Supporting Documents for COVID-19 IVD Test Kits Special Access Notification

1. Copy of Legal Manufacturer's QMS ISO 13485 certificate
2. Pre-market Approval / Registration Certificate / Emergency Use Authorization
3. Instruction for Use (IFU) and Product Brochure
4. Full performance report / Clinical Study report provided by the Legal Manufacturer
5. Copy of Establishment License of the applicant (for company)
6. Information on Batch Lot No.
7. Letter of Authorization as Authorized Representative from the Legal Manufacturer.