



**Guidance for MT-MDF07  
Application for Designated Premises  
to be approved for the performing  
of Point-of-Care Covid-19 Tests**

## 1. Introduction

Point-of-Care Covid-19 Tests carried out in Malta in accordance with Subsidiary Legislation 458.61 - *Testing of COVID-19 Regulations*, need to be performed on designated premises certified by the Malta Medicines Authority (MMA).

## 2. Scope

The purpose of this Guidance Document is to provide comprehensive instructions to applicants registering designated premises with the MMA to conduct Point-of-Care Covid-19 testing in Malta, in accordance with Subsidiary Legislation 458.61 - *Testing of COVID-19 Regulations*.

## 3. Terms, Definitions and Abbreviations

### *Applicant*

Any local person (Premises Owner/Manager) who wishes to designate their premises in Malta or Gozo as Point-of-Care Covid-19 Test swabbing sites.

Accountable to ensure that the site indicated in the MT-MDF07 Application Form meets the general safety and performance requirements for the operation of Point-of-Care Covid-19 Testing as per criteria mandated in the Application Form and:

- 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 Premises for performing Point-of-Care Covid-19 Tests*

#### *(Designated premises)*

Designated premises identified for the delivery and testing of Point-of-Care Covid-19 Tests pursuant to Subsidiary Legislation 458.61 - *Testing of COVID-19 Regulations*.

### *Health care professional (HCP)*

Definition as assigned in the Health Care Professions Act (Chapter 464). Health Care Professionals may perform Point-of-Care Covid-19 Tests as assigned by the responsible HCP assigned for designated premises.

### *MT-MDF07 Application for Designated Premises to be approved for the performing of Point-of-Care Covid-19 Tests (MT-MDF07 Applicant form)*

Applicants are required to submit this Application Form (and any supporting documentation requested in the Form) to the MMA for review.

### *Point-of-Care Covid-19 Tests*

Point-of-Care Covid-19 Tests means any test that does not require the submission of the test specimen to a laboratory and that is intended to be used to detect and identify the presence of SARS-CoV-2 or any other marking agent related to it.

### *Responsible health care professional (Responsible HCP)*

Responsible HCP assigned for the designated premises.

Responsible to ensure that the site indicated in the MT-MDF07 Application Form meets the general safety and performance requirements for the operation of Point-of-Care Covid-19 testing as per criteria mandated in the MT-MDF07 Application Form and:

- 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  
Responsible to ensure that individuals assigned to perform Point-of-Care Covid-19 tests at the designated premises are warranted healthcare professionals and have been fully trained to perform Point-of-Care Covid-19 tests on behalf of the registered premises.

L.N.: Legal Notice

MMA: Malta Medicines Authority

## 4. Specific Guidance

### 4.1 Applicant submissions

The MT-MDF07 Application Form may be submitted by any local person who wishes to designate their premises for Point-of-Care Covid-19 testing. Applicants may be first time applicants or registered applicants who wish to amend the details issued on the Point-of-Care Covid-19 Tests Approval Certificate.

### 4.2 General Details related to the Application Process

#### 4.2.1 Application Form

The Application Form related to this guidance document is *MT-MDF07 Application for Designated Premises to be approved for the performing of Point-of-Care Covid-19 Tests*, which may be accessed from the MMA website: <https://medicinesauthority.gov.mt/medicaldevices>

#### 4.2.2 Application Format

MT-MDF07 Application Form is in a fillable pdf format. Form should be filled in electronically using the shaded areas. Handwritten forms may not be accepted if writing is considered illegible.

Forms should be signed and submitted as a scanned copy or as a signed pdf file.

#### 4.2.3 Official Languages

The official languages in Malta are Maltese and English. MT-MDF07 Application Forms and supporting documentation for the registration process must be completed in either Maltese or English.

#### 4.2.4 Submission

A fully completed and signed MT-MDF07 Application Form with supporting documentation should be forwarded electronically to the MMA to: [mdforms.medicinesauthority@gov.mt](mailto:mdforms.medicinesauthority@gov.mt)  
An electronic receipt acknowledgment will be sent to the applicant.

#### 4.2.5 Application Review Timeline

Upon submission of all relevant documentation:

- a processing timeframe of up to **30 calendar days commences for Standard applications**
- a processing timeframe of up to **10 calendar days commences for Fast Track applications**

Processing timeframe applies from receipt of the Application Form at the MMA.

Applicant will be notified of additional documentation or clarifications required by the MMA. A stop-clock will be initiated and restarted upon receipt of responses. If further queries arise

or responses are not satisfactory, the applicant is informed, and clock stops/starts accordingly with the cycle repeating itself.

#### **4.2.6 Approval Criteria**

The MMA shall issue its approval or rejection following the consideration of all relevant documents, and any other information as may be deemed necessary to ensure fulfilment of the authorisation requirements submitted by the applicant.

#### **4.2.7 Issuing of Approval**

Applicants will receive an Approval Certificate via email, indicating approval of the designated premises.

Approved premises and responsible HCP details will be registered and made visible on the COVID Rapid Testing Malta web application.

It is the responsibility of the applicant to update the MMA of any changes in the application / premises details.

#### **4.2.8 Approval Validity**

The validity of the Approval Certificate is **1 year from the date of issue**.

Applicants will be notified of the approaching expiry date.

#### **4.2.9 Non-compliances**

The MMA may, from time to time, inspect the registered premises or request additional information from the applicant / responsible HCP, as deemed necessary.

Penalties may be issued in line with Subsidiary Legislation 458.61 - *Testing of COVID-19 Regulations*.

Approvals may be revoked at the discretion of the Superintendent of Public Health.

### **4.3 General Details related to the Application Form**

#### **4.3.1 Filling in the Registration Form**

**All sections must be completed** by the applicant.

The MT-MDF07 Application Form is divided as follows:

- Section A: Application Introduction
- Section B: Request for Premises to be Approved
- Section C: Premises Details
- Section D: Responsible Healthcare Professional Details
- Section E: Declaration Forms
- Section F: Details of Payment
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission
- Designated Premises Declaration Form
- Terms and Conditions

#### **4.3.2 Section A: Application Introduction**

The applicant must document the application date and provide their name, surname, e-mail address, contact number and ID number.

#### **4.3.3 Section B: Application Type**

Applicants must tick mark as applicable to clearly indicate the type of application that will be submitted to the MMA.

- **Initial request**

Initial requests indicate that the premises listed in the MT-MDF07 Application Form have never been registered as designated premises for Point-of-Care Covid-19 testing.

- **Revision of submitted details for approved application**

Applicants choosing this option will have received an Approval Certificate by the MMA. It is the responsibility of the applicant to update the MMA of any changes in the registration details. MMA must also be notified of any registered designated premises that will no longer be utilised for Point-of-Care Covid-19 Testing. Applicants choosing this option must submit a full MT-MDF07 Application Form to notify the MMA of any changes / withdrawals to the registered details.

#### **4.3.4 Section C: Premises details**

This section of the MT-MDF07 Application Form is used to record the name and a description of the proposed Point-of-Care Covid-19 Test designated premises.

Applicants must include detailed plans of the premises layout and proposed testing set up, highlighting the flow of patients in and out of the premises.

Applicants requesting registration for multiple premises need to submit an individual application per proposal.

#### **4.3.5 Section D: Responsible Healthcare Professional**

This section of the form is used to record the responsible HCP assigned for the Premises.

#### **4.3.6 Section E: Declaration Forms**

Applicants must indicate the signed Declarations Forms being included with the Application submission.

#### **4.3.7 Section F: Details of Payment**

Reference should be made to the *GL-MDF07 Guidance on fees in relation to Medical Devices* available on the MMA website:

<https://medicinesauthority.gov.mt/medicaldevices>

The proof of payment documentation must be attached with the application submission.

#### **4.3.8 Data Protection Consent Statement**

Applicant and responsible HCP must confirm consent, by ticking the box in this section, to the processing of personal data by the MMA and an understanding that this data shall be processed in accordance with the General Data Protection Regulation (GDPR).

#### **4.3.9 Malta Medicines Authority Declaration for Form Submission**

Applicant (owner/manager) must sign the Malta Medicines Authority Declaration Form to confirm that all the information submitted within the Application Form is correct and complete.

#### **4.3.10 Designated Premises Declaration Form**

Applicant (owner/manager) and the responsible HCP must mark off all the criteria listed in the Declaration Form and sign off the document to confirm an understanding and adherence to the local legislative requirements, Ministry of Health guidelines in relation to Point-of-Care Covid-19 testing process and premises, and general safety and performance requirements.

#### **4.3.11 Terms and Conditions**

Terms and conditions applicable for approved applications.

#### 4.3.12 Documents Required

The documents to be submitted with this Application Form are:

- Proof of payment (softcopy)

**Any additional documents relevant to the proposed premises must be made available to the MMA upon request.**

**For an application to be considered for review, all sections must be filled in completely and accurately as per this guidance document. Sections not applicable to your organisation must be filled in with N/A.**

## 5. References

Subsidiary Legislation 458.61 - *Testing of COVID-19 Regulations*:

<https://medicinesauthority.gov.mt/medicaldevices>

Health Care Professions Act (CAP. 464):

<https://legislation.mt/eli/cap/464/eng>

Ministry for Health: Standards on the use of Point-of-Care Rapid Antigen Tests for SARS-CoV-2: <https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Pages/rapid-antigen-testing.aspx>

Malta Medicines Authority: Medical Devices Forms and Guidance Documents:

<https://medicinesauthority.gov.mt/medicaldevices>

*Approvals on file*

List of Appendices

N/A