

## Details of Amendments of Import and Export Regulations

CCC Code	Description of Goods	Amended Import Regulation	Amended Export Regulation
3002.15.00.10-3	COVID-19 Antigen Home/Self Test	504 F03 MW0	
3002.15.00.90-6	Other immunological products, put up in measured doses or in forms or packings for retail sale	823 MP1	523

Import Code	Code Explanation
(Blank)	Import permitted (free from licensing)
406	For importation of veterinary medicines (including raw material pharmaceutical products, pharmaceutical products, and biological products): (1) a) A "veterinary medicine dealer license" and a "veterinary medicine import license" (non-licensed importers shall be authorized by the license holder) issued by the Council of Agriculture, Executive Yuan, are prerequisite; or b) if the imported goods are raw (bulk) materials limited to the self-use of veterinary drug manufacturer, a "license for manufacturing veterinary medicine" containing the active ingredient(s) issued by the Council of Agriculture, Executive Yuan and a "Notice For Importing Raw (Bulk) Material Limited to The Veterinary Drug Manufacturer Self Use" issued by the Bureau of Animal and Plant Health Inspection and Quarantine, Council of Agriculture, Executive Yuan are prerequisite. 2) If the imported goods are samples or gifts, a "Notice for Importing Veterinary Medicines Samples" issued by the Bureau of Animal and Plant Health Inspection and Quarantine, Council of Agriculture, Executive Yuan is prerequisite.

- 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.
- 506 Importation of drugs (including pharmaceutical products, active pharmaceutical ingredients, diagnostics and biological products) for human use requires either of the following: (1) a photocopy of the drug (import) license issued by the Ministry of Health and Welfare together with a photocopy of the license of the pharmaceutical firm; or (2) an approval issued by the Ministry of Health and Welfare.(3)Importing antibiotics and their other derivatives for research use, or experiment use should list the special code DHM99999999506 on the import application and is exempted from the above regulations.
- 823 (1) Importation of medicines for human use is governed by the regulation of "506". (2) Importation of veterinary medicines is governed by the regulation of "406". (3) Importation of medical equipment is governed by the regulation of "504". (4) Importation of foods and food-relevant products is governed by the regulation of "F01". (5) Importation of commodity not belong to the aforesaid items shall be exempted from "the said regulations, but a clear indication that the commodity is not to be used as human medicines, veterinary medicines, medical equipment, foods and food-relevant products" is required.
- F01 Importation of foods shall follow the "Regulations for Inspection of imported Foods and Related Products".The importer shall apply for inspection to the Food and Drug Administration,Ministry of Health and Welfare(FDA).(Note:Please contact FDA for relevant inspection requirements of food imports.)
- F03 Importation of medical devices shall follow the "Regulations Governing Border Inspection and Examination of Imported Medical Devices". The importer shall apply for inspection to the Food and Drug Administration, Ministry of Health and Welfare (FDA).

MP1 (1) Importation of Mainland China products in this category is conditionally permitted. The importation should conform to the regulations of "Consolidated List of Conditional Import Items of Mainland China Origin and Regulations Governing Import of Mainland China Origin Commodities".(2) Importation of items on the "Consolidated List of Conditional Import Items of Mainland China Origin and Regulations Governing Import of Mainland China Origin Commodities" with "MXX" code requires Import Permit issued by the BOFT; Importation of items without "MXX" code shall be subject to the general code of import permit issuance.

MW0 Importation of Mainland China products is prohibited.

Export Code	Code Explanation
(Blank)	Export permitted (free from licensing)
523	(1)For exportation of commodities under this item of medicines for human use, a photocopy of medicine permit issued by the Ministry of Health and Welfare is required. (For re-export of the imports, the photocopy of the medicine permit is not required)(2)For exportation of medicines not for human use, should list the special code DHM99999999523 on the export application and is exempted from the above regulations.