

[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]