NEWS RELEASE

Feb. 22 , 2019

New type of surgical masks – first in Japan! (*1) Cufitec® Surgical Masks from NBC Meshtec were cleared by the U.S. Food and Drug Administration (FDA) as a medical device under the name "Surgical Mask with Antimicrobial/Antiviral Agent".

On January 3 (Thursday), 2019, **Cufitec® Surgical Masks** that are manufactured and sold by Nisshin Seifun Group company NBC Meshtec Inc. (president: Akiya Fukada) were cleared as medical devices by the U.S. Food and Drug Administration (FDA), classified as a Surgical Mask with Antimicrobial/Antiviral Agent (class 2,510 (k)). NBC Meshtec is the first Japanese company to obtain this clearance

(*1) As of January 3, 2019. Investigation by our company.

■ Cufitec® Surgical Masks: Overview of antimicrobial/antiviral surgical masks

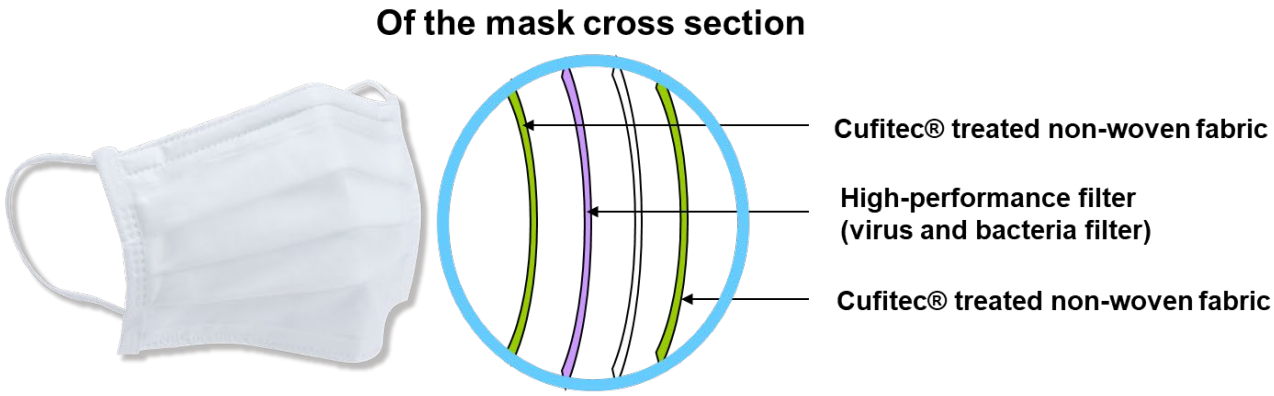
The **Cufitec® Surgical Masks** (*2) from NBC Meshtec were developed in order to reduce the risk of infection caused by the spread of viruses adhering to the mask surface when the mask is removed and disposed of.

Cufitec® Surgical Masks are composed of 4 layers of non-woven fabric, with an antimicrobial/antiviral treatment applied to the outer and face side layers (Figure 1). It has been confirmed that this antimicrobial/antiviral non-woven fabric functions to inactivate 99.99% or more of influenza viruses of various types within 5 minutes.

In addition, because it was also confirmed that these masks satisfy the FDA standards for safety and medical mask performance, they were cleared as FDA medical devices (class 2,510 (k)).

(*2) Cufitec® is an virus and bacteria control technology utilizing nano-particles of a monovalent copper compound.

Figure 1: Structure of Cufitec® Surgical Masks



* This product is not a medical device intended for the treatment or prevention of illnesses in Japan.

Table 1: Virus strains used in the performance tests

Virus type	Virus strain name
A/H1N1	A/Virginia/ATCC2/2009
	A/WS/33
A/H3N2	A/Kitakyusyu/159/93
	A/Victoria/210/09
	A/Virginia/ATCC6/2012
	A/Hong Kong/8/68
	A/Udorn/307/72
B	B/Lee/40
	B/Taiwan/2/62

■ "510 (k)" clearance

In order to sell a medical device in the United States, it is necessary to satisfy the standards established by the FDA. Because an antimicrobial/anti-viral surgical mask is classified as a Class 2 medical device, 510 (k) clearance is necessary. **Cufitec® Surgical Masks** passed the tests (*3) required for this clearance and was cleared by the FDA as a medical device (510 (k) number: K182766).

(*3) Tests required for 510 (k) certification

In order to obtain clearance, in addition to satisfying the basic required anti-virus performance of deactivating 99.99% of viruses within 5 minutes, it is necessary to prove that this basic performance can be maintained even when affected by repeated virus exposure, contact with user saliva, breathing, and other factors. Test results from a minimum of 3 lots are required.

In order to verify safety, in addition to basic safety tests such as the cytotoxicity test, primary skin irritation test, and skin sensitization test, it is also necessary to conduct chemical safety tests to ensure safety in the unlikely event that the antimicrobial/anti-viral agent somehow becomes separated or elutes from the mask.

The bacterial filtration efficiency, particulate filtration efficiency, synthetic blood penetration resistance, differential pressure, flammability, and other performance standards required of surgical masks must also be satisfied.

■ Future plans

NBC Meshtec intends to expand sales of FDA-cleared Cufitec® Surgical Masks and antimicrobial/anti-viral non-woven fabrics in Japan and overseas, and also to utilize the company's original "Cufitec®" virus and bacteria control technology in order to further create clean, safe, and comfortable environments.

Please direct any inquiries regarding the product or technologies to the following.
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