Contents of File submitted to stability committee
For Registered Medical Devices Submitted To Variation Department

***Main Requirements:**

1-Computarized application form stamped and signed

2-letter signed and stamped clarifying the required changes.

And confirm that there is not any other change in the old registration report.

3-Copy of old registration report

***Additional Requirements:**

I-For Shelf Life Extension:

-Stability Study

-Biocompatibility Study (for local medical devices and medical devices from non-reference country).

II-For Addition or Changing of Sterilization Method:

-Performance Data for new sterilization method.

-Comparison study between old& new sterilization methods.

-Stability study including sterilization Validation Report.

-Biocompatibility Study.

III-For Changing or Adding Package (Apply Only For Primary Package Change):

-Old package description

-New package description

-Stability Study including Packaging validation report.

-Biocompatibility Study (for local medical devices and medical devices from non-reference country).

-Sample of old &new package configuration change.

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IV-For Changing of storage condition:

-Protocol of stability study.
-Storage conditions (Temperature, for how long, no. of samples).
-Evaluation of tests done.
-Calculation of shelf life.
-Conclusion for the study.
-Biocompatibility Study.

***ملحوظة:**

سوف يتم تسليم الطلبات السابقة أصل موقع ومختوم +٥ نسخ من ال application&additional requirements للعرض علي اللجنة العلمية المتخصصة لتقييم دراسات الثبات(Biocomptability)الخاصة بالمستلزمات الطبية

مع تقديم تعهد بأن جميع المستندات المقدمة في ال٥ نسخ مطابقة تماما لما تم تقديمه في ملف الثبات والملف المقدم لقسم المتغيرات

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