued a letter on March 24, 2020 (later revised on March 28, 2020) authorizing the emergency use of certain imported disposable filtering facepiece respirators (FFRs or respirators) that are not approved by The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC).

Respirators covered by the scope of this EUA are now eligible for import and use in healthcare settings, despite not meeting other FDA requirements. Respirators eligible for authorization are:

1) Disposable FFRs that have been designed, evaluated and validated to meet a given performance standard and have corresponding acceptable product classifications as follows:

Jurisdiction	Performance Standard	Acceptable product classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
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 1st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

Note: This EUA also creates the right for interested to petition the FDA to authorize the distribution of other non-NIOSH respirators approved under standards used in other countries that are similar to NIOSH-approved respirators. To date, only Domex Model 1020 respirators manufactured in South Africa have been approved.

2) Disposable FFRs which have a marketing authorization in one of the following regulatory jurisdictions
    a. European CE Mark

b. Australia Register of Therapeutic Good (ARTG) Certification of Inclusion
c. Health Canada Licence
d. Japanese Pharmaceuticals and Medical Device (PMDA)/Ministry of health Labour and Welfare (MHLW)

Certain Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (April 3, 2020)

The FDA issued a letter on April 3, 2020 authorizing the emergency use of certain imported non-NIOSH approved disposable filtering facepiece respirators (FFRs or respirators) that are manufactured in China, and for which data exists that supports the respirators' authenticity. Respirators covered by the scope of this EUA are now eligible for import and use in healthcare settings, despite not meeting other FDA requirements otherwise required by applicable federal law. Respirators eligible for authorization must be:

1) Manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA;
2) Has regulatory authorization under a jurisdiction other than China that can be authenticated and verified by FDA; or
3) Demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by FDA (including respirators designed and validated according to China's standards)

Manufacturers and/or importers must first request approval from the FDA and demonstrate that the disposable non-NIOSH-approved respirator(s) manufactured in China meets at least one of the three criteria above. **Lawful importation under this EUA may only occur once the eligible respirator has been added by the FDA to Appendix A.** The FDA adds respirators to Appendix A only after confirming the criteria for issuance are met. The current list of approved manufacturers and respirator models are found here: https://www.fda.gov/media/136663/download

2.3.1.2 Ventilators

Ventilators: Ventilators, Ventilator Tubing Connectors and Ventilator Accessories (March 24, 2020)

The FDA issued a letter on March 24, 2020 authorizing the emergency use of ventilators, ventilator tubing connectors, and ventilator accessories that meet certain criteria for safety, performance and labeling, which have successfully submitted a request for authorization. Respirators covered by the scope of this EUA are now eligible for import and use in healthcare settings, despite not meeting other FDA requirements otherwise required by applicable federal law.

Appendix B lists all currently authorized ventilators, ventilator tubing connectors and ventilator accessories authorized under this EUA: https://www.fda.gov/media/136528/download

Ventilators, ventilator tubing connectors, and ventilator accessories eligible for inclusion under this EUA are not currently marketed in the U.S., or are currently marketed in the U.S. but has been modified sufficiently to trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA.

2.3.2. Imports Made Pursuant to "Emergency Discretion Policy" Guidance Documents

What are "Enforcement Discretion Policy" Guidance Documents?

The FDA has published a series of **nonbinding** "Enforcement Policy Discretion" Guidance Documents which outline the FDA's intent to waive enforcement of certain applicable regulations during the COVID-19 Public Health Emergency. These Guidance Documents explicitly "**do not establish any rights for any person and is not binding on the FDA or the public**" and aim to "clarify the regulatory landscape…to expand the availability of" needed products. They go further than EUAs in waiving otherwise applicable FDA regulations, and require only that the products not cause "undue risk." They will remain in effect only for the duration of the Public Health Emergency related to COVID-19 declared by HHS.

"Enforcement Discretion Policy" Guidance Documents Published by FDA for Import of Certain Medical Devices During COVID-19 Public Health Emergency

The FDA has thus far (as of 4/8/2020) published "Enforcement Discretion Policy" Guidance Documents concerning the import and distribution of nine classes of medical devices. We have provided the full list of "Enforcement Discretion Policy" Guidance Documents in the Additional Resources. We go into greater detail below for two critical product classes.

2.3.2.1. Face Masks and Respirators

The FDA has adopted these new policies to help "expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by health care professionals in healthcare settings." Below are the most relevant to manufacturers, exporters and distributors.

