*[To be printed on company letterhead]*

**Thailand FDA & Singapore HSA Reliance Model Consent Form**

Medical Devices Branch
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

*[Date]*

Dear Sir/Madam,

We, *[Singapore Company Name]*, the Registrant for registration of medical device(s) stated below, hereby grant Thailand FDA the access to the submission dossier(s)/evaluation summary of the medical device(s) submitted to HSA, for the purpose of Thailand FDA and Singapore HSA Reliance Model evaluation as stated below.

**Singapore List of Medical Device(s):**

| Device Name | Device Registration number | Job reference number of main submission | Job reference number of(s) all change notifications filed to date | Device Product Identifier |
|---|---|---|---|---|
| | | | | |
| | | | | |

**Thailand FDA Submission Information:**
Full Company Name:
Full Name of Company Contact Person:
Thailand FDA submission reference number:
Submission date (DD/MM/YYYY):

We hereby also declare that by participating in this regulatory reliance program, I understand that:

(i) The evaluation report will be shared only after a product is approved by Singapore HSA.

(ii) For approved medical devices where change notifications had been submitted since initial premarket approval,

(a) for **technical changes,** the change notification evaluation report will be appended together with the main premarket evaluation report, and

(b) for **notification and administrative changes**, the latest information on the Singapore Medical Device Register (SMDR) for the device will also be appended.

Yours Sincerely,

*[Signature]*
*[Full Name and Title of Senior Company Official]*
*[Stamp with name and address of company]*