Guidance for Application Forms MT-MDF12 and MT-MDF13 for a Derogation from the Conformity Assessment Procedures of Medical Devices

1. Introduction

The Malta Medicines Authority (MMA) application form for Derogation from the Conformity Assessment Procedures of Medical Devices addresses distinct circumstances that require unique derogations within the regulatory framework. MDR Article 59 and Article 97 and IVDR Article 54 and Article 92 enable the national competent authority to grant local or Union wide market access for medical devices while the devices are not yet fully compliant with the relevant EU Regulations especially in cases where a scarcity of suitable alternatives is present within the market.

Any further clarification on this guidance document may be obtained from MMA, by sending an email to *mdforms.medicinesauthority@gov.mt*.

2. Scope

The purpose of this guidance document is to provide comprehensive instructions to the user on how to apply for a MDR Article 59/ Article 97 or IVDR Article 54/ Article 92 Derogation from the Conformity Assessment Procedures of Medical Devices. This guidance is intended to offer a robust approach towards the proficiency and control of how the user must accurately complete and submit the application form.

3. Terms, Definitions and Abbreviations

Abbreviations

DoC	Declaration of Conformity
GDPR	General Data Protection Regulation
IFU	Instructions for Use
ISO	International Organization for Standardization
IVD	In vitro diagnostic medical device
IVDR	In Vitro Diagnostic Regulation (EU) 2017/746
MDR	Medical Device Regulation (EU) 2017/745
MMA	Malta Medicines Authority
PMS	Post Market Surveillance
QMS	Quality Management System

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 & (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.

[Regulation (EU) 2017/745& (EU) 2017/746]

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]

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 & (EU) 2017/746]

Medical Device

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

[Regulation (EU) 2017/745]

4. Specific Guidance

4.1 Applicants applying through the Derogation from the Conformity Assessment Procedures of Medical Devices Form MT-MDF12 or MT-MDF13

The application form for Derogation from the Conformity Assessment Procedures of Medical Devices, may be submitted by a manufacturer or an authorised representative as applicable.

4.2 General Details related to Applying

Application Form Title

The application forms related to this guidance document are *MT-MDF12 - Application Form for MDR Article 59 and IVDR Article 54 for a Derogation from the Conformity Assessment Procedures of Medical Devices*, or *MT-MDF13- Application Form for MDR Article 97 and IVDR Article 92 for a Derogation from the Conformity Assessment Procedures of Medical Devices*, which may be accessed from the MMA website https://medicinesauthority.gov.mt/medicaldevices.

Application Format

The application is in a fillable pdf format which must be filled in electronically using the grey-shaded areas. Handwritten application forms will not be accepted.

Acknowledgement

Once the application form has been successfully received and reviewed, an acknowledgment will be sent to the applicant's electronic address.

Official Languages

The official languages in Malta are Maltese and English. The application form and all supporting documentation must be completed in either Maltese or English.

4.3 Filling in the Application Form

All sections must be completed.

The Registration Form is divided as follows:

- Section A: Application Details
- Section B: Manufacturer Details
- Section C: Authorised Representative Details
- Section D: Information About the Product
- Section E: Mandatory Documents
- Section F: Details of Payment
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

Section A: Application Introduction

This section is divided into three parts:

A.1: Type of Application

The applicant should indicate the regulation and article number being applied for and whether it is a first application or an extension**.**

A.2: Date of Application and Applicant details

The individual completing the application shall provide the following information: Date of the application, applicant's name, surname, email address and contact number.

A3: Applicant Organisation Status

The applicant shall indicate whether the organisation functions as a manufacturer, in which case Section B should be completed, or as an authorized representative, in which case both Sections B and C need to be filled in.

Section B & C

The applicant's organisation name and the organisation registration number must be inputted in the fields provided in Section B&C. The organisation registration number is given to organisations that have already registered with the MMA. For further information on organisation registration kindly refer to guidance document *GL-MDF02 'Guidance for Application for Organisation Registration in relation to Medical Devices'* and application *MT-MDF02 'Application Form for Organisation Registration in relation to Medical Devices'* which may be accessed from the MMA website https://medicinesauthority.gov.mt/medicaldevices.

