Guidance on fees in relation to Medical Devices

1. Introduction

The competent authority for medical devices is Malta Medicines Authority (MMA).
This guidance document is intended to assist applicants in identifying the correct fees to accompany applications/activities related to medical devices. Proof of payment is to be uploaded, as per guidance document of the respective activity.

2. Scope

The purpose of this guidance document is to outline the initial and/or renewal fees related to:

- distributors/importers of medical devices and/or in-vitro medical devices (covering also vigilance activities);
- manufacturers of medical devices and/or in-vitro medical devices;
- designation and extension of scope of a notified body;
- authorised representatives;
- audits and inspections of activities by the economic operators;
- applying for Certificates of Free Sale;
- applying for device registration, placing a medical device on the European Market through Malta;
- applying for derogations
- clinical investigations and performance studies
- applying for designated premises to be approved for the performing of Point-of-Care Covid-19 Tests
- applying for notification of Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the Local Market
- applying for the use of a Non-CE marked medical device in Malta
- search function of medical devices database;
- requests for scientific advice.

3. Terms, Definitions and Abbreviations

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]

Clinical Investigation

Any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.
[Regulation (EU) 2017/745]

Conformity Assessment Body

A body that performs third-party conformity assessment activities including calibration, testing, certification and inspection.

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

Designated premises

Any premises designated pursuant to regulations in local Subsidiary Legislation 458.61 of Medicines Act (Cap. 458) - *Testing of COVID-19 Regulations, 2021.*

[Subsidiary Legislation 458.61 – Testing of Covid-19 Regulations]

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 & (EU) 2017/746]

Economic Operator

A manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3) of Regulation (EU) 2017/745.

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

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 & (EU) 2017/746]

In Vitro Diagnostic medical device

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]

National Derogations

Both Directives 90/385/EEC and 93/42/EEC, as well as Regulation (EU) 2017/745, empower national competent authorities, on a duly justified request, to authorise the placing on the market of medical devices for which the relevant conformity assessment procedures have not been carried out, but the use of which is in the interest of public health or patient safety or health ('national derogation').[1]

Notified Body

A conformity assessment body designated in accordance with the Regulations.
[Regulation (EU) 2017/745 & (EU) 2017/746]

[1] European Commission Communication from the Commission: Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745 (2020/C 171/01).

Performance Study
A study undertaken to establish or confirm the analytical or clinical performance of a device. [Regulation (EU) 2017/746]

Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19
Any test that is intended to be used to detect and identify the presence of SARS-CoV-2 or any other marking agent related to it.
[Subsidiary Legislation 458.61 – Testing of Covid-19 Regulations]

Union-wide derogations
Regulation (EU) 2017/745 also empowers the Commission to extend, in exceptional cases, the validity of a national derogation for a limited period of time to the territory of the Union ('Union-wide derogation'). Those Union-wide derogations should be regarded as a measure of last resort, only to be considered in exceptional cases to ensure patient health or safety or to protect public health. The measure enables the Commission and Member States to address potential shortages Union wide of vitally important medical devices in an effective manner. [1]

Abbreviations:

CFS:	Certificates of Free Sale
CI:	Clinical Investigation
DoC:	Declaration of Conformity
FOC:	Free of charge
IVDR:	In Vitro Diagnostic Devices Regulation
L.N.:	Legal Notice
MDR:	Medical Devices Regulation
MDRP:	Medical Device Registered Person
PMCF:	Post-market Clinical Follow-up
PMPF:	Post-market Performance Follow-up
PS:	Performance Study
S.L.:	Subsidiary Legislation

4. Specific Guidance

The below table displays the relevant application forms mentioned throughout this guidance document.

