

Section 4: Comparator

4.1 Applicability of section 4

Is there a comparator included in the clinical investigation?.

Yes No

If yes, the section from 4.2 needs to be completed.

4.2 Type of comparator

Therapy
Placebo
No treatment
Medical device

4.2.1 Medical device as comparator

Is the comparator medical device CE marked?	Yes	No
If yes, will the CE marked comparator medical device be used in the clinical investigation within the scope of its CE mark?	Yes	No
Generic denomination:		
Device trade name:	Model:	
Device name:		
European Medical Device Nomenclature :		
Medical device classification:		
Device description:		

Intended (clinical) purpose:
Does the comparator device contain or incorporate medicinal substance(s)?
Yes No If yes, please provide the medicinal substance(s) name(s):
The comparator device incorporates, as an integral part, or it is manufactured using: Non-viable tissues of human origin or their derivatives with an ancillary action Non-viable cells of human origin or their derivatives with an ancillary action Non-viable tissues of animal origin or their derivatives with an ancillary action Non-viable cells of animal origin or their derivatives with an ancillary action Non-viable biological substance other than those referred to in the previous points None of these proposals/Not applicable
Additional comparators could be added by using a duplicated section 4, in appendix to this application form