Check list of the locally manufactured in vitro diagnostics registration does not have any international quality certificate

اولاً: مستندات خاصة بطالب التسجيل :

1. قائمة مرقمة بمحتوى ملف التسجيل.
2. ايصال الدفع الخاص بمقابل الخدمات.
3. طلب رسمي من مقدم الطلب مختوم وموقع من مدير الشركة وفقا للنموذج المعلن من قبل الادارة.
4. تعهد المصنع بالالتزام بتطبيق آليات المأمونية.
5. أصل التفويض صادر من المصنع معتمد من رئيس مجلس الادارة مع التصديق البنكي عن التوقيع بالشخص المسئول عن التعامل مع الإدارة المركزية للمستلزمات الطبية
6. المصـــانع المحلية:
   - السجل التجاري.
   - البطاقة ضريبية.
   - رخصة التشغيل صادرة من الهيئة العامة للتنمية الصناعية.

   مصانع المنطقة الحرة:
   - السجل التجاري.
   - البطاقة ضريبية.
   - الترخيص الصادر من الهيئة العامة للاستثمار والمناطق الحرة بمزاولة النشاط بنظام المناطق الحرة.

ثانياً: الملف الفني **(Technical documentation)**:

1. **Administration**:
   1. Name of manufacturer
   2. Address of manufacturer
   3. Address of any associated manufacturing sites
   4. Statement of legal liability
   5. License of manufacturing no. (attachment)
   6. Name of authorized person
   7. Authorized person Delegation Letter (attachment)
   8. Name of contact person
   9. Tel
   10. Fax
   11. E- mail
   12. Web address
   13. 13485:2016, and CE certificate according to IVD, or IVDR If present (attachment)
   14. Declaration of conformity /or letter of declaration according to the adopted regulation (attachment)
       N.B: the adopted regulation to be one of the GHTF member

2. **Device description**
   - Name of the device.
   - Brand name.
   - Variant:codes,references, or sizes.
   - Intended use.
   - Risk classification according to European regulations) European directive 79/98/ EEC).
   - Description of principle of the assay and methodology used.
   - Description of individual components included in the IVD.

   Where applicable, the following should also be provided**:**
   - A description of the accessories, other IVDs and other products that are not medical devices which are intended to be used in combination with the IV.
   - For assays requiring instrumentation, a description of the relevant instrumentation characteristics or details of dedicated instrumentation to be used.
   - A description of any software to be used.
   - A complete list of any configurations or variants of the IVD, other than kit size, that will be made available.
3. **Device history (Transitional State only)سابقة الأعمال:**
   - A summary of the product history in domestic market and any other countries (attachment).
   - A list of countries or regulatory jurisdictions, approximate numbers of IVDs and/or period of time supplied, summary of any adverse events, recalls,corrective/preventive actions or refusal to approve for supply (attachment)
4. **Risk analysis and control summary.**
5. **Design and / or manufacturing information.**
6. **Clinical evidence report (if IVDR applied).**
7. **Clinical summary report (if IVDR applied).**
8. **Performance evaluation (Attachment).**
   - diagnostic sensitivity
   - diagnostic specificity
9. **Product Validation and Verification (Attachment).**
   1. Specimen type**:**
      - A list of all appropriate specimen type(s) suitable for use with the IVD must be provided, including anticoagulants, matrices
        N.B: Analytical performance study reports should include information about the nature of the specimen types tested (e.g., spiked, wild type etc.) and the geographic location where specimens were obtained, as appropriate
      - Any special instructions or conditions associated with specimen collection.
      - specimen stability, appropriate storage conditions and where applicable, transport conditions storage includes elements such as duration, temperature limits, number of freeze/thaw cycles.

2. Accuracy: = both trueness and precision(Reproducibility and repeatability).
    - Reproducibility should include information about studies to estimate total variability and as appropriate, between-day, between-run, between-sites, between-lots, between-operators and between-instrument variability.
    - Repeatability should include information about studies to estimate total variability and as appropriate, within-run variability.
    - The results of testing should include samples that represent the full range of expected analytic concentrations within the target population.
3. Analytical sensitivity:
    - specimen characterization and number of replicates tested at each concentration.
    - Calculations used to determine the assay sensitivity should be included.
4. Analytical specificity:
    - Information relating to any studies conducted to determine the effect caused by potentially interfering or cross-reacting substances or agents on test results should be provided.
    - Consideration should be given to both exogenous and endogenous factors expected to be encountered.
5. Measuring range of assay:
    - A summary of the studies conducted to define the assay measuring range should be included for both linear and non-linear systems.
    - Information provided should describe the lower limit of detection and how this was determined (e.g., preparation of dilutions, standards, number of replicates) and include an investigation into any potential effects of Prozone or high-dose hook effect, if applicable
6. Traceability of calibrator and controls:
    - Information summarizing the traceability of calibrators and trueness control materials should be provided, if applicable.
    - Methods used to determine traceability to reference material of a higher order, acceptance criteria, and the assignment and validation of values should be included.
7. Determination of assay cut-off:
    - A summary of the process used to establish the assay cut-off should be provided.
    - Information provided should be based on the population studied, method(s) used to establish the true status and any statistical methods used to generate results e.g., ROC curve.
8. Verification and validation of instrumentation/software:
   The study report should include a summary of performance testing undertaken conducted in a valid end-user environment
9. Stability study.

10. **Labeling:**
    - Inner and outer labels
    - Instructions for Use
    - Advertising material (e.g., brochures, web-pages, published advertisements, etc.), where available.
11. **Manufacturing process and control**

    Bill of materials, and components
    - Certificates of compliances of materials and components from the supplier
    - Manufacturer inspection and testing
    - Approved suppliers list and supplier evaluation criteria
12. **In process inspection and testing**
13. **Finished product assembly and testing reports**
14. **Product release process and statement of compliance**
15. **Manufacturer testing reports**
16. **Commitment to follow up with medical device PMS.**