Application Form	Title of Application
MT-MDF01	Application Form for Certificates of Free Sale (CFS) for Medical Devices
MT-MDF02	Application Form for Organisation Registration in relation to Medical Devices
MT-MDF03	Application Form for Medical Device Registration to place Medical Devices on the EU Market
MT-MDF04	Request Form for the Use of a Non-CE Marked Medical Device in Malta
MT-MDF05	Application Form for Notification of Medical Devices Placed on the Local Market
MT-MDF06	Application Form to be submitted when applying for Designation as a Notified Body under the Medical Devices Regulation (MDR) / In Vitro Diagnostic Devices Regulation (IVDR)
MT-MDF07	Application for Designated Premises to be approved for the performing of Point-of-Care Covid-19 Tests
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-MDF11	Application Form for Medical Device Registered Person (MDRP)
MT-MDF12	Application Form for MDR Article 59 and IVDR Article 54 for a Derogation from the Conformity Assessment Procedures of Medical Devices
MT-MDF13	Application Form for MDR Article 97 and IVDR Article 92 for a Derogation from the Conformity Assessment Procedures of Medical Devices
MT-MDF14	Application for Pre-Submission Meeting Request
MT-MDF15	Clinical Investigation – Application / Notification form under the Medical Devices Regulation (EU) 2017/745
MT-MDF16	Performance Study – Application / Notification under the In-Vitro Diagnostic Regulation (EU) 2017/746
MT-MDF19	Request Form for Advice on Making Available Medical Device / In-Vitro Diagnostic Products in Malta
MT-MDF20	Request Form for Medical Device / In-Vitro Diagnostic Confirmation of Risk Classification

4.1 Distributor fees in relation to medical devices and in-vitro diagnostic medical devices

These fees are related to a distributor/importer with reference to making available on the local market medical devices and in-vitro diagnostic medical devices. These fees also include activities covered, including vigilance. Initial and renewal fees are applicable, as indicated in the table below:

Distributor / Importer Fee **(Medical Devices & In-Vitro Diagnostic Medical Devices)**	**€**
MT-MDF02 Initial Registration of Distributor / Importer (renewable annually)	500
MT-MDF05 Notification fee per device (renewable annually)	15
MT-MDF02 Change in Organisation Registration Application details	100
MT-MDF05 Amending Notification of Medical Device (Revise) Withdrawal incurs no charge	100
MT-MDF11 Application Form for Medical Device Registered Person (MDRP) (renewable annually)	100

The fee for initial registration is payable by each distributor of medical devices. Standard and fast-track service options are available. The fast-track service is offered at double the original fee.

The notification fee per device is related to the number of medical devices made available by the distributor. This notification fee for devices is renewable annually.
Where entities recognised in the manufacturer section (including both manufacturers and authorised representatives) also act as distributors of medical devices to the local market, the above fees shall also apply.

MDRP application is submitted by the person registering for the MDRP role. The MDRP status is granted irrespective of the organisation/s that the applicant might represent. Standard and fast-track service options are available. The fast- track service is offered at double the original fee. The registration fee is renewable annually.

4.2 Manufacturer fees in relation to medical devices and in-vitro diagnostic medical devices

The fees related to initial registration and renewal fee for a manufacturer with reference to medical devices and in-vitro diagnostic medical devices are listed in the table below.
The annual renewal fee depends on the number of employees, operating within the organisation, directly or indirectly involved in the design, manufacture, testing, supply, regulatory, governance and application of the quality management system for the devices manufactured. The annual fee is charged to cover the cost of the Authority's market surveillance activities.

Manufacturer Fees **(Medical Devices & In-Vitro Diagnostic Medical Devices)**	**€**
MT-MDF02 Initial Registration of Manufacturer	2,500
MT-MDF02 Annual Fee:	
> 150 employees	25,000
100 – 150 employees	18,000
50 – 99 employees	12,000
16 – 49 employees	5,000
5 – 15 employees	1,250
< 5 employees	250
Change in Organisation Registration Application details	100

Where the manufacturer also acts as a distributor of medical devices to the local market, fees quoted in Section 4.1 shall also apply.

4.3 Authorised Representative fees

The fees related to initial registration and annual renewal fee for an authorised representative are listed in the table below. The renewal fee depends on the number of manufacturers represented by the authorised representative, with a maximum amount of €6,000.

Authorised Representative Fees	**€**
MT-MDF02 Initial Registration of Authorised Representative	500
MT-MDF02 Annual Fee per Manufacturer represented (maximum €6,000)	1,000
MT-MDF02 Change in Organisation Registration Application details	100

Where the authorised representative also acts as a distributor of medical devices to the local market, fees quoted in Section 4.1 shall also apply.

4.4 Notified Body fees

The fees related to initial setup, extension of scope and annual renewal fee for a notified body are listed in the table below. The annual fee covers the local administrative costs, excluding local and international inspections.

