# ANNEX 1: Change Notifications arising from the EU MDR/IVDR related changes to registered medical devices.

**Medical Device MDR/IVDR Changes** *(Declaration Template)*

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

Medical Devices Cluster

Health Products Regulation Group

Health Sciences Authority

*[Date]*

Dear Sir/Madam,

*[Name of Company]*, the Registrant of the medical device(s) stated below, hereby declare that the change(s) to the medical device(s) in this Change Notification application:

[ ]  is/are due to EU MDR/IVDR updates

[ ]  fulfils all the following aspects:

•      No change to existing scope of approved intended use/ indications

•      No change to material

•      Compliance with international standards (e.g REACH)

•      No new safety and performance data

•      No change to method of use, device design and specification

•      No additional pre-clinical/clinical validation is required to support safety and effectiveness

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

*[List containing product names of medical devices and identifiers]*

I, the Registrant, declare that the above information has been verified with the Product Owner and is accurate.

Yours Sincerely,

*[Signature]*

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

*[Name and address of company]*