**Approval of Amendment**

**Bangkok Hospital Headquarters - Institutional Review Board**

No……………………

This document is a record of review and approval acceptance of a study protocol.

**Protocol Title :**

**Principal Investigator :**

**Affiliation :**

**IRB Protocol No. :**

**Research site :**

**Type of document : Protocol Amendment**

**Date of Meeting :**

**Date of Approval :**

 This is to certify that Bangkok Hospital Headquarters - Institutional Review Board is in full Compliance with International Guidelines for Human Research Protection such as the Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP), ISO14155 for medical device study.

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 ( ) Date

 Chairman of Institutional Review Board