

## New License Application

1. License Requirement under the Act:

*“Section 15 (1) No establishment shall import, export or place in the market any registered medical device unless it holds an establishment license granted under this Act.”*

2. Different roles of establishment under the Act:

- A. Manufacturer
- B. Authorized Representative
- C. Importer
- D. Distributor

3. YouTube link for MeDC@St 2.0 navigation.

- a) [Establishment License - New Registration AR/Distributor/Importer \(youtube.com\)](#)
- b) [Establishment License - New Registration Manufacturer \(youtube.com\)](#)

4. General Process Flow for New License Application:

