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Taiwan initiates new measures for management of medical masks

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New measures aim to control the quality of imported medical masks and differentiate domestic medical masks from those imported

Taiwan has recently initiated two new measures to reinforce the management of medical masks. Since July 7th, 2020, the country began to implement border random inspection of medical masks. From September 24th, 2020, domestically manufactured medical masks are required to be marked with government-issued debossed stamps. These measures aim to control the quality of imported medical masks and differentiate domestic medical masks from those imported.

As the COVID-19 pandemic continues to affect the entire world, the demand for medical masks, as well as the production capacity, continues to increase. To enhance border inspection of imported medical masks, Taiwan Food and Drug Administration amended Regulations for the Inspection and Examination of Imported Medicaments, so that medical masks are included in border inspection.

In addition to license of medical devices, imported medical masks are also obliged to meet examination standards, which are divided into different categories, including “general medical masks”, “surgical masks”, "surgical D2 masks" with corresponding inspection items, such as bacteria filtration efficiency, differential pressure, sub-micron filtration efficiency, and respiratory air impedance. On the principles of risk management, imported products will go through batch-by-batch or random-selected batch inspection and only those passing the inspections will be cleared to enter Taiwan. Those failing to pass the inspection will be returned, so our citizens can rest assured that medical masks used meet our standards for quality and performance.

In addition, for the general public to conveniently recognize domestically manufactured medical masks, from September 24th, 2020 on, all flat medical masks made in Taiwan (including general medical masks and surgical masks) shall bear two debossed stamps "Made In Taiwan"and "MD",which stand for "medical device ". The two stamps will be marked within 1.5 cm distance to the edge of each mask, so flat medical masks will not be mixed with general masks. This announcement will not affect Medical N95 or equivalent respirator masks, nor 3-dimensional masks or medical masks for export only.