**Manufacturer:** (Name and Address)

**Investigational device(s):** (List all the devices subject to investigation that do not have a CE-marking, including their names and exact versions, e.g. Exampledevice version 1.0)

**Title of the clinical investigation:** (Full title of the clinical investigation)

**Statement of the manufacturer and confirmation according to Annex XV of Regulation (EU) 2017/745**

(Do not change the following wording)

Product requirements: I confirm that the devices listed above conform to the general safety and performance requirements according to Annex I of Regulation (EU) 2017/745 apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

Access of Swissmedic to additional documentation: I confirm that the documentation is being kept available for Swissmedic in accordance with chapter III of Annex XV of Regulation (EU) 2017/745 for a period of at least 10 years (15 years in case of implantable devices) after the clinical investigation with the devices in question has ended, or, in the event that the devices are subsequently placed on the market, at least 10 years after the last device has been placed on the market.

Date, signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Name and function in printed characters]

**Manufacturer:** (Name and Address)

**Investigational device(s):** (List all the devices subject to investigation that do not have a CE-marking, including their names and exact versions, e.g. Exampledevice version 1.0)

**Title of the clinical performance study:** (Full title of the clinical performance study)

**Statement of the manufacturer and confirmation according to Annex XIV of Regulation (EU) 2017/746**

(Do not change the following wording)

Product requirements: I confirm that the devices listed above conform to the general safety and performance requirements according to Annex I of Regulation (EU) 2017/746 apart from the aspects covered by the clinical performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

Access of Swissmedic to additional documentation: I confirm that the documentation is being kept available for Swissmedic in accordance with chapter II of Annex XIV of Regulation (EU) 2017/746 for a period of at least 10 years after the clinical performance study with the devices in question has ended, or, in the event that the devices are subsequently placed on the market, at least 10 years after the last device has been placed on the market.

Date, signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Name and function in printed characters]