

**Trial Scheme for Expedited Approval of  
Class II/III/IV 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**

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

**2. Device Description**

*(Include 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.)*

**3. Intended application**

*(Include intended clinical application, user population, etc.)*

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

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

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

*(Device and components included in visible and clear image quality. For any scanned digital colour images, the resolution should be at least 200 dpi. For digital colour photographs, the pixel size should be at least 1024x768.)*

**6. Substantial equivalent device listed under MDACS**

*(Provide list of substantial equivalent device(s) currently listed under MDACS with format suggested below)*

Listing No. (HKMD No.)	Make	Model	AMDNS Term	AMDNS Code	Description	Remarks

**7. Evidence to support substantial equivalence**

*(Provide summary comparison information to identify similarities and differences in intended use, indications for use, key specifications and performances)*

<u>Comparison</u>	<u>Device under application</u>	<u>Substantial equivalent device</u>
<u>Indications for use</u>	<u>Blood pressure measurement</u>	<u>Blood pressure measurement</u>
<u>Range</u>	<u>Cuff pressure range 0 to 299 mmHg</u> <u>Pulse Rate: 40 to 180 beats/min</u>	<u>Cuff pressure range 0 to 300 mmHg</u> <u>Pulse Rate: 30 to 200 beats/min</u>
<u>...</u>	<u>...</u>	<u>...</u>