

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

No reported deaths;

No reported serious deterioration in the state of health<sup>1</sup> of any person; and

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

This declaration is made with respect 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 (2<sup>nd</sup> 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]*

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