

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.”

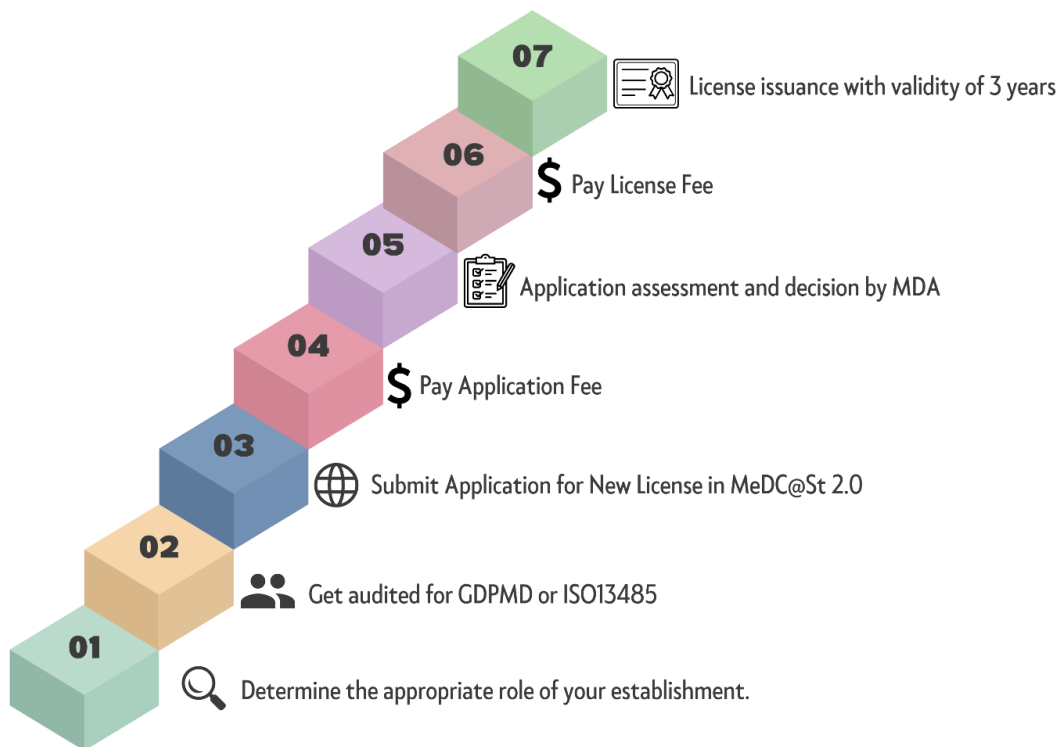
2. Different roles of establishment under the Act:

- 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:



