##### ANNEX 3

**Safety Declaration Template**

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

Medical Devices Cluster

Health Products Regulation Group

Health Sciences Authority

*[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 three years from *[dd/mm/yyyy] to [dd/mm/yyyy]* **(Condition 1) or** since market introduction of the medical device(s), globally **(Condition 2)**:

No reported deaths;

No reported serious deterioration in the state of health1 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 Section 30(10) of the Health Products Act (Cap. 122D) and may result in the cancellation of registration of the above medical devices under Section 37(1) of the Act.

Yours sincerely,

*[Signature]*

*[Full Name and Title of Senior Company Official]*

*[Name and Address of Company]*

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1 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.