檔號		保存年限
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台灣醫療暨生技器材工業同業公會 收文 114. 2. 04 檔號: 114039

經濟部國際貿易署　函

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受文者：台灣醫療暨生技器材工業同業公會

發文日期：中華民國114年1月23日
發文字號：貿管理字第1140000123號
速別：普通件
密等及解密條件或保密期限：
附件：如文

主旨：有關貴會會員建議禁止CCC9018.90.80.90-7「其他第9018節所屬之貨品」項下「膀胱鏡」自中國大陸輸入案，請查照。

訂

說明：

一、復貴會114年1月3日醫材字第114004號函。

二、經查CCC9018.90.80.90-7「其他第9018節所屬之貨品」項下共計開放「木質壓舌片」等22項貨品（如附件），倘膀胱鏡非屬該項下開放之貨品，則為禁止進口之中國大陸物品。

正本：台灣醫療暨生技器材工業同業公會
線　副本：經濟部產業發展署

署長 劉盛廉

J-1140000123

經濟部國際貿易署
進口大陸物品查詢

No.	CCC號列	貨　　名	實施日期	輸入規定	特別規定
1	9018.90.80.90-7EX	<1>木質壓舌片 Wooden spatula <2>電子藥丸 Electron pilular <3>無菌手術刀片 Sterile disposable surgical blade <4>避孕用子宮內裝置 Intra-uterine contraceptive device <5>採血筆 Lancing device <6>採血針 Lancet <7>血袋（含抗凝血劑，附抽血針頭） Blood bag (with anticoagulant and needle) <8>彎型端對自動縫合器 Curved EEA stapler <9>一次性使用單採血液成分分離機收集套組 Disposable single blood component separator <10>白血球過濾器 Leukocyte reduction filter for blood <11>灌食機（灌食幫浦） Enteral feeding pump <12>拋棄式電動脈衝沖洗器 Disposable electronically pulsed lavage suction apparatus <13>動物（老鼠）線圈 Animal(mouse) Coil <14>無菌拋棄式拆針器 Sterile Disposable Staple Remover <15>無菌拋棄式皮膚縫合器 Sterile Disposable Skin Stapler <16>骨科用手術器械（包裝標示「供骨科用」） Orthopaedic surgical instrumentation(The labeling of ' used for orthopaedic' on the package) <17>面罩式光療儀 Light therapy mask <18>耳鼻喉科動力系統電源控制台（無論含或不含腳踏開關） Ear, Nose, Throat (ENT) Power Console (whether or not foot control is included) <19>鼻竇沖吸系統 Sinus wash delivery system <20>呼吸道氣囊壓力監控儀	<1>103/11/11 <2>103/11/11 <3>103/11/11 <4>103/11/11 <5>103/11/11 <6>103/11/11 <7>103/11/11 <8>103/11/11 <9>104/09/10 <10>103/11/11 <11>103/11/11 <12>103/11/11 <13>103/11/11 <14>103/11/11 <15>103/11/11 <16>104/09/10 <17>106/04/18 <18>107/11/06 <19>109/07/10 <20>109/07/10 <21>110/01/11 <22>113/03/26	530 MP1	

經濟部國際貿易署
進口大陸物品查詢

No.	CCC號列	貨　　名	實施日期	輸入規定	特別規定
1	9018.90.80.90-7EX	Airway ballon pressure monitor <21>壓力槍 Inflation Device <22>負壓輔助靜脈引流控制器 Vacuum Assisted Venous Drainage (VAVD) Controller	<1>103/11/11 <2>103/11/11 <3>103/11/11 <4>103/11/11 <5>103/11/11 <6>103/11/11 <7>103/11/11 <8>103/11/11 <9>104/09/10 <10>103/11/11 <11>103/11/11 <12>103/11/11 <13>103/11/11 <14>103/11/11 <15>103/11/11 <16>104/09/10 <17>106/04/18 <18>107/11/06 <19>109/07/10 <20>109/07/10 <21>110/01/11 <22>113/03/26	530 MP1	

經濟部國際貿易署
貨品輸出入規定查詢

製表日期：114/01/20

No.	CCC 號列	貨　　名	號列實施	輸入規定	輸出規定
1	9018.90.80.90-7	其他第９０１８節所屬之貨品 Other articles of heading No. 9018	103/11/11	530 MP1	

輸入規定：

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ＤＨＭ０００００００００５０４。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.
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，應向國際貿易署辦理輸入許可證；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 International Trade Administration; Importation of items without "MXX" code shall be subject to the general code of import permit issuance.