MAYA sticker

Regulatory Considerations in the U.S.

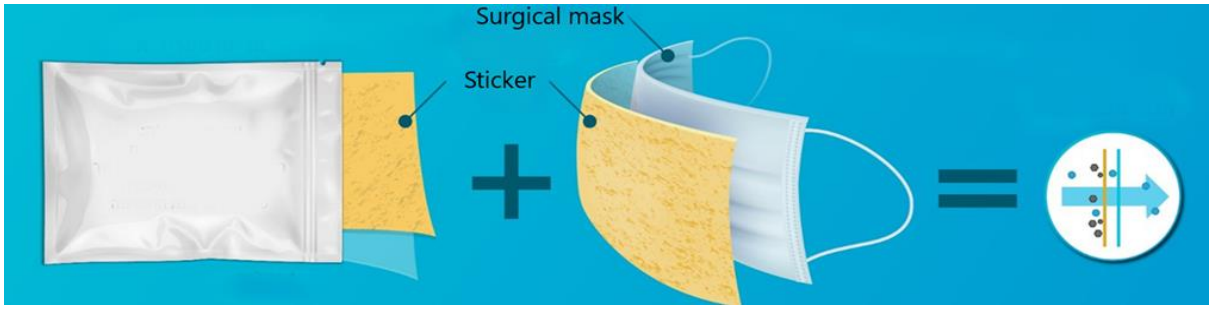
Date: 19th May 2020

There is an urgent need to provide effective, affordable and user-friendly countermeasures to fight viral infections.

the MAYA sticker is composed of nano-fibers soaked with the antiviral agent povidone iodine and is attached to the **outer side** of surgical masks.

The MAYA stickers are produced by 3D electrospinning technology that allow incorporation of povidone-iodine inside the nano-fibers to trap and inactivate viruses.

The MAYA sticker **does not come in contact with the face** but is adhered to the outer side of the mask by the user.



According to pre- and clinical trials, the MAYA sticker improves the antiviral capacity of surgical masks and face-masks, elongate their effective-period by inactivation of the trapped microorganisms and allow to convert simple home-made face-covers and low quality surgical masks into effective antiviral protectors.

As per the definition of the US Food and Drug Administration (FDA), The MAYA stickers are not considered as 'masks' or 'surgical masks' as they do not cover the user's nose and mouth and, actually, do not touch the user's face[1].

Practically, the MAYA stickers could be considered as an additional-layer of the surgical mask, which is not an inherent part of the surgical mask, but added to it upon application.

In general, all health care employers must always comply with standards of the Occupational Safety and Health Administration (OSHA) that require PPE to protect workers and that apply to infectious disease hazards.

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[1] Face masks and respirators are regulated by FDA when they meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Generally speaking, face masks fall within this definition when they are intended for a medical purpose, including for use by health care professionals[1]. FDA-regulates "Surgical mask with antimicrobial/antiviral agent" under 21 CFR 878.4040 (Code: OUK).

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MAYA
Anti-viral Protective Sticker

The MAYA sticker and the FDA's intended approach according to Emergency Use Authorizations (EUAs): The MAYA sticker answers the demands of the FDA under the Emergency Use Authorization (EUA) that are intended to help increase availability of effective devices to front-line personnel during the public health emergency.

FDA's steps to expand the availability and quality of Respiratory Countermeasures that are targeted to help address the urgent public health concerns caused by shortages of effective face masks and respirators.

In order to help foster the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, for the duration of the public health emergency, FDA does not intend to object to the distribution and use of face masks that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with several regulatory requirements where the face mask does not create an undue risk in light of the public health emergency.

FDA recognizes that, when alternatives, such as FDA-cleared masks or respirators, are unavailable, individuals, including healthcare professionals, might improvise personal protective equipment (PPE). FDA does not intend to object to individuals' distribution and use of improvised PPE when no alternatives, such as FDA-cleared masks or respirators, are available[2].

[2] "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" issued March 25, 2020. U.S. Department of Health and Human Services. Food and Drug Administration. Center for Devices and Radiological Health.

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