

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

Signed on behalf of *< Please add manufacturer name >*

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

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