##### ANNEX 2

**Marketing History 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 the medical devices have been marketed in

the independent reference regulatory agency’s jurisdiction for at least three years. The first date of market introduction in *[jurisdiction/country]* was *[mm/yyyy]*

OR

Singapore for at least three years. The first date of market introduction in Singapore was *[mm/yyyy]*

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 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]*