

## Appendix 4 – Declaration of Interest

Name of the Clinical Evaluator: [first name and last name]

Name and mark of the Clinical Evaluation Plan: [name and mark]

Name and mark of the Clinical Evaluation Report: [name and mark]

Time spent on the clinical evaluation: [months/days]

STATEMENT	ANSWER
Have you participated as an investigator in clinical studies of the device, or in pre-clinical testing of the device?	
Do you have any ownership/shareholding in a company that can possibly be affected by the outcome of the evaluation?	
Have you participated in any projects sponsored by the manufacturer?	
Did you receive any benefits such as traveling or hospitality of any kind while in connection with the work as an investigator or external consultant?	
Do you have any interests in connection with the manufacturing of the device or its constituent?	
Do you have any interests in connection with intellectual property, such as patents, copyrights, and similar whether pending, issued, or licensed possibly affecting the outcome of the evaluation?	
Do you have any other interests or sources of income possibly affected by the result of the evaluation?	
Are there any financial interests of family members from the manufacturer or medical device company, sponsor or partner, living in the same residence as the evaluator, under and able to whom the evaluator's rights transferred?	

**Commented [AES1]:** Include the name of the person assigned

**Commented [AES2]:** Include the name and the mark of the

**Commented [AES3]:** Include the name and the mark of the

**Commented [AES4]:** Include the time spent for the clinical

**Commented [AES5]:** If the answer is "Yes," state here in which

**Commented [AES6]:** If the answer is "Yes," state here the

**Commented [AES7]:** If the answer is "Yes," state here in which

**Commented [AES8]:** If the answer is "Yes," state here what

**Commented [AES9]:** If the answer is "Yes," state here what

**Commented [AES10]:** If the answer is "Yes," state here what

**Commented [AES11]:** If the answer is "Yes," state here what

**Commented [AES12]:** If the answer is "Yes," state here what

[organization name]

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Clinical Evaluator

[name]

[signature]

[date]

[Manufacturer]'s responsible person

[job title]

[name]

[signature]

**Commented [AES14]:** Include the name of your organization.

**Commented [AES13]:** Include the name of the clinical evaluator.

**Commented [AES15]:** Include the job title of the responsible person.

**Commented [AES16]:** Include the name of the responsible person.