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Changes on FDA Approval of Disposable Filtering Facepieces and China issues new rules for export of Medical Use Face Masks

By **IVT Staff Apr 28, 2020 7:00 am EDT**

In the midst of ongoing struggles to provide frontline medical personnel with N95 or Approved Medical Grade Face Masks the FDA issued an exception to their terms of authorization under the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)) to further protect the public's health and safety.

This exception came late last month following the review of resources available for import to the United States. As shortages for PPE remain high, the FDA issued the list of non-NIOSH approved imported disposable Filtering Facepiece Respirators (FFRs) from specific regulatory jurisdictions, and which have been designed, evaluated, and validated to meet a given performance standard (as approved of by the FDA).

Guidelines have been set to use the FFRs in the following way, and from the corresponding areas as specified in Table 1.

1. Authorized respirators listed in Exhibit 1 for use in healthcare settings by healthcare personnel (HCP)4 when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.
2. Authorized respirators listed in Exhibit 1 that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system for use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

Jurisdiction	Performance Standard	Acceptable product classifications	Standards/Guidance Docs	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

Table 1. Disposable FFRs that have been designed, evaluated, and validated to meet a given performance standard and have corresponding acceptable product classifications

Like many recent temporary guidances, this exception for emergency use of specially authorized FFRs is limited to the scope of authorization set forth by the FDA and will expire as the public emergency resolves. (Download the FDA Letter to Stakeholders)

Meanwhile, as many countries struggle to find both short and long term solution to PPE and FFR shortages, China has issued some new regulations of their own. Effective April 1, 2020, China has issued Orderly Export of Medical Supplies, a temporary order which strictly regulates the export of any COVID-19 related medical devices or supplies from China. This order cover two important criteria that any device manufacturer must have in place:

1. The device must be registered in China through a Medical Device Product Registration Certificate.
2. The exporter must prove that the device complies with the regulations of the importing country as they apply to that device.

附件 1

出口方和进口方共同声明

Joint Declaration of the Exporter and the Importer

产品名称（含规格、型号）Product Name (including specifications and model)	产品数量 Product Quantity	中国质量标准名称或国外质量标准名称 The Name of Quality Standards of China or the Foreign Country	进口国（地区）Importing Country/Region	生产厂商 Producer

出口方和进口方确认上述产品符合□中国质量标准/ □国外质量标准（请勾选），且符合双方协议确定的产品质量标准。进口方保证协议确定的产品质量标准符合进口国（地区）对该产品的质量标准要求，并确认接受上述产品的质量标准。

The exporter and the importer hereby confirm that the above products are compliant with the □quality standards of China/ □quality standards of foreign country (please tick the box) and the quality standards stipulated in the agreement between the parties. ***The importer shall guarantee the product quality standards stipulated by the agreement are compliant with the quality requirements of the importing country/region, and shall confirm it has accepted the quality standards of the above products.***

进口方承诺严格依照协议不将所购口罩用于医用用途，并提示第三方不可用于医用用途，如因进口方或第三方使用、维护、保管不当造成损失的，出口方、生产厂商不承担责任。

The importer shall commit to strictly abide by the agreement and not use the face masks it purchases for medical purposes and to warn any third party against using the face masks for medical purposes. The exporter or the producer is not liable for any losses caused by the inappropriate use, maintenance or keeping of the face masks by the importer or any third party.

本声明一式两份，双方各执一份。

This declaration is made in duplicate, one original for each party.

特此声明。

出口方（盖章）
Exporter (Seal)
年 月 日

进口方（签字）
Importer (Signature)
年 月 日