Notified Body Fees Procedures	**€**
MT-MDF06 Initial Setup of Notified Body	30,000
MT-MDF-06 Extension of Scope	10,000
MT-MDF-06 Annual Fee (annual inspection included in fee)	20,000

4.5 Audit / Inspection fees

The audit and inspection fees related to market surveillance are listed in the table below. The fee depends on the number of members within the surveillance team and the time frame of the mentioned activity. If the activity is 8 hours, a whole working day, the 'per day' fee is applicable. Otherwise, 'per hour' fee applies.

The MMA, as part of its market surveillance activities, shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. This also includes, amongst others, any further assessments, including confirmation of corrective actions and surveillance assessments. Established principles regarding risk assessment and risk management, vigilance data and complaints will be particularly taken into account. Both announced and, if necessary, unannounced audits/inspections of the premises of economic operators shall be carried out.

The fees below refer to the unannounced or 'for-cause' local reviews, addressing a particular issue or to verify compliance. International surveillance fees will be addressed on a case-by-case basis.

Audit / Inspection Fees	**€**
Per day, per member of the surveillance team	1,500
Per hour, per member of the surveillance team	200

4.6 Certificates of Free Sale for medical devices

A manufacturer or an authorised representative having its registered place of business in Malta, may request, for the purpose of export, a certificate of free sale. This certificate issued by the MMA declares that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE marking in accordance with the legislation may be marketed in the European Union.

The fee for Certificates of Free Sale is per Declaration of Conformity. Standard and fast-track service options are available. The fast-track service is offered at double the original fee.

Certificate of Free Sale	**€**
MT-MDF01 Application for Certificate of Free Sale for medical devices (per DoC)	100

4.7 Device registration, placing a medical device on the European Market through Malta

A manufacturer or authorised representative may request the placing of a medical device onto the European Market, through Malta. An application form must be completed per DoC.

Standard and fast-track service options are available. The fast-track service is offered at double the original fee.

Device Registration on European Market -	**€**
MT-MDF03 Device Registration – placing a medical device on the European market (per DoC)	100
MT-MDF03 Amending Registration of Medical Device (Revise) Withdrawal incurs no charge	100

4.8 Application for Derogation from the Conformity Assessment Procedures of Medical Devices

The Malta Medicines Authority (MMA) may grant an exemption from the conformity assessment procedures set out in the MDR and IVDR. An exemption may be granted after having performed an evaluation in accordance with MDR article 59 or article 97; or IVDR article 54 or article 92. The non-complying device must not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Application for Derogation	**€**
MT-MDF12 Application Form for MDR Article 59 and IVDR Article 54 for a Derogation from the Conformity Assessment Procedures of Medical Devices	1,000
MT-MDF13 Application Form for MDR Article 97 and IVDR Article 92 for a Derogation from the Conformity Assessment Procedures of Medical Devices	1,000

4.9 Application for Clinical Investigations and Performance Studies

All Clinical Investigations and Performance Studies shall be subject to both scientific and ethical reviews. Clinical Investigations and Performance Studies cannot commence without prior authorisations from both the Malta Medicines Authority and the Ethics Committee.

Application / Notification	**€**
MT-MDF14 Application form for Pre-Submission Meeting Request	1,000
MT-MDF15 Clinical Investigation – Application / Notification form under the Medical Devices Regulation (EU) 2017/745	5,000
MT-MDF16 Performance Study – Application / Notification under the In-Vitro Diagnostic Regulation (EU) 2017/746	5,000

4.10 Applications related to Point-of-Care Covid-19 Testing

These include:

i. applying for designated premises to be approved for the performing of Point-of-Care Covid-19 Tests
ii. applying for notification of Point-of-Care Covid-19 Test/s or Device/s for Self-Testing for Covid-19 to be placed on the local market

4.10.1 Designated premises to be approved for the performing of Point-of-Care Covid-19 Tests

The owner/manager of designated premises is to apply for the premises to be approved for the performing of performing of Point-of-Care Covid-19 Tests, by health care professionals.
The certificate issued by the MMA declares that the location has been approved as designated premises for the performing of performing of Point-of-Care Covid-19 Tests, in accordance with the local Subsidiary Legislation 458.61 of Medicines Act (Cap. 458) - Testing of COVID-19 Regulations, 2021. Applicable fees are as per table: Applications related to Point-of-Care Covid-19 Testing. The fast-track service is offered at double the original fee.

