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-MDF10/03
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Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate

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
Any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the Regulations.
[Regulation (EU) 2017/745 Article 2(32) & (EU) 2017/746 Article 2(25)]

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.
[Regulation (EU) 2017/745 Article 19 & (EU) 2017/746 Article 17]

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.
[Regulation (EU) 2017/745 Article 2(13) & (EU) 2017/746 Article 2(13)]

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.
[Regulation (EU) 2017/745 Article 2(34) & (EU) 2017/746 Article 2(27)]

Health Care Professional
A person who is authorised in accordance with the provisions of the Health Care Professions Act as a medical practitioner, dental surgeon, midwife, nurse, pharmacy technician or pharmacist.
[Health Care Professions Act Cap. 464]

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.
[Regulation (EU) 2017/745 Article 2(33) & (EU) 2017/746 Article 2(27)]

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.
[Regulation (EU) 2017/745 Article 2(14) & (EU) 2017/746 Article 2(14)]

In vitro diagnostic medical device (IVD)
Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software 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 on one or more of the following:

a) concerning a physiological or pathological process or state;
b) concerning congenital physical or mental impairments;
c) concerning the predisposition to a medical condition or a disease;
d) to determine the safety and compatibility with potential recipients;
e) to predict treatment response or reactions;
f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices.
[Regulation (EU) 2017/746 Article 2(2)]

Manufacturer
A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.
[Regulation (EU) 2017/745 Article 2(30) & (EU) 2017/746 Article 2(23)]

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
The application is in a fillable pdf format which must be filled in electronically using theshaded areas.

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 working days commences for Standard Applications**
- a process timeframe of up to **10 working 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 the Distributor/ Importer premises for Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 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.

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 document 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

Standards for the importation, sale and use of devices for self-testing for Covid-19 by the public:
https://hpdp.gov.mt/idcu/covid_19/mandatory_standards

https://hpdp.gov.mt/sites/default/files/2022-12/Standards%20for%20the%20use%20of%20self%20testing_010522_0.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

Signatures on File

List of Appendices

N/A