**Appendix 2**

**Trial Scheme for Expedited Approval of**

**Class II/III/IV General Medical Device Listing Applications**

**Device Profile**

*(Note: Please provide precise and concise information within 4 pages of A4 papers in font size 10 or larger)*

1. **Technological Background**

*(Brief information about technological background of the device, intended application and/or technique.)*

1. **Device Description**

*(General description on device and associated components/accessories needed in order to achieve the intended use. Indicate device and associated components/accessories that are included in this application.)*

1. **Intended application**

*(Intended clinical application, user population, etc.)*

1. **Material/Substance subjected to control by other local ordinance(s)**

*(Material(s)/substance(s) in the device that is/are subjected to control by other local ordinance(s).)*

1. **Image/Photo of the device and components included**

*(Illustration of device appearance, dimensions, and/or labeling.)*