Section B: Manufacturer Details

The manufacturer contact details shall correspond with the details on the Declaration of Conformity (DoC) of the medical device being notified. It is the responsibility of the manufacturer to update the MMA of any changes in these contact details.

Section C: Authorised Representative Contact Details

This section must be completed in the event that the manufacturer is not located in an EU Member State. In such a case, both contact details of the authorised representative, and the manufacturer they represent need to be filled in. It is the responsibility of the authorised representative to update the MMA of any changes in these contact details.

Section D: Information About the Product

The applicant is required to provide specific information including the Name of device(s) for which the derogation is being requested as per DOC, the Catalogue Number of the device (s), its/their Intended Purpose, the requested derogation period, and the underlying reason for seeking the derogation.

In addition, the applicant is requested to indicate whether the medical device(s) in question is/are of vital importance with regard to public health and patient safety or health. The reasons for this determination should be specified. Furthermore, it is important to address whether there is an existing lack of suitable substitutes on the market.

Finally, the applicant must specify whether there are any indications in the technical dossier, or data from vigilance or market surveillance activities, concerning devices of previous generations or with similar characteristics, that the device(s) applied for may be harmful for patient health or safety or public health. If such a scenario applies, the indications should be specified.

Section E: Mandatory Documents

The following Supporting documentations must be in attachment:

- Declaration of Conformity (DoC)
- Instructions for Use (IFU)
- Labelling of Device (mock-up or images of full product labelling required)
- CE Certificate
- Confirmation letter by notified body that application for MDR/IVDR certification has been accepted and contract with manufacturer signed, including expected timeline of conformity assessment procedure.
- Document(s) containing vigilance or market surveillance data to prove that the device(s) can be used in a safe and appropriate way for the patient and other person(s) involved. The documentation should also contain information that supports a positive benefit/risk balance.

- Short description from which date and for which reason the device is not or will not be in compliance with MDR/IVDR
- List of changes from the date of application of the MDR/IVDR and the manufacturer's assessment of changes and their potential significance
- MDR/ IVDR QMS certificate or confirmation by manufacturer that the QMS is in accordance with article 10(9) of the MDR or article 10(8) of the IVDR with supporting documents including a valid ISO13485 certificate.
- Confirmation by manufacturer for continuous application of MDR/IVDR requirements in relation to PMS, vigilance and market surveillance including commitment by manufacturer to proactively inform the Competent Authority about any safety related corrective or preventive actions.

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 relevant proof of payment document must be attached.

Service

Upon submission of all the relevant documentation, a standard processing timeframe of 90 working days commences.

In case an extension of the derogation is required, the applicant needs to reapply 3 months prior to the end of the approval of the derogation period.

Should the MMA require any further information or clarification, this will be communicated to the applicant. A stop-clock will be initiated, and the clock will be 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.

Proof of Payment

This document will be verified by the Finance & Corporate Services Unit at the MMA, confirming receipt of funds.

Data Protection Consent Statement

Applicant shall 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).

Malta Medicines Authority Declaration for Form Submission

Applicant shall sign the MMA declaration that all the information submitted within this request form is correct and complete.

4.4 Documents Required

The documents to be submitted with this application form are:

- Proof of payment (softcopy)
- Mandatory Documents listed in Section E

Any additional documents relevant to the function of the organisation/medical device must be made available to the MMA, upon request.

For an application to be considered, 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

GL-MDF07 Guidance on fees in relation to Medical Devices

GL-MDF02 'Guidance for Application for Organisation Registration in relation to Medical Devices'

MT-MDF02 'Application Form for Organisation Registration in relation to Medical Devices'

Cap 458 Act no VII of 2020, An Act to amend the Medicines Act
https://legislation.mt/eli/act/2020/7/eng

S.L. 458.59 Medical Devices and In-Vitro Diagnostic Medical Devices Provision On The Maltese Market Regulations
https://legislation.mt/eli/sl/458.59/eng

Subsidiary Legislation 458.61 - *Testing of COVID-19 Regulations*
https://legislation.mt/eli/sl/458.61/eng

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

Signatures on file

List of Appendices
N/A