

Shelf-Life Statement

[To be printed on Letterhead of Manufacturer]

Regarding the change of shelf life (Extension, reduction or correction)

Name and Address of Manufacturer

< Please add Manufacturer Name >

< Please add Manufacturer Address >

We hereby confirm the following with regard to the medical device < Please add product name (with listing codes/catalogue numbers unless needed to identify the product) as it appears in the registration license

Registered Shelf life	< Please add registered shelf life of the finished product (and its components if applicable) either in days or in months >
New shelf life	< Please add new shelf life (proposed shelf life) of the finished product (and its components if applicable) either in days or in months >
Proposed change	Extension or reduction or correction of the product shelf life
Justification	Mention the justification for the proposed change
Reason	Mention the reason for the proposed change

Signed on behalf of < Please add manufacturer name or whom it authorizes >

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.