

## Details of Amendments of Import Regulations

CCC Code	Description of Goods	Original Import Regulation	Amended Import Regulation
9018.39.00.20-3	Silicone stomach tubes (nasogastric/orogastric tubes)		504

Import Code	Code Explanation
(Blank)	Import permitted (free from licensing)
504	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.