

Section 4: Comparator

4.1 Applicability of section 4

Is there a comparator included in the performance study?

Yes No

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

4.2 Type of comparator

In Vitro Diagnostic Medical Device

Other, please specify:

4.2.1 In Vitro Diagnostic Medical Device as comparator

Is the comparator in vitro medical device CE marked?

Yes No

If yes, will the CE marked comparator in vitro medical device be used in the performance study within the scope of its CE mark?

Yes No

Generic denomination:

Device trade name:

Model:

Device name:

European Medical Device Nomenclature (weblink):

Medical device classification:

Classification rule:

Device description:

Intended purpose:

Does the comparator device include tissues, cells, and substances of animal, human or microbial origin?

Yes

No

If yes, please provide further information on the tissues, cells, substances of human, animal or microbial origin:

Additional comparator for performance could be added by using a duplicated section 3, in appendix to this application form.