Quick Guide
Submitting COVID-19 Rapid Antigen Test (RAT) Applications

Prepare for application

- **Application form**
  - For marketing approval from EU, USA, Canada, Australia, Japan,
    applicable form# MD-IVD (2022 Edition)
  - For marketing approval from Mainland China,
    applicable form# MD-IVD (2022 年試版)

  Point to note:
  - (C003) AMDNS code: 41618 / 41572
  - (C005) Intended use same as stated in Instruction for Use (IFU)
  - (C008) Class C according to Rule 3.3
  - (C011) Professional use only / self-use

- **Supporting documents**
  - For Legal Manufacturer
    - ISO13485 certificate or YY/T 0287 certificate
    - LRP designation letter (Appendix 2, GN-01)
  - For Local Responsible Persons (LRP)
    - Business registration certificate

    Documented procedures for
    - Keeping of transaction records
    - Management of product recalls and field safety notices
    - Handling of reportable adverse events in Hong Kong
    - Temperature requirements of COVID-19 RAT during storage and transportation
    - Complaints handling
    - Maintenance and service arrangements (if applicable)

    References:
    - [COP-01] Code of Practice for Local Responsible Persons
    - [GN-03] Guidance Notes for Adverse Event Reporting by Local Responsible Persons
  - For COVID-19 RAT
    - Labelling
      - Device & package labels
      - Special Listing Information (4.4.13, GN-01)
      - IFU in English and/or in Chinese for professional use or in English & Chinese for self-use
    - Risk management report(s) / summary

      Including but not limited to:
      - Overall diagnostic sensitivity
      - Diagnostic sensitivity at different Ct ranges
      - Overall diagnostic specificity
      - Ability on detecting variants, e.g. Delta & Omicron
      - Limit of detection
      - High-dose Hook Effect
      - Precision
      - Potential interfering substances
      - Potential cross-reactivity
      - Stability / Shelf-life

      Submit independent evaluation report(s), if any
    - Performance evaluation report(s)
    - Marketing approval(s)

      EU:
      1. EC Declaration of Conformity + EC certificate, or
      2. EC Declaration of Conformity + EU free sale certificate

      US FDA:
      1. EUA letter, or
      2. 510(k) letter + Certificate to Foreign Government (CFG)

      Australia TGA: ARTG certificate + AUS Declaration of Conformity

      China NMPA: Product registration licence (産品注冊証) + manufacturing license (生產許可証)

      Japan MHLW: Free sale certificate (in English) + manufacturing license

      Health Canada (HC): Medical device license

      # More than ONE marketing approvals can be submitted. The model(s) of all submitted marketing approvals should be identical.
    - Essential requirements / General safety and performance requirements checklist or Essential principles conformity checklist

      EU: Essential requirements / General safety and performance requirements checklist + Essential principles declaration of conformity (Appendix III, GN-06)

      US FDA / Australia TGA / China NMPA / Japan MHLW / Health Canada (HC): Essential principles conformity checklist for in vitro diagnostic medical devices

Please ensure the document checklist is completed before application submission.

02 Mar 2022

Document Checklist for COVID-19 Rapid Antigen Test (RAT) Listing Applications

Items	Checked (✓)
Application Form	
Listing based on marketing approval from EU, USA, Canada, Australia, Japan, applicable form# MD-IVD (2022 Edition)	☐
Listing based on marketing approval from Mainland China, applicable form# MD-IVD (2022 年試版)	☐
AMDNS code: 41618 / 41572	☐
Intended use same as stated in Instruction for Use (IFU)	☐
Class C according to Rule 3.3	☐
Professional use / self-use	☐
Supporting Documents	
For Legal Manufacturer	
Quality Management system certificate	
● ISO 13485 certificate	☐
● YY/T 0287 certificate	☐
Local Responsible Persions (LRP) designation letter (Appendix 2, GN-01)	☐
For LRP	
Business registration certificate	☐
Documented procedures	
● Keeping of transaction records	☐
● Management of product recalls and field safety notices	☐
● Handling of reportable adverse events in Hong Kong	☐
● Temperature requirements of COVID-19 RAT during storage and transportation	☐
● Complaints handling	☐
● Maintenance and service arrangements (if applicable)	☐
For COVID-19 RAT	
Labelling	
● Device & package labels	☐
● Special Listing Information (4.4.13, GN-01)	☐

● Instruction for use in English	☐
● Instruction for use in Chinese (Mandatory for self-use)	☐
Risk analysis report / summary	☐
Performance evaluation report	
● Overall diagnostic sensitivity	☐
● Diagnostic sensitivity at different Ct ranges	☐
● Overall diagnostic specificity	☐
● Ability on detecting variants, e.g. Omicron	☐
● Limit of detection	☐
● High-dose Hook Effect	☐
● Precision	☐
● Potential interfering substances	☐
● Potential cross-reactivity	☐
● Stability / Shelf-life	☐
Marketing approval(s)	
EU:	
● EC Declaration of Conformity + EC certificate	☐
● EC Declaration of Conformity + EU free sale certificate	☐
US FDA:	
● EUA letter	☐
● 510(k) letter + Certificate to Foreign Government (CFG)	☐
Australia TGA: ARTG certificate + AUS Declaration of Conformity	☐
China NMPA: Product registration licence (產品注冊証) + manufacturing license (生產許可証)	☐
Japan MHLW: Free sale certificate (in English) + manufacturing license	☐
Canada HC: Medical device license	☐
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EU: Essential requirements / General safety and performance requirements checklist + Essential principles declaration of conformity (Appendix III, GN-06)	☐
US FDA / Australia TGA / China NMPA / Japan MHLW / Health Canada (HC): Essential principles conformity checklist for in vitro diagnostic medical devices	☐