For office use only: Medical Device Approval Form received on:

Medical Device Approval Form Reference No.

MT-MDF07

Application for Designated Premises to be approved for the performing of Point-of-Care Covid-19 Tests

The application is valid when submitted with the relevant documents. Filled in applications should be forwarded to mdforms.medicinesauthority@gov.mt.

Refer to the *GL-MDF11 - Guidance for MT-MDF07 Application for Designated Premises to be approved for the performing of Point-of-Care Covid-19 Tests* & *GL-MDF07 - Guidance on fees in relation to Medical Devices.*

Guidance documents and Application Form are available on the Malta Medicines Authority website: https://medicinesauthority.gov.mt/medicaldevices.

June 2023

Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt

SECTION A: APPLICATION INTRODUCTION

Date of Application:

Applicant Details (Premises Owner/Manager)

Name & Surname:
E-mail Address:
Contact Number/s:
ID Number:

SECTION B: REQUEST FOR PREMISES TO BE APPROVED

- ☐ **Initial request**
- ☐ **Revision of submitted details for approved application**
  - ☐ Revise Owner/Manager details
  - ☐ Revise Responsible Healthcare Professional details
  - ☐ Revise Premises details (updates within approved premises)
  - ☐ Withdraw request

  Certificate Reference:

SECTION C: PREMISES DETAILS

Premises Name:
Address:
E-mail Address:
Contact Number/s:
Premises Type:
Description of Premises: *Include detailed plans of premises layout and proposed testing set up, highlighting the flow of patients in and out of the premises.* *Attach supporting documentation (ex. photos, premises plan).*

SECTION D: RESPONSIBLE HEALTHCARE PROFESSIONAL DETAILS

Name & Surname:
E-mail Address:
Mobile Number:
ID Number:
Profession:
Profession Registry Number:

SECTION E: DECLARATION FORMS

Signed Declarations Forms in attachment:

- ☐ Malta Medicines Authority Declaration for Form Submission
- ☐ Designated Premises Declaration Form

SECTION F: DETAILS OF PAYMENT

- ☐ Proof of Payment attached (Standard fee)
- ☐ Proof of Payment attached (Fast-track fee)

Data Protection Consent Statement

- ☐ *The applicant and responsible healthcare professional hereby consent to the processing of their personal data by the Malta Medicines Authority and understand that this data shall be processed in accordance with the General Data Protection Regulation (GDPR), Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016, repealing Directive 95/46 EC, the Data Protection Act (Chapter 586 of the Laws of Malta) and the Malta Medicines Authority Data Protection Policy (P-MA05).*
  The applicant and responsible healthcare professional also understand that the Malta Medicines Authority shall process this personal data in line with the purposes they are initially collected for. Exceptions to the latter include when the data subject consents to the new purpose, when there is a legal provision requiring or allowing the new processing or when the new purpose is deemed compatible with the purposes the personal data were initially collected for.

Malta Medicines Authority Declaration for Form Submission

I, the applicant, declare that all information given in the application form is true, complete and correct. I also bind myself to inform immediately any change to details in the application form and annexes, where relevant, to the Malta Medicines Authority.

Company Name (if applicable):

Applicant Name & Surname:

Applicant Position:

Applicant Signature:

Date:

Designated Premises Declaration Form

All criteria must be read, understood and marked accordingly

The Premises Owner/Manager and Responsible Healthcare Professional, declare that they adhere to the following:

- ☐ Subsidiary Legislation 458.61 - *Testing of COVID-19 Regulations*
- ☐ Ministry for Health latest Standards on the use of Point-of-Care Covid-19 Tests for SARS-CoV-2.
- ☐ Designated swabbing and waiting areas must be separate from other areas in the premises.
- ☐ Swabbing must be scheduled by appointment only. Appointments must be sufficiently staggered to avoid people congregating while waiting.
- ☐ Individuals entering the premises are required to wear a mask whilst inside the property and to apply sanitizer when entering/exiting the premises.
- ☐ Surfaces that come into direct contact with patients being swabbed, should be cleaned and disinfected between appointments. Other areas within the designated premises should be cleaned and disinfected daily.

Applicant (Owner/Manager)	**Responsible Healthcare Professional**
Name & Surname:	Name & Surname:
Signature:	Signature:
Date:	Date:

Annex 1: Terms and Conditions

- Approved premises will be issued an **Approval Certificate for Point-of-Care Covid-19 Tests Premises** by the Malta Medicines Authority.

- No testing services can be performed prior to receipt of the Certificate.

- Certificate validity is **1 (one) year from Date of Issue**.

- The Certificate is issued by the Malta Medicines Authority based on the information and declarations forwarded. Any changes to the information submitted in the Application must be immediately notified to the Malta Medicines Authority.

- **Certificate may be revoked at the discretion of the Superintendent of Public Health.**