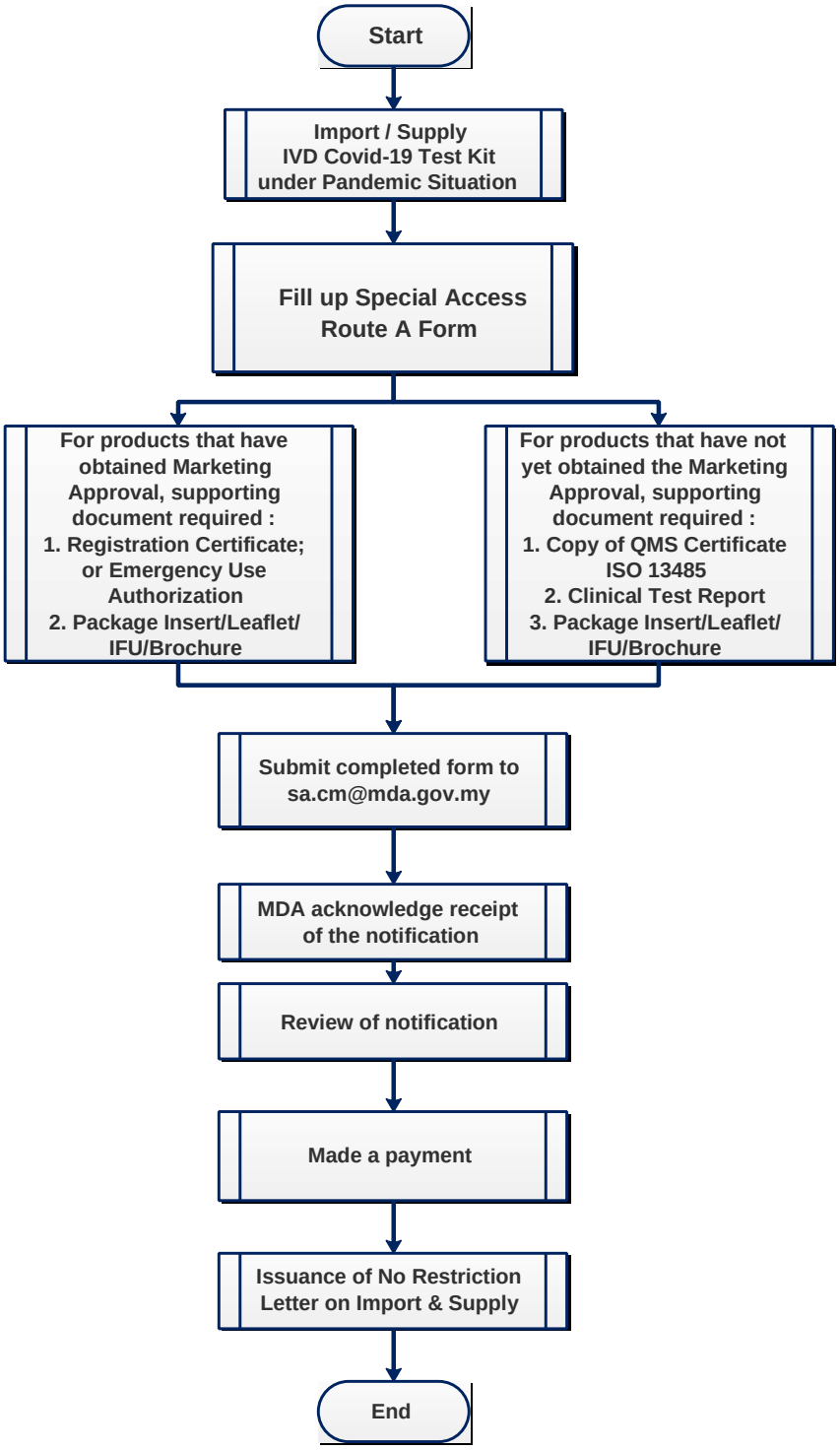
Start
Import / Supply IVD Covid-19 Test Kit under Pandemic Situation
Fill up Special Access Route A Form
For products that have obtained Marketing Approval, supporting document required : 1. Registration Certificate; or Emergency Use Authorization 2. Package Insert/Leaflet/ IFU/Brochure
For products that have not yet obtained the Marketing Approval, supporting document required : 1. Copy of QMS Certificate ISO 13485 2. Clinical Test Report 3. Package Insert/Leaflet/ IFU/Brochure
Submit completed form to sa.cm@mda.gov.my
MDA acknowledge receipt of the notification
Review of notification
Made a payment
Issuance of No Restriction Letter on Import & Supply
End