**Appendix 1**

**Trial Scheme for Expedited Approval of**

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

**DECLARATION**

1. We,            *[name and address of the Applicant]*, have read and agreed to the Terms and Conditions of “Trial Scheme for Expedited Approval of Class II/III/IV General Medical Device Listing Applications” and have also read related documents issued by the Medical Device Division (MDD).
2. We declare that, regarding the device in this application:
3. There are no reported deaths or serious injury (local and worldwide)
4. There are no active recalls, field safety corrective actions or adverse incidents (local and worldwide)
5. We fully understand and agree that any future changes or additions to the requirements of the Medical Device Administrative Control System (MDACS) can be imposed by the Department of Health without prior notice. We hereby undertake to comply with the latest requirements of the MDACS that are in force.
6. We confirm that we have neither amended any wording in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

|  |  |
| --- | --- |
| Signature: Name:      Position:      Contact telephone number:      The Applicant (Local Responsible Person):      LRP Listing Number:      Date:       |  |
| (Company Chop) |