Guidance for Request Form for the Use of a Non-CE Marked Medical Device in Malta on a Named-Patient Basis

1. Introduction

All medical devices considered to be in conformity with the requirements of European Union (EU) medical devices legislation shall bear the CE marking of conformity. The CE marking shall be affixed visibly, legibly and indelibly to the device or its packaging. It is an obligation for all distributors to verify that before making any medical device available on the EU market, the device has been CE marked and that the EU declaration of conformity (DoC) of the device has been drawn up.

In exceptional cases, a product may be marketed outside the EU, a CE mark is not yet available and the potential benefits in using this medical device outweigh the potential risks to the patient in using it. In such circumstances, an authorised healthcare practitioner may apply for a specific non-CE marked device to be procured, for a specified intended use, on a named-patient basis. The medical device may not be legally marketed in Malta and in the European Union.

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

2. Scope

The purpose of this guidance document is to outline the requirements for a healthcare practitioner applying for the use of a non-CE marked medical device in Malta on a named-patient basis to the Malta Medicines Authority. Refer to applicable local legislation.

3. Terms, Definitions and Abbreviations

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.

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.

Medical Device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,

- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

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

Note: The term 'medical device' in this guidance document also refers to in-vitro diagnostics.

EU: European Union

4. Specific Guidance

4.1 Applicants for the use of a non-CE marked medical device in Malta on a named-patient basis

The application form for the use of a non-CE marked medical device in Malta on a named-patient basis may be requested by an authorised healthcare practitioner registered with the Medical Council Malta.

4.2 Authorisation for use of a non-CE marked medical device

The Malta Medicines Authority will issue a special authorisation for the procurement of a specific non-CE marked medical device, with its relevant accessories and disposables, on a named-patient basis upon the specific request of a healthcare practitioner.

4.3 General Details related to Applying

4.3.1 Request form title

The request form related to this guidance document is *MT-MDF04 – Request Form for the Use of a Non-CE Marked Medical Device in Malta on a Named-Patient Basis,* which may be accessed from the Malta Medicines Authority website https://medicinesauthority.gov.mt/ under the section for medical devices.

4.3.2 E-Form

The request is an e-form which must be filled in electronically using the available grey-shaded areas. Handwritten forms will not be accepted. A signed scanned copy of the completed e-form and supporting documentation must be uploaded.

4.3.3 Delivery Address

The official authorisation for use of a non-CE marked medical device shall be sent in electronic format to the applicant on the address provided in the request form.

4.3.4 Official Languages

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

4.4 Filling in the Request Form

All sections of the request form must be completed by the healthcare practitioner. The request form is divided as follows:

- Section A – Application Introduction
- Section B – Details of applicant Healthcare Practitioner
- Section C – Patient details
- Section D – Hospital/Clinic Details
- Section E – Medical Device Details
- Section F – Clinical Benefit-Risk Assessment
- Section G – Manufacturer & Importer Details
- Data Protection Consent Statement
- Medical Specialist Declaration Form
- Malta Medicines Authority Declaration for Form Submission

4.4.1 Section A: Application Introduction

The date of application will be completed automatically. The individual completing the application shall provide their name, surname, email address and contact number.

4.4.2 Section B: Details of Applicant Healthcare Practitioner

Personal and contact details of the applicant healthcare practitioner shall be inputted in this section, together with the Medical Council registration number. Should the applicant not have a registration number, the appropriate section must be completed with N/A.

4.4.3 Section C: Patient Details

Personal details of the patient and their condition shall be inputted in this section. The patient must give their consent to the use of the non-CE marked device by signing the relevant disclaimer.

4.4.4 Section D: Hospital/Clinic Details

Details of the health institution where the patient is receiving treatment shall be inputted in this section.

4.4.5 Section E: Medical Device Details

Details of the non-CE marked medical device to be procured, its intended use and the advantages of using this device over similar CE marked devices shall be inputted in this section. Documents verifying the performance of this device shall be provided.

4.4.6 Section F: Clinical Benefit-Risk Assessment

Details of how the potential benefits, in using this medical device for the declared intended use, outweigh the potential risks to the patient shall be described, including the consequences to be expected to the patient's condition if the requested device is not authorised.

4.4.7 Section G: Manufacturer and Importer Details

Names and contact details of the manufacturer and local importer shall be inputted in this section.

4.4.8 Data Protection Consent Statement

Applicant shall confirm consent, by ticking the box in this section, to the processing of personal data by the Malta Medicines Authority and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR).

4.4.9 Medical Specialist Declaration Form

Applicant shall sign the Medical Specialist Declaration Form stating that full responsibility for use of the non-CE marked medical device is being taken.

4.4.10 Malta Medicines Authority Declaration for Form Submission

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

4.5 Documents required

The documents to be submitted with this request form are:

- Documents verifying the performance of the non-CE marked device (softcopy)

Any additional documents relevant to the function of the medical device must be made available to the Malta Medicines Authority, upon request.

For an application to be considered, all sections must be filled in completely and accurately as per this guidance document.

5. References

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

Legal Notice 321 Medical Devices and In-Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations, 2020
https://legislation.mt/eli/ln/2020/321/eng

EU legislations- Medical Devices and In-Vitro Diagnostic Medical Devices
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=ET

Signatures on files

List of Appendices

N/A