Renewal License Application

1. Renewal Requirement under the Act and Establishment License Condition:

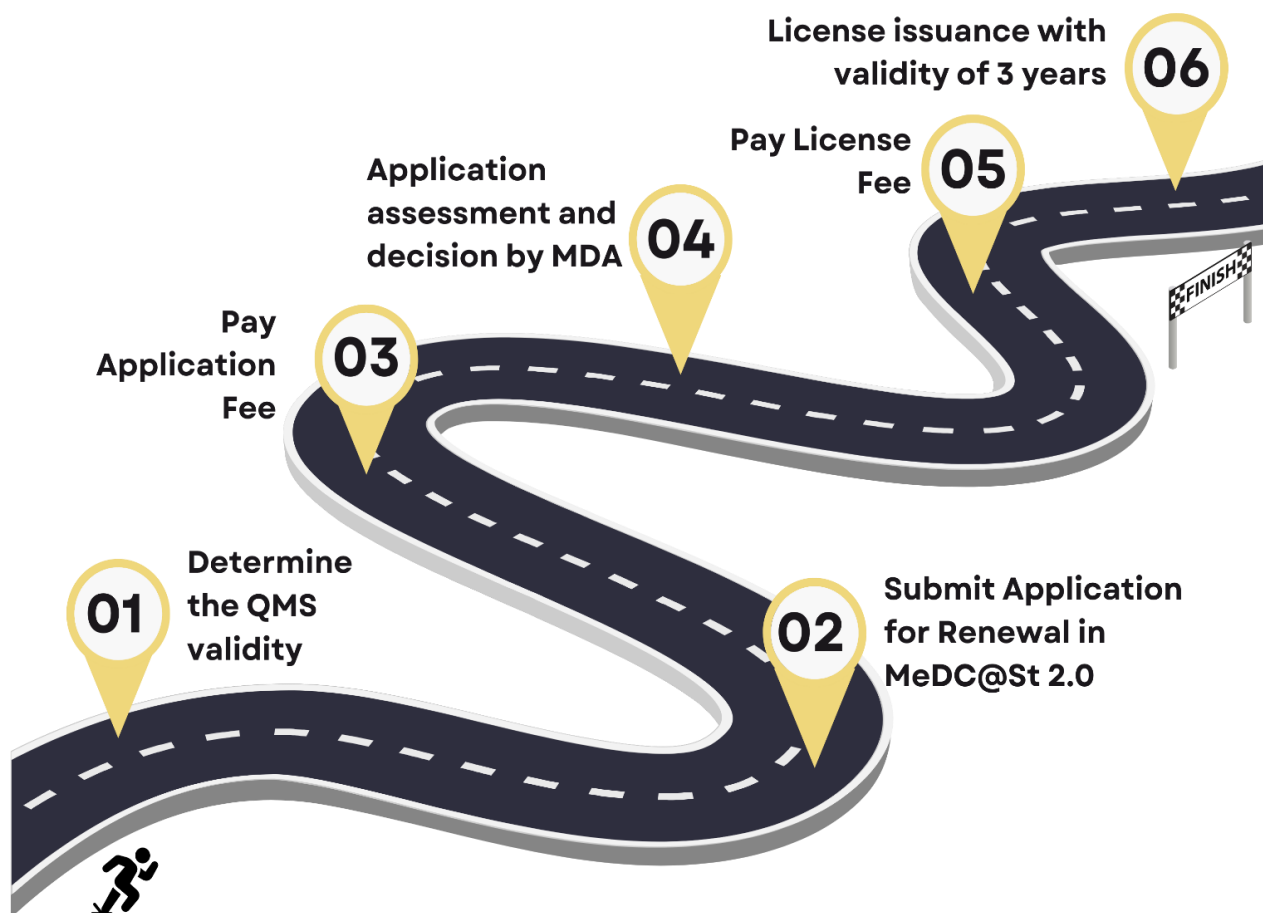
“Section 24 (1) A licensee may apply for renewal of its establishment licence to the Authority not later than one year before the expiration date of the establishment licence.”

“Licensee may apply for renewal of establishment license not later than ninety (90) days prior to expiry of license.”

2. YouTube link for MeDC@St 2.0 navigation.

- a) [Establishment License - Renewal \(youtube.com\)](#)

3. General Process Flow for Renewal Application:



License Amendments

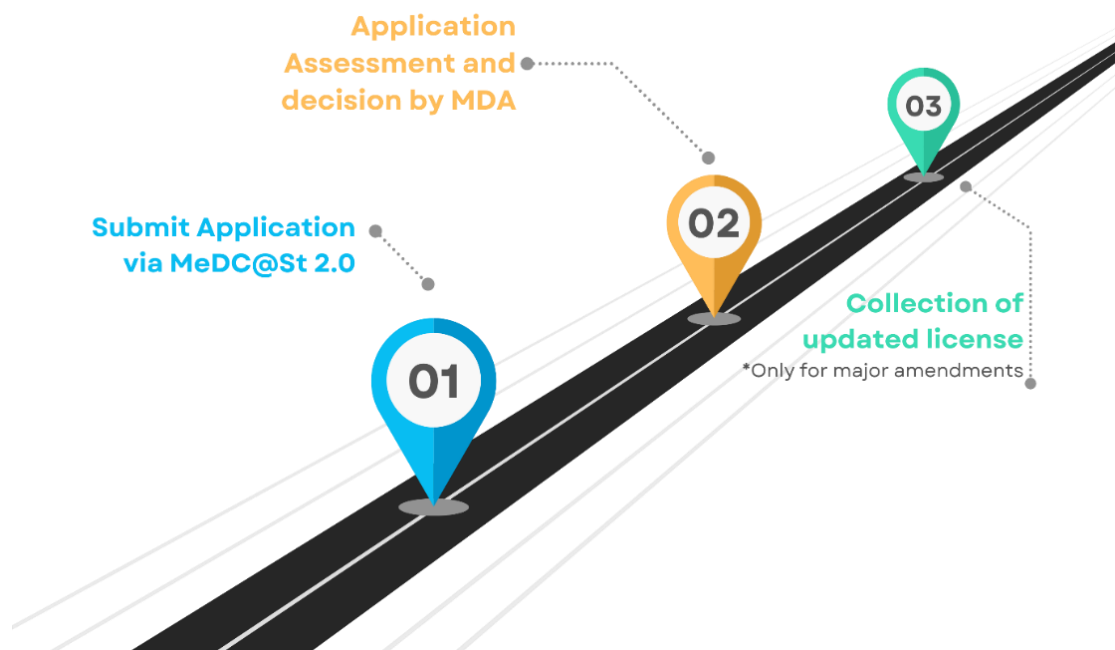
1. Introduction:

