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經濟部國際貿易局　公告

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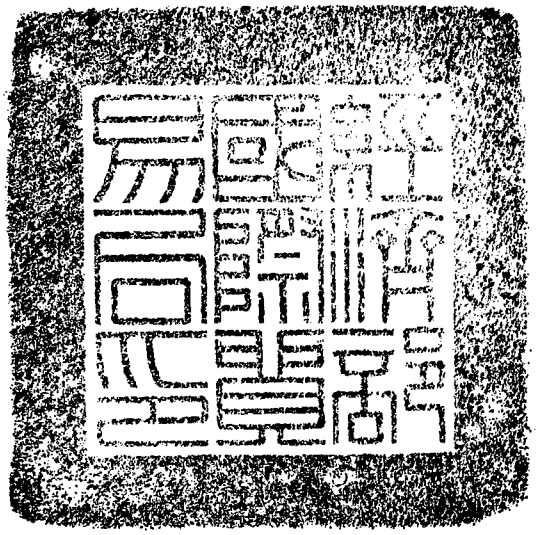

主旨：公告自107年5月1日起CCC9018.90.80.90-7「其他第9018節所屬之貨品」1項貨品之輸入規定代號修正為「530」，並列入「海關協助查核輸入貨品表」。

依據：貨品輸入管理辦法第8條第1項及衛生福利部107年3月1日衛授食字第1071401835號函。

公告事項：檢附貨品輸入規定變更明細表1份如附件。

局長 楊珍妮

經濟部國際貿易局
貨品輸入規定變更明細表

貨品號列	貨　　名	原　列 輸入規定	改　列 輸入規定
9018.90.80.90-7	其他第９０１８節所屬之貨品 Other articles of heading No. 9018	504 MP1	530 MP1

號列項數: 1

經濟部國際貿易局
貨品輸入規定變更明細表

輸入規定代號	說明
(空白)	准許（免除簽發許可證）。 Import permitted (free from licensing)
504	一、進口人用醫療器材應依下列規定辦理：（一）應檢附衛生福利部核發之醫療器材許可證影本或同意文件，並應申報填列醫療器材許可證號碼（十四碼）。（二）如屬危險性醫療儀器，除應檢附衛生福利部核發之醫療器材許可證影本，及申報填列醫療器材許可證號碼（十四碼）外，並須檢附衛生福利部核准醫療機構購置之同意文件。二、非供人用者免依上述規定辦理。 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.

經濟部國際貿易局
貨品輸入規定變更明細表

輸入規定代號	說明
530	一、進口人用醫療器材應依下列規定辦理：（一）應檢附衛生福利部核發之醫療器材許可證影本或同意文件，並應申報填列醫療器材許可證號碼（十四碼）。（二）如屬危險性醫療儀器，除應檢附衛生福利部核發之醫療器材許可證影本，及申報填列醫療器材許可證號碼（十四碼）外，並須檢附衛生福利部核准醫療機構購置之同意文件。（三）進口專供藥物臨床試驗計畫之試驗用檢體採集耗材套組，於進口報單填列專用代碼ＤＨＭ００００００００５０４。二、非供人用者免依上述規定辦理。 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. (3) Importation of laboratory kit for medicaments (drugs and medical devices) clinical trial use should list the special code DHM00000000504 on the import application.2. Importation of medical devices which are not for human use are exempted from the above regulations.

經濟部國際貿易局
貨品輸入規定變更明細表

輸入規定代號	說明
MP1	（一）大陸物品有條件准許輸入，應符合「大陸物品有條件准許輸入項目、輸入管理法規彙總表」之規定。（二）「大陸物品有條件准許輸入項目、輸入管理法規彙總表」內列有特別規定「ＭＸＸ」代號者，應向國際貿易局辦理輸入許可證；未列有特別規定「ＭＸＸ」代號者，依一般簽證規定辦理。 (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.