

Letter of no change

[To be printed on Letterhead of Manufacturer]

Name and Address of Manufacturer

< Please add Manufacturer Name >

< Please add Manufacturer Address >

We hereby declare that regarding the medical device < Please add product name (with listing codes/catalogue numbers if needed to identify the product) as it appears in the registration license, **there is no change in raw material, shelf life, packing& packaging, sterility, method of analysis, stability studies, GMDN code, intended use, classification, inner and outer labels.** *NB: The previous mentioned items are changed according to the requested change.*

The only change is (mention the proposed change whether it is addition or change, mentioning the registered and new status, from——to——)

< Please clarify any added abbreviations >

Signed on behalf of < Please add manufacturer name >

Authorised signatory:		
< please add authorised signatory name and title >	< Please apply signature and manufacturer stamp >	< Please add date of applying signature >
Name & Position	Signature & Stamp	Date

- Lines in blue are for clarification purpose only and to be deleted in the signed document.

- Wording in green between marks “ ” may be used where applicable.