**Certification of Independent Physician Who is Not Otherwise Participating in the Clinical Investigation of the Test Article**

I have reviewed the information provided and certifications made by the Treating Physician and certify that all of the following statements are true:

* The patient was confronted by a life-threatening or severely debilitating situation necessitating the use of the investigational drug or device; and
* Informed consent could not be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from the patient; and
* Time was not sufficient to obtain consent form the patient’s legally authorized representative, and
* No alternative method of approved or generally recognized therapy was available that provided an equal or greater likelihood of saving the life of the patient.

**Name of Independent Physician:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Independent Physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**