

## Details of Amendments of Import Regulations

CCC Code	Description of Goods	Previous Import regulation	Current Import regulation
6307.90.50.31-1	Medical masks, of textile materials	839	839*
6307.90.50.39-3	Other masks, of textile materials	470	
<b>Import Regulation Code</b>			
(Blank)	Import permitted (free from licensing)		
470	<p>1. Apply for this permit from the BOFT, MOEA. However, application for permit is waived if the total quantity of imported non-medical masks is fewer than 250 or the total quantity of imported medical and non-medical masks combined is fewer than 250. The special waiver code FT999999999998 shall be filled in on the import declaration.</p> <p>2. Visitors entering with fewer than 250 medical and non-medical masks need not apply for a permit.</p>		
839	<p>1. Apply for this permit from the BOFT, MOEA. However, application for permit is waived if the total quantity of imported non-medical masks is fewer than 250 or the total quantity of imported medical and non-medical masks combined is fewer than 250. The special waiver code FT999999999998 shall be filled in on the import declaration.</p> <p>2. Procedures shall be handled in accordance with regulations 504 and F03.</p> <p>3. Visitors entering with fewer than 250 medical masks are exempt from regulation 504.</p> <p>4. Visitors entering with medical masks are exempt from regulation F03.</p> <p>5. Visitors entering with fewer than 250 medical and non-medical masks combined need not apply for a permit and are exempt from regulation 504.</p>		

839*	<p>1.Procedures shall be handled in accordance with regulations 504 and F03.</p> <p>2.Visitors entering with fewer than 250 medical masks are exempt from regulation 504.</p> <p>3.Visitors entering with medical masks are exempt from regulation F03.</p>
504	<p>1. Importation of medical devices for human use must be handled according to the following regulations: (1) A photocopy of the medical devices pre-marketing license or an approval document issued by the Ministry of Health and Welfare should be submitted. In addition, the number of the pre-marketing license (consisting of 14 letters and digits) must be declared and listed in the import declaration . (2) If the medical devices being imported are dangerous, then besides the photocopy of the medical device pre-marketing license and the license number declared and listed in the import declaration, an approval of the medical institutions/facilities procurement from the Ministry of Health and Welfare is also required. 2. Importation of medical devices which are not for human use are exempted from the above regulations.</p>
F03	<p>Importation of medical devices shall follow the"Regulations governing the border inspection of imported Pharmaceuticals". The importer shall apply for inspection to the Food and Drug Administration, Ministry of Health and Welfare (FDA).</p>