Face masks, face shields, and N95 respirators not intended for a medical purpose:

- Face masks, face shields, and N95 respirators are subject to regulation by the FDA as Class I or Class II medical devices only when they are intended for a medical purpose (i.e. labeled or otherwise intended for use by a health care professional; labeled or otherwise intended for use in a health care facility or environment; they include any drugs, biologics, or anti-microbial/anti-viral agents) In such cases, FDA marketing authorization is not required, and all other requirements of the FD&CA do not apply to manufacturers, importers and distributors of these products.
- **FDA does not intend to object to individuals' distribution and use of non-FDA approved masks or respirators, including to healthcare professionals** (where FDA-cleared masks or respirators are unavailable)

Face masks intended for a medical purpose that are not intended to provide liquid barrier protection; *Face shields intended for a medical purpose; Surgical masks intended to provide liquid barrier protection; Alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available*[1] *(**including KN/KP95; KN/KP 100 respirators**)*

[1] The FDA only states that because they "cannot confirm the authenticity of the respirators described above, FDA recommends that importers take appropriate steps to verify the authenticity of the product they import."

- FDA does not intend to object to the import or distribution of the above classes of products, without compliance with the following regulatory requirements, where distribution and use do not create undue risk[2]:
    - Prior submission of a premarket notification under section 510(k) of the FD&CA and 21 C.F.R. § 807.81;
    - Registration and Listing requirements in 21 C.F.R. § 807;
    - Quality System Regulation requirements in 21 C.F.R. § 820;
    - Reports or corrections and removals in 21 C.F.R. § 806; and,
    - Unique Device Identification requirements in 21 C.F.R. § 830 and 21 C.F.R. § 801.20.

2.3.2.2. Gowns, Gloves, and Other Apparel

The FDA has adopted these new policies to help "expand the availability of surgical apparel for healthcare professionals, including gowns, hoods, togas, and surgeon's and patient examination gloves during this public health emergency." Below are the FDA policies most relevant to manufacturers, exporters and distributors.

Gowns and other apparel not intended for a medical purpose; G*loves not intended for a medical purpose*

- Gowns, gloves and other apparel are subject to regulation by the FDA as Class I or Class II medical devices only when they are intended for a medical purpose (i.e. labeled or otherwise intended for use by a health care professional; labeled or otherwise intended for use in a health care facility or environment; they include any drugs, biologics, or anti-microbial/anti-viral agents. FDA marketing authorization is not required, and all other requirements of the FD&CA do not apply to manufacturers, importers and distributors of these products.

Non-surgical gowns and minimal-to-low barrier protection surgical apparel

- Gowns not intended for use as a "surgical gown," and minimal-to-low barrier protection surgical apparel such as shoe covers, caps, and surgical suits, are Class I Medical Devices exempt from premarket notification requirements under 510(k)
    - In evaluating whether a gown is not a "surgical gown" FDA will consider whether: 1) it is labeled as a gown other than a surgical gown (e.g., isolation gown); it is not described in its labeling as surgical gown; and, it includes statements relating to barrier protection, and such statements are for only minimal or low barrier protection (e.g., ANSI/AAMI PB70 barrier protection Level 1 or 2)
- General Controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device
- FDA does not intend to object to the import or distribution of the above classes of products, without compliance with the following regulatory requirements, where distribution and use do not create undue risk:
    - Registration and Listing requirements in 21 C.F.R. § 807;
    - Quality System Regulation requirements in 21 C.F.R. § 820;
    - Reports or corrections and removals in 21 C.F.R. § 806; and,

[2] Note that the determination of what constitutes "undue risk" is a highly technical exercise and the standards vary by product class.

- Unique Device Identification requirements in 21 C.F.R. § 830 and 21 C.F.R. § 801.20.

Moderate-to-high barrier protection surgical gown; Patient examination gloves; Surgeon's Gloves

- "Surgical gowns" are considered Class II Medical Devices subject to premarket notification requirements under 510(k)
  - The FDA considers a gown to be a "surgical gown" (e.g. ANSI/AAMI PB70 barrier protection Level 3 or 4) if it is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material in moderate or high-risk situations
  - In evaluating whether a gown is a "surgical gown" the FDA will consider whether: 1) it is labeled or described as such; 2) it has statements relating to moderate or high-level barrier protection; and/or, 3) it has statements that it is intended for use during sterile procedures
- "Patient examination gloves" are Class I (reserved) Medical Devices and subject to premarket notification requirements under 510(k)
  - The FDA considers gloves to be "patient examination gloves" if they are a non-powdered disposable device intended for a medical purpose that are worn on the examiner's hand or finger to prevent contamination between patient and examiner
- "Surgeon's gloves" are Class I (reserved) Medical Devices and subject to premarket notification requirements under 510(k)
  - The FDA considers gloves to be "surgeon's gloves" if they are a non-powdered disposable device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.
- FDA does not intend to object to the import or distribution of the above classes of products, without compliance with the following regulatory requirements, where distribution and use do not create undue risk:
  - Prior submission of a premarket notification under section 510(k) of the FD&CA and 21 C.F.R. § 807.81;
  - Registration and Listing requirements in 21 C.F.R. § 807;
  - Quality System Regulation requirements in 21 C.F.R. §§ 820;
  - Reports or corrections and removals in 21 C.F.R. § 806; and,
  - Unique Device Identification requirements in 21 C.F.R. § 830 and 21 C.F.R. § 801.20.