In the context of establishment licenses, an amendment can be categorized as either major or minor.

2. YouTube link for MeDC@St 2.0 navigation.

- a) [Establishment License - Ammendment Minor \(youtube.com\)](#)
- b) [Establishment License - Amendment Major \(youtube.com\)](#)

3. General Process Flow for License Amendments Application:



Surrender of Establishment License

1. Introduction:

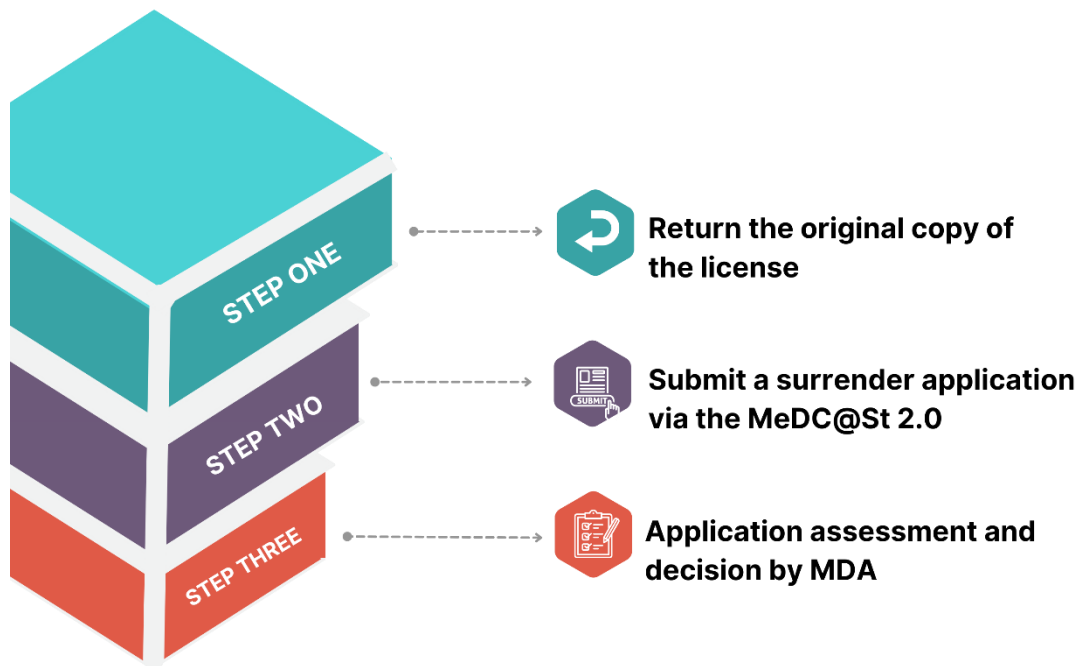
A licensee may, by notice in writing, surrender its license by forwarding the establishment license to the authority. Surrendering the license also meant the establishment is no longer allowed to conduct its activities related to Medical Devices.

The process for submitting an amendment minor application is also facilitated through the MeDC@St 2.0 platform.

