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)