**ภาคผนวก 6**

**Safety Declaration Template**

*[To be printed on Company Letterhead of Applicant]*

Medical Device 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 there are no safety issues globally that the use of the medical device(s) when used as intended by the Product Owner, in the last one year from *[dd/mm/yyyy]*:

( ) No reported detail;

( ) No reported serious deterioration in the state of health1 of any person, and

( ) No open field safety corrective actions (including recalls) at the point if submission of this application.

This declaration is made with respect to the following medical device(s).

[List containing product manes of medical devices]

I, the applicant, am aware that marking a declaration which I know to be false is an offence under the Medical Device Act (B.E.2008), 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 Office]*

*[Company stamp]*

1 Serious deterioration in the state of health, in relation a person means: (a) a life-threatening illness or injury suffered by the person; (b) a permanent impairment of a bodily function of the person; (c) any permanent damage to any part of the person’s body; or (d) a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.