

Plant Registration for importing medical device into Taiwan

Simplified mode of European Union technical cooperation program (or countries/areas that sign for cooperation with Taiwan) (only applicable for factories in countries of European Union-Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland. New member- Cyprus (Greek part), the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia, which participated in “Taiwan-European Union Factory Investigation Report and Technical Cooperation Program”, or the countries/areas that have signed the agreement for cooperation)

Scope of TCP:

- Area: manufacturing plant is located in EU
- Organization: Notified body under AIMD/MDD/IVDD
- EU Partner under TCP:
 - (1) **BSI (UK) (CE0086)**
 - (2) **G-Med (France) (CE 0459)**
 - (3) **Medical Device Certification (Germany) (CE0483)**
 - (4) **NSAI (Ireland) (CE0050)**
 - (5) **TUV Product Services (Germany) (CE0123)**
 - (6) **TUV Rheinland Product Safety (Germany) (CE0197)**
 - (7) **KEMA (Netherlands)**
 - (8) **DGM (Denmark)**
 - (9) **AMTAC (UK)**
 - (10) **MEDCERT (Germany)**
 - (11) **SGS (UK)**
 - (12) **UL (UK)**

Required documents:

- (1) - **Fill in the Basic Information of Factory from 2.1- 3.9 on GMP application form (instruction documents is not required).**
 - **Issue the statement letter from original factory to declare/demonstrate Basic Information of Factory from 3.1-3.9 on GMP application form is effective and true et al.**

(2) **Cover Letter:** the cover letter is not necessary if the audit report is issued within one year. If the audit report is issued over than one year, you need to provide a general letter or email format issued by the notified body to demonstrate the audit report is most recent.

(3) **Audit report:** the report of the latest date when European Union (or the countries/areas that have signed the agreement for cooperation) conducted on-site inspection at the original factories)

(4) **ISO13485**

(5) **Free Sales Certificate:** it must meet the following requirement:

(1) Shall state the product's name & model (or type), and the manufacturer's name & address.

(2) Shall state that the device(s) is/are freely sold in its home market.

(3) Shall be legalized by Taiwan's representative(embassy) in your country.

(4) Valid for two years from the issue date.

(5) Shall be the original.

(6) If the highest health authority does not have jurisdiction over such device(s), the certificate may be issued by other responsible departments.