Applications related to Point-of-Care Covid-19 Testing Premises	**€**
(MT-MDF07 Designated Premises to be approved for the performing of Point-of-Care Covid-19 Tests (initial request/ annual renewal)	350
MT-MDF07 Amending details in application for designated Premises to be approved for the performing of Point-of-Care Covid-19 Tests (revise premises details within approved premises)	175
MT-MDF07 Amending details in application for designated Premises to be approved for the performing of Point-of-Care Covid-19 Tests (revise details of owner/manager and/or details of responsible health care professional)	50

4.10.2 Notification of Point-of-Care Covid-19 Test/s or Device/s for Self-Testing for Covid-19 to be placed on the local market

The distributor/importer wishing to place a Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 on the local market may send a request to the MMA. Application should be accompanied by the relevant documentation for each test to be notified. Applicable fees are as per table: Applications related to Point-of-Care Covid-19 Testing. The fast-track service is offered at double the original fee.

Notification of Point-of-Care Covid-19 Testing or Device for Self-Test	**€**
MT-MDF10 Notification of Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the local market (initial request/ annual renewal)	200

4.11 Application for the Use of a Non-CE marked medical device in Malta

Public and private healthcare professionals within health institutions requesting to use non-CE Marked medical devices in Malta are to apply through MT-MDF04. Applications should be accompanied by the relevant documentation. Applicable fee is as per table below.

Application for Use of a Non-CE marked medical device in Malta	**€**
MT-MDF04 Use of a Non-CE marked medical device in Malta	500

4.12 Application for request for Advice or Confirmation of Risk Classification

Public and private healthcare professionals or economic operator may require further assistance by applying through MT-MDF19 & MT-MDF20. Applications should be accompanied by the relevant documentation. Applicable fee is as per table below.

Application for request for Advice on Making Available Medical Device / In-Vitro Diagnostic Products in Malta	**€**
MT-MDF19 Request Form for Advice on Making Available Medical Device / In-Vitro Diagnostic Products in Malta	500
MT-MDF20 Request Form for Medical Device / In-Vitro Diagnostic Confirmation of Risk Classification	100

4.13 Customs Documentation and Product Compliance Evaluation

Importers may require further assistance by applying through MT-MDF22. Applications should be accompanied by the relevant documentation. Applicable fee is as per table below.

Application for Customs Documentation and Product Compliance Evaluation	**€**
MT-MDF22 Application for Customs Documentation and Product Compliance Evaluation	250

4.14 Other Activity fees

Other activities offered are:

- search function of medical devices database;
- requests for scientific advice.

Activity	€
Search fee of medical devices database	50
Scientific Advice request	2,300

5 Payment

5.1 Method of Payment

Fees must be paid to the MMA bank account, details of which are:

HSBC Malta plc.
Gżira Branch
Malta

Account No. 039-011176-002
Swift Code MMEBMTMT
IBAN MT78MMEB44392000000039011176002

Whenever a payment is effected in respect of an application/activity, the below details need to be submitted to finance.medicinesauthority@gov.mt and mdforms.medicinesauthority@gov.mt:

- The name of the company effecting payment
- The name of the company on behalf of which the payment is effected (where applicable)
- The amount paid
- Date of payment
- Payment details e.g. type of application / activity, invoice number (where applicable).

5.2 Incorrect Payments

If the fees paid are more than those that are due, the respective account is credited accordingly and applicant duly informed.

If the fees paid are less than those that are due, the applicant is informed to pay the outstanding balance.

Refunds are only given at the discretion of the MMA.

5.3 Annual / Renewal fees

Annual fees can be paid directly into the bank account of the MMA (refer to section 4.7.1). An invoice is issued by the Finance and Corporate Services Unit on a yearly basis, based on the initial date of registration.

5.4 Proof of Payment

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

6. 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

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

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

European Commission Communication from the Commission: Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745 (2020/C 171/01).
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020XC0519%2801%29

Signatures on file

List of Appendices

N/A