2. YouTube link for MeDC@St 2.0 navigation.

a) [Establishment License - Surrender \(youtube.com\)](#)

3. General Process Flow for Surrender License Application:



Change of Ownership Application

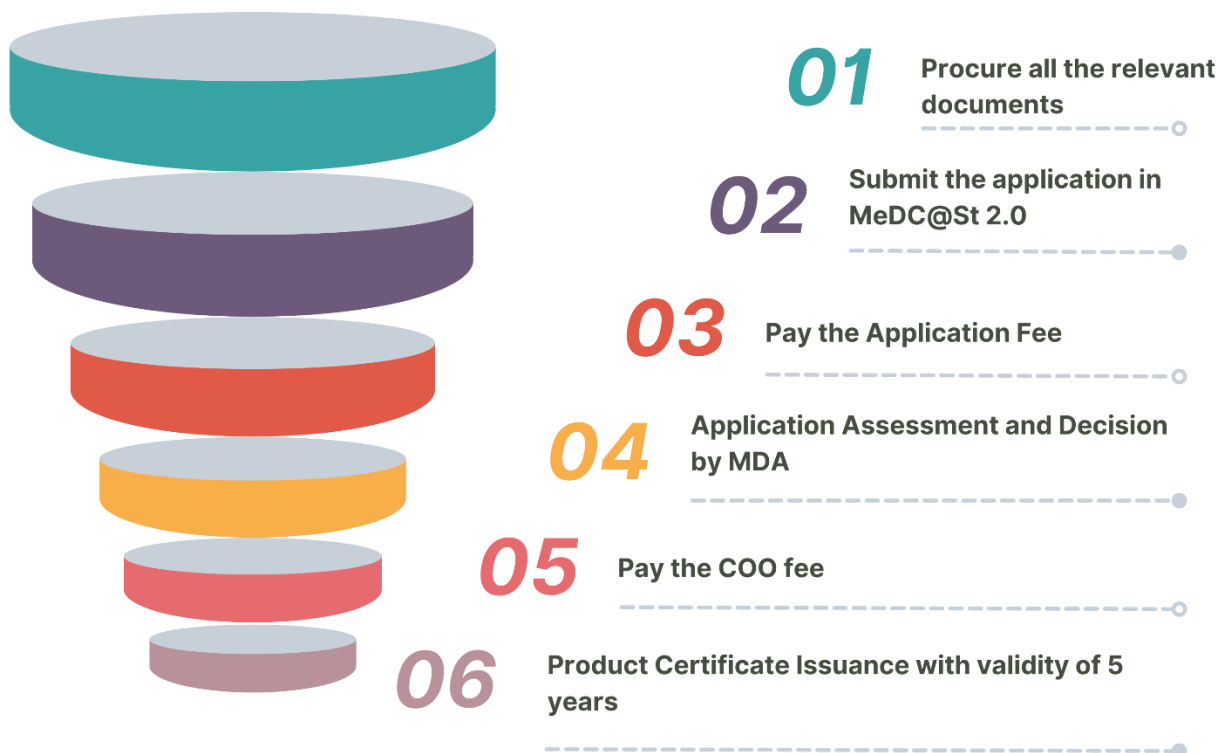
1. Introduction:

A Change of Ownership for medical device registration refers to the process where ownership of a registered medical device is transferred from one party to another. The application for change of ownership should be made by the new AR after the medical device is already registered with the Medical Device Authority (MDA).

2. YouTube link for MeDC@St 2.0 navigation.

- a) [Establishment License - Change of Ownership \(youtube.com\)](https://www.youtube.com/watch?v=...)

3. General Process Flow for Change of Ownership Application:



Withdrawal Application

1. Introduction:

The withdrawal application for establishment licensing refers to the process by which an establishment that initially applied for a license decides to withdraw or drop that application. This withdrawal process is distinct from the surrender of an establishment license, where an existing licensee voluntarily surrenders their license by notifying the relevant authority to cease any activities related to Medical Device registration and distribution.

2. YouTube link for MeDC@St 2.0 navigation.

- a) [Establishment License - Withdrawal \(youtube.com\)](#)

3. General Process Flow for Withdrawal Application:

