



MALTA

**MEDICINES
AUTHORITY**

**Guidance for MT-MDF10 Application Form
for Notification of Point-of-Care Covid-19 Test or
Device for Self-Testing for Covid-19
to be placed on the Local Market**

Ref No: GL-MDF10/02

November 2022

Medical Devices, Pharmaceutical Collaboration Directorate

Page 1

1. Introduction

Applicants interested in placing a Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 on the local market, need to submit an Application Form (MT-MDF10 Application for Notification of Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the Local Market) to the Malta Medicines Authority (MMA), in accordance with Subsidiary Legislation 458.61.

2. Scope

The purpose of this Guidance Document is to provide comprehensive instructions to applicants submitting an application to the MMA for placing Point-of-Care Covid-19 Tests or Devices for Self-Testing for Covid-19 on the local market, in accordance with Subsidiary Legislation 458.61.

3. Terms, Definitions and Abbreviations

Abbreviations

DoC:	Declaration of Conformity
EU:	European Union
IVD:	In-Vitro Diagnostic Medical Device
IFU:	Instructions for Use
L.N.:	Legal Notice
MD:	Medical Device
MMA:	Malta Medicines Authority

Definitions

Applicant

Person acting on behalf of a Distributor/Importer who wishes to place Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 on the market in Malta.

Authorised Representative

An authorised representative means any natural or legal person established within the European Union (EU) who has received and accepted a written mandate from a manufacturer located outside the EU, to act on the manufacturer's behalf in relation to specified tasks with regards to the latter's obligations under the applicable IVD Regulations/Directives.

Declaration of Conformity (DoC)

An EU Declaration of Conformity is a mandatory written declaration that manufacturers or their authorised representative need to sign to declare their products' compliance with EU legislative requirements.

Device Labelling

The written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

Distributor

Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

Importer

Any natural or legal person established within the Union that places a device from a third country on the Union market. The importer shall place on the Union market only devices that are in conformity with Article 13 of the Regulations (EU) 2017/745 & (EU) 2017/746.

Instructions for Use (IFU)

The information provided by the manufacturer to inform the user of a device's intended purpose and proper use, and of any precautions to be taken.

In vitro diagnostic medical device (IVD)

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Manufacturer

A natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by those persons themselves or on their behalf by a third party.

MT-MDF10 Application Form for Notification of Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the Local Market (MT-MDF10 Application Form)

Applicants are required to submit this MT-MDF10 Application Form and supporting documentation to the MMA for review of the proposed Test Kits.

Point-of-Care Covid-19 Test

MT-MDF10 application form is applicable for any point-of-care 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.

Device for Self-Testing for Covid-19

A testing device for the identification of the presence of Covid-19 which is intended by the manufacturer to be used by persons, not acting within the capacity of health care professionals or health care workers. MT-MDF10 application form is not applicable for self-test devices identifying the presence of antibodies. A kit intended for 'professional use only' must not be sold as a self-test.

4. Specific Guidance

4.1 Applicant submissions

The MT-MDF10 Application Form may be submitted solely by local Distributors and Importers in relation to distribution of Point-of-Care Covid-19 Test/s or Device/s for Self-Testing for Covid-19 in Malta. Applicants may be first time applicants or previous applicants who wish to amend the details issued on the Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 Notification Letter.

4.2 General Details related to the Application Process

4.2.1 Application Form

The Application Form related to this guidance document is *MT-MDF10 Application Form for Notification of Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the local market*, which may be accessed from the MMA website:

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

4.2.2 Application Format

MT-MDF10 Application Form is in a fillable pdf format. Form should be filled in electronically using the shaded areas/tick marks. Handwritten Application Forms may not be accepted if writing is not legible.

Application Form 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. All 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-MDF10 Application Form with supporting documentation should be forwarded electronically to the MMA to:

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 process timeframe of up to **10 calendar days commences for Fast Track Applications**

Processing timeframe applies from receipt of the MT-MDF10 Application Form at the MMA. Should the MMA require any further information or clarification, this will be communicated to the applicant. 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 for Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 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 a Notification Letter via email, indicating that the Device has been reviewed by the MMA and may be placed on the local market.

