Antigen Rapid test Conditional Approval Requirements

1. **Section 1: Application form:**

Establishment Name:	**Fill**
Commercial Registration certificate (CR) With relevant activity addition details 1. **Name:** Wholesaling of pharmaceutical and medical goods, tools and surgical devices and orthopedic devices. **Code:** 464904 (To import medical device from the manufacturer) Only importer /local agent can apply for Product assessment/ registration	**Attach CR document**
Authorization letter *(Commercial Agency certificate to be submitted within 60 days)	**Attach**
Full Name of authorized contact	**Fill**
Authorized contact position	**Fill**
Email	
Phone number	
Address	**physical and postal address**
Storage Availability Yes or No (mandatory)	**Fill**
Listing done	**Yes** ☐ **No** ☐ ***Mandatory**
After sale support letter **(showing responsibility of the local agent to the requested medical device on the local agent head letter)**	**Attach**

Section 2: Manufacturer information:

Test	
Legal Manufacturer name	**Fill**
Legal Manufacturer Address	**Fill**
Manufacturer site (If different)	**Fill**
Manufacturer site Address (If different)	**Fill**
ISO 13485 certificate	**Attach**

for the legal Manufacturer	
Swab	
Legal Manufacturer name	**Fill**
Legal Manufacturer Address	**Fill**
ISO 13485 certificate for the legal Manufacturer	**Attach**

Section 3: Medical Device Information

Medical Device Name	**Fill**
Medical Device Model	**Fill**
Medical Device Category	**Fill**
Medical Device classification	**Fill**
GMDN	**Fill**
Medical Device description	**Fill**
Medical Device Intended use	**Fill**
First year sold	**Fill**
Audit report if high risk or upon request of DGPA&DC	**Attach**

Section 4: Device Labeling

Labeling of the device inclusive of	
Test : label +Manual + Instruction For Use + Package insert Picture of the device/IVD **To attach Arabic translated IFU by the legal manufacture if product for home use /(self-test antigen rapid).**	**Attach**
Swab label + picture	**Attach**

Section 7: Required Certificates:

Test quality certificate : **(attached)**	CE certificate (if applicable)	**Attach**
	Design examination certificate (if applicable)	**Attach**
	Full quality assurance(if applicable)	**Attach**
Swab quality certificate : **(attached)**	CE certificate (if applicable)	**Attach**
	Design examination certificate (if applicable)	**Attach**
	Full quality assurance(if applicable)	**Attach**

*** If applicable if they are high risk or self-test**

Section 8: Clinical performance

Test : Performance data / analytical performance for example : accuracy/ sensitivity Swab : Biocompatibility report	**Attach**

Section 9: Post market control

Post Market History if high risk or upon request of DGPA&DC	**Attach**

Section 10: Status of device distribution

Country of origin regulatory authority approval	**Attach**
Free sale certificate from original country regulatory authority	**Attach**
Free sale certificate from one of reference countries competent regulatory authority Reference countries for example (**USA, Canada, Australia, Japan, EU, KSA**).	**Attach**
Reference countries approvals: (**USA, Canada, Australia, Japan, EU, KSA**).	**Attach**
List of Countries where the product was sold	**Attach list**

Section 11: Declaration of conformity

Test Declaration of Conformity	**Attach**
Swab Declaration of Conformity	**Attach**

Section 12 : Grouping & Bundling:

Sr. No	Product Description	Intended Purpose	Category	Classification	Manufacturer name	Trade/Brand Name	Model Number

Note:

1. **To submit sample along with the conditional approval requirement form.**
2. **Only requests from local agents/importers are accepted. Distributors must refer to their local agents to apply for the Device Approvals.**
3. **Medical device activity must be whole sale for clearance purposes, and store availability is mandatory.**
4. **If device is for Professional use: Approval of device should be followed with service license and validation of results which should obtained through relevant authorities as appropriate.**
5. **Request will be cancelled after 60 days if there is no reply from the applicant.**
6. **Further requirement may be requested based on DGPA&DC needs.**