Guidance for Good Distribution Practice in relation to Medical Devices

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1. Introduction

The purpose of this document is to provide guidance to economic operators in the practice of importation and distribution of medical devices and in vitro diagnostics for human use. This guidance will assist local operators to comply with obligations listed in the two EU Regulations (hereafter to be referred to as 'the Regulations') (EU) 2017/745 Medical Device Regulation (MDR) for medical devices and (EU) 2017/746 In-Vitro Diagnostics Regulation (IVDR) for in-vitro diagnostic medical devices published in April 2017, and the applicable local legislation, accessible from:https://medicinesauthority.gov.mt/medicaldevices . For the purpose of this document, all devices and accessories shall be referred to collectively as 'medical devices' unless otherwise specified.

The range of medical devices available is vast and they are used by a broad variety of users from the general public in their homes, to the most critically ill patients in specialist clinical settings. The quality and performance of medical devices either directly affects patients' safety and health or the harm could be indirect e.g. in the form of false positive and false negative results. These failures can also endanger other persons besides the patients e.g. if devices fail to detect highly contagious life-threatening diseases. Proper distribution procedures all along the supply chain, from the site of manufacture up to the end user, in line with manufacturers' recommendations, should ensure that the devices are in optimum condition to perform according to their intended use. Deviations occurring at any stage in the supply route may lead to undesirable and in some cases extremely serious consequences.

This is a best practice guidance document with the relevant essential requirements for economic operators making medical devices available on the local market and will essentially constitute good distribution practice (GDP) for medical devices.

2. Definitions

For the purposes of this Guidance, the following definitions from the Regulations apply:

'**accessory for a medical device'** means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

'authorised representative' means 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;

'**benefit-risk determination'** means the analysis of all assessments of benefit and risk of possible relevance for the use of the device

‘**CE marking of conformity**’ or ‘**CE marking’** means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Regulations and other applicable Union harmonisation legislation providing for its affixing;

‘**clinical benefit’** means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;

‘**clinical performance’** means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer;

‘**corrective action’** means action taken to eliminate the cause of a potential or actual non-conformity or other;

‘custom-made device’ means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs;

‘**device deficiency’** means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer;

‘distributor’ means 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;
N.B. the term ‘distributor’ in this Guidance document may also refer to importers (unless specifically mentioned) as well as to manufacturers/authorised representatives who also act as local distributors.

‘economic operator’ means a manufacturer, an authorised representative, an importer or a distributor;

‘Field Safety Corrective Action (FSCA)’ means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

‘**health institution’** means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

‘**importer**’ means any natural or legal person established within the Union that places a device from a third country on the Union market;

‘incident’ means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

'instructions for use' means 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;

'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

'label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

'**making available on the market'** means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

'**manufacturer'** means 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;

'**market surveillance'** means the activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

'medical device' means 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.

'notified body' means a conformity assessment body designated in accordance with the Regulations

'**performance'** means the ability of a device to achieve its intended purpose as stated by the manufacturer;

'placing on the market' means the first making available of a device, other than an investigational device, on the Union market