

Details of Amendments to Import Regulations

CCC Code	Description of Goods	Original Import Regulation	Amended Import Regulation
9031.80.00.91-8	Other measuring or checking instruments, appliances and machines for medical use, not specified or included elsewhere in this chapter		504

Import Regulation Code

(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.