

Marketing History Declaration Template

(To be printed on Company Letterhead of Applicant)

Medical Devices Control Division
Thai Food and Drug Administration
Ministry of Public Health

[Date]

Dear Sir/Madam,

I, *[name of Company]*, the applicant for registration of the medical device(s) stated below, hereby declare that the medical devices have been marketed in the *independent reference regulatory agency's* jurisdiction for at least one year. The first date of market introduction in *[jurisdiction/country]* was *[mm/yyyy]* respectively

This declaration shall apply to the following medical device(s):

[List containing product names of medical devices]

I, the applicant, am aware that making a declaration which I know to be false is an offence under the Medical Device Act (B.E.2551), Medical Device Act (2nd edition B.E.2562) and other applicable laws that may be in forced. I acknowledge that any non-compliance with any registration condition issued by the Thai Food and Drug Administration in relation to medical devices registered with the Medical Device Control Division may result in the suspension or cancellation of the medical devices registration.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]

[Company stamp]