MALTA MEDICINES AUTHORITY

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

Medical Device Approval Form Reference No.

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

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

Refer to the *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.*

Guidance and Application Form are available on the Malta Medicines Authority website www.medicinesauthority.gov.mt.

June 2023

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www.medicinesauthority.gov.mt

SECTION A: APPLICATION INTRODUCTION

Date of Application:

Applicant Details

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

SECTION B: APPLICATION TYPE

☐ **First application**

☐ **Revision of submitted details for notified *MT-MDF10 Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19***

- ☐ Amend Organisation details
- ☐ Amend **Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19** details
- ☐ Withdraw notified **Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19**

Notification Reference:

SECTION C: ORGANISATION DETAILS

Organisation Name:
Contact Name:
Address:
Malta Business Registry Number:
E-mail Address:
Contact Number/s:

SECTION D: POINT-OF-CARE COVID-19 TEST OR DEVICE FOR SELF-TESTING FOR COVID-19

D.1 Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19- Type
☐ Nucleic Acid Amplification Test (NAAT)
☐ COVID Rapid Antigen Test (RAT)
Indicate if:
☐ Self-Test
☐ Professional Use only
☐ Both

D.2 Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 - Details
Product Name:
Manufacturer Name: **Manufacturer Address:**
Authorised Representative Name (if applicable): **Authorised Representative Address:**
Supplier from where Applicant (Organisation) acquired the Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 **Supplier Name:** **Supplier Address:**
Sample/s may be requested at the request of the Malta Medicines Authority.

SECTION E: MANDATORY

Supporting documentation in attachment:

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

SECTION F: DETAILS OF PAYMENT

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

Data Protection Consent Statement

- ☐ *The applicant hereby consents to the processing of their personal data by the Malta Medicines Authority and understands 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, the Data Protection Act (Chapter 586 of the Laws of Malta) and the Malta Medicines Authority Data Protection Policy (P-MA05). The applicant also understands 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:

Name & Surname:

Position:

Signature:

Date:

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

All criteria must be read, understood and marked accordingly

The Applicant declares that they adhere to the following:

- ☐ Subsidiary Legislation 458.61 - Testing of COVID-19 Regulations
- ☐ Standards issued by the Superintendent of Public Health regarding Covid-19 testing
- ☐ Information supplied with the Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 reaching the end user, including the product labelling and Instructions for Use leaflet, are in the Maltese or English language, in line with the local legislative requirements.

- ☐ Importers / Distributors placing these *in-vitro* diagnostic medical devices on the local market are operating in line with the applicable EU and Maltese legislative requirements:
  http://www.medicinesauthority.gov.mt/mdlegislation

Applicant (on behalf of the Organisation)

Organisation Name:

Name & Surname:

Signature:

Date:

Annex 1: Terms and Conditions

- Applicants will receive a **Letter of Notification for Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19** approved by the Malta Medicines Authority.

- No Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 may be distributed before receipt of the Notification Letter.

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

- The Notification Letter 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.

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