It is the responsibility of the applicant to update the MMA of any changes in the Application / Product Details.

4.2.8 Approval Validity

The validity of the Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 Notification Letter 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 Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 Distributor/Importer premises and/or request additional information from Distributor/Importers as deemed necessary.

4.3 General Details related to the Application Form

4.3.1 Filling in the Registration Form

All sections must be completed by all applicants.

The Registration Form is divided as follows:

- Section A: Application Introduction
- Section B: Application Type
- Section C: Organisation Details
- Section D: Point-Of-Care Covid-19 Test or Device for Self-Testing for Covid-19
- Section E: Mandatory Documents
- Section F: Details of Payment
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission
- Declaration Form for Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the local market
- Annex 1: Terms and Conditions

4.3.2 Section A: Application Introduction

The individual completing the application must document the application date and provide their name, surname, email address and contact 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.

- **First Application**
- **Revision of submitted details for notified Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 applications**

Applicants choosing this option will have received a prior Notification letter by the MMA. It is the responsibility of the Applicant to update the MMA of any changes in the Organisation details, Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 details or intention to withdraw the notified Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 from the market. Applicants choosing this option must submit a full Application to notify the MMA of any changes / withdrawals.

4.3.4 Section C: Organisation Details

Applicants must be Malta based operators (Distributors/Importers) and must provide the organisation name, address, Malta Business Registry Number and company contact details.

Applicants should include the name and official title of a contact within the organisation (generally the Manager and/or Owner of the organisation).

Organisations operating in Malta that are not registered with the Malta Business Registry should contact the MMA prior to submitting the Application.

4.3.5 Section D: Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 Details

This section of the form is used to record the proposed Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 details.

Applicants must tick:

- the relevant test type
- if the testing device is: a self-test, for professional use only or both.

Applicants must submit the full product details, including the:

- Product Name (name must reflect the product that will be placed on the market)
- Manufacturer Name & Address
- Authorised Representative Name & Address (where applicable)
- Supplier Name & Address - from where Applicant (Organisation) acquired the Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19

The MMA may request sample/s of the Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19.

4.3.6 Section E: Mandatory Documents

Applicants must tick-mark to indicate supporting documentation being submitted as part of the Application Form. All documents are required:

- Declaration of Conformity (DoC)
- Instructions for Use (IFU)
- Device labelling (mock-up or images of full product labelling)
- For Device for Self-Testing for Covid-19: Two (2) independent evaluations
- For Device for Self-Testing for Covid-19: Proof of the self-test being authorised by other EU Member States
- Proof of payment (softcopy)

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 must confirm consent, by ticking the box in this section, to the processing of personal data by the MMA and understands 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 must sign the Malta Medicines Authority Declaration to confirm that all the information submitted within the MT-MDF10 Application Form is correct and complete.

4.3.10 Declaration Form for Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the local market

Applicant must tick mark all the criteria listed in the Declaration Form and sign off the document to confirm an understanding and adherence to the local legislative requirements, Standards issued by the Superintendent of Public Health regarding Covid-19 testing, and requirements in relation to Distribution and Importation of In-Vitro Medical Devices.

4.3.11 Annex1: Terms & Conditions

Terms and conditions applicable for approved notifications.

Any additional documents relevant to the Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 application 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, Legal Notice 357 of 2021, as amended by Legal Notice 118 of 2022

<https://legislation.mt/eli/sl/458.61/eng>

Ministry for Health latest 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>

Standards for the importation, sale and use of devices for self-testing for Covid-19 by the public:

<https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Documents/Standards%20for%20the%20importation,%20sale%20and%20use%20of%20devices%20for%20self-testing%20for%20Covid-19%20by%20the%20publicv1.pdf>

EU legislations- Medical Devices and In-Vitro Diagnostic Medical Devices

https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

Malta Medicines Authority: Medical Devices Forms and Guidance Documents:

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

Approvals on file

List of Appendices

N/A