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

Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate

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 Article 2(32) & (EU) 2017/746 Article 2(25)]

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)]

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) of the Medical Device Regulation and of those referred to in the first paragraph of this point.

[Regulation (EU) 2017/745 Article 2(1)]

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.

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: List of Mandatory Documents
- Section F: Details of Payment
- Section G: Commitments
- Data Protection Consent Statement
- Malta Medicines Authority Declaration for Form Submission

Section A: Application Introduction

This section is divided into four 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.

A.3 Information concerning the submitted application

The applicant should indicate whether similar applications have been submitted in other EU/EEA countries and if so, the countries should be specified. All decisions made by the selected competent authority should be provided.

A4: 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.

Sections B &C

The applicant's organisation name and the organisation registration number must be inputted in the fields provided in Sections B and C as indicated in Section A4. 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/EEA 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.

The applicant is requested to indicate and provide relevant information on whether the device is authorised in another jurisdiction (e.g. FDA or other regulatory bodies). The applicant is also requested to indicate whether any procedures with another notified body have been initiated, in case the identification number of the notified body should be provided. A justification should be given if the applicant has no intention to certify the device. The applicant should indicate whether the device is exempt from the involvement of notified body.

In addition, the applicant is requested to indicate whether the medical device(s) in question is/are of vital importance regarding the health or safety of patients, users or other persons or to other aspects of the protection of public 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. If applicable, the applicant should indicate what suitable alternatives are available 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

health or safety of patients, users or other persons, or to other aspects of the protection of public health. If such a scenario applies, the indications should be specified.

Section E: Mandatory Documents

The following Supporting documentations must be in attachment:

- List of the device (s) concerned, including the following details: trade name, reference, UDI, risk class, and certificate number (if applicable)
- Description of the devices concerned
- Intended use(s) of the device(s)
- Decisions already made by other EU/EEA Member States regarding derogation requests for the devices concerned
- Marketing authorisations obtained in other jurisdictions (e.g., USA, Japan, Australia, United Kingdom) if applicable.
- Intention to stock pile the device before the certificate expires and for how long these stocks will be available
- Declaration of Conformity (DoC)-latest version
- EC Certificate-latest version
- Instructions for Use (IFU)
- Labelling of Device (*mock-up or images of full product labelling required)*
- Confirmation letter by notified body that application for MDR/IVDR certification has been accepted and contract with manufacturer (in accordance with MDR Annex VII 4.3) is signed, including expected timeline of conformity assessment procedure
- For Authorised Representatives: Copy of letter of designation issued by the manufacturer
- The latest surveillance audit report including the date, any potential safety-related shortcomings as identified by the notified body during the audit and a confirmation by the notified body on a satisfactory resolution
- Commitment by the notified body to inform the CA about major safety-related shortcomings identified during the conformity assessment procedure
- For notified bodies that have ceased certification, provide an official document from the notified body specifying the reasons for the cessation
- Report(s) containing vigilance or post-market surveillance data including incidents, serious incidents and field safety corrective actions 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 ratio for the concerned device/s
- List of changes implemented from date of application of the MDR/ IVDR and the manufacturer's assessment of these changes including their potential significance
- MDR/IVDR QMS certificate or Confirmation by Manufacturer that QMS is in accordance with article 10(9) of the MDR or article 10(8) of the IVDR. (A valid ISO 13485 certificate is accepted as proof of compliance)
- Confirmation by manufacturer for continuous application of MDR/IVDR requirements in relation to post market surveillance, vigilance and market surveillance including

commitment by manufacturer to proactively inform the Competent Authority about any safety related corrective or preventive actions

- Proof of need for the exemption:

  For IVDs: evidence demonstrating the interest in health protection;

  For MDs: evidence showing that the use is in the interest of public health, patient health, or patient safety
- Step-by-step roadmap for acquiring the new certificate or restoring the suspended certificate (if applicable)

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.

Section G: Commitments

The applicant shall recognise and confirm that:

1. The concerned device(s) comply with the essential requirements as per Regulation (EU) 2017/745 or Regulation (EU) 2017/746.
2. The benefit risk balance is positive as confirmed through the clinical evaluation report and vigilance data.
3. The requirements of post market surveillance, vigilance and market surveillance as per Regulation (EU) 2017/745 or Regulation (EU) 2017/746 will be applied. The post-market surveillance of the device(s) will be maintained and include proactive actions

to monitor the performance of the device(s) and to notify all incidents to the (Malta) Medicines Authority in line with the regulations.

4. The (Malta) Medicines Authority reserves the right to modify the conditions of the derogation or to revoke it entirely based on the information received.
5. If a derogation is granted, the (Malta) Medicines Authority must be regularly updated on the progress towards obtaining the new certificate. Upon request, audit reports and any related CAPA (Corrective and Preventive Action) plans must be submitted.
6. The (Malta) Medicines Authority must be promptly informed once the necessary certificate(s) are obtained, or when a suspended certificate is reestablished. The manufacturer must promptly cease marketing device(s) under the derogation as soon as the certification is reinstated. Any delays in the certification process must be communicated to the (Malta) Medicines Authority without delay.
7. To provide evidence to the (Malta) Medicines Authority that the healthcare facility, end user or other relevant parties are informed that the concerned devices are being supplied under the framework of a derogation.
8. The manufacturer or authorised representative must share all relevant information with the (Malta) Medicines Authority, ensuring that nothing that could pose a risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health is intentionally withheld.
9. The (Malta) Medicines Authority must be notified of any other relevant information pertaining to this derogation.

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:

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

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

For an application to be considered, all sections must be filled in completely and accurately in accordance with 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

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

MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC.

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec19

MDCG 2022-11 MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR and IVDR requirements

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec19

MDCG 2022-18 MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

https://health.ec.europa.eu/document/download/ccfb20a8-82d4-4216-8d11-4ce127be431e_en?filename=mdcg_2022-18_en_1.pdf

MDCG 2022-18 ADD.1. MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate - Addendum 1

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

MDCG 2022-8 Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec19

Signatures on File