3. Sanctions and Penalties for Violations of FDA Regulations Regarding Import of Medical Devices

Customs' primary penalty statute, 19 U.S.C. § 1592, provides for the assessment of penalties for the entry or attempted entry of merchandise by material false statements or omissions. Cases of negligence may result in the assessment of penalties up to two times the loss of revenue or 20% of the entered value of the merchandise for of non-revenue violations. Cases of gross negligence may result in the assessment of penalties up to four times the loss of revenue or 40% of the entered value of the merchandise for non-revenue violations, while cases involving fraud may be penalized up to the full

domestic value of the merchandise. CBP also has seizure authority under this statue to secure the payment of penalties and additional seizure authority to prevent the entry of inadmissible merchandise.

CBP also has criminal sanctions available which provide for a maximum of two years' imprisonment, a fine, or both, for each violation involving a fraudulent importation or attempted importation.

4. Customs and Border Protection (CBP) Instructions for Filing Personal Protective Equipment (PPE) and Medical Devices During COVID-19 (April 5, 2020)

CBP has published instructions, applicable during the COVID-19 Public Health Emergency, regarding the entry treatment of certain PPE and medical devices imported for 1) personal use; 2) pursuant to an EUA, or; 3) pursuant to FDA "Guidance Documents."

4.1 Non-FDA-Regulated General Purpose Personal Protective Equipment

PPE for general purpose or industrial use (that is, products that are not intended for use to prevent disease or illness) are not regulated by FDA. For these types of products, entry information should not be transmitted to FDA. At the time of entry for these products, Importers should transmit entry information to US Customs and Border Protection (CBP) using an appropriate HTS code with no FD Flag; or using an appropriate HTS code with an FD1 flag and do a 'disclaim' for FDA.

4.2 Products Authorized for Use by Health Care Professionals Pursuant to an EUA

When importing such products, entry information should be submitted to FDA; however reduced FDA information is required for review. At the time of entry, Importers should transmit an Intended Use Code of 940.000: Compassionate Use/Emergency Use Device, and an appropriate FDA product code. Under this Intended Use Code, the Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are optional.

4.3 Products Regulated by FDA as a Medical Device, Not Authorized by an EUA, But Where an Enforcement Discretion Policy has been Published in Guidance

When importing such devices, entry information should be submitted to FDA. At the time of entry, Importers should transmit Intended Use Code 081.006: *Enforcement discretion per final guidance*, and an appropriate FDA product code. Under this Intended Use Code, the Affirmations of Compliance for medical devices (such as the Registration, Listing, and Premarket numbers) are optional.

Additional Resources

EUAs

- Imported, Non-NIOSH-Approved Disposable Facepiece Respirators: https://www.fda.gov/media/136403/download
- Non-NIOSH-Approved Disposable Facepiece Respirators Manufactured in China: https://www.fda.gov/media/136664/download
    - Appendix A: https://www.fda.gov/media/136663/download
- Ventilators, Ventilator Tubing Connectors and Ventilator Accessories: https://www.fda.gov/media/136423/download

"Enforcement Discretion Policy" Guidance Documents

- Face Masks and Respirators: https://www.fda.gov/media/136449/download
- Gowns, Gloves, and Other Apparel: https://www.fda.gov/media/136540/download
- Ventilators and Accessories: https://www.fda.gov/media/136318/download
- Clinical Electronic Thermometers: https://www.fda.gov/media/136698/download
- Infusion Pumps and Accessories: https://www.fda.gov/media/136701/download
- Sterilizers, Disinfectant Devices, and Air Purifiers: https://www.fda.gov/media/136533/download
- Remote Ophthalmic Assessment and Monitoring Devices; https://www.fda.gov/media/136733/download
- Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices; https://www.fda.gov/media/136734/download
- Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring: https://www.fda.gov/media/136290/download

CBP

- CSMS #42272898 - Information for Filing Personal Protective Equipment and Medical Devices During COVID-19: https://content.govdelivery.com/bulletins/gd/USDHSCBP-2850882?wgt_ref=USDHSCBP_WIDGET_2

CDC

- Strategies for Optimizing the Supply of N95 Respirators: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/
    - Note: CDC Lists KN/KP 95 and KN/KP 100 under "Respirators Approved Under Standards Used in Other Countries That Are Similar to NIOSH-Approved N95 Facepiece Respirators" and therefore recommended for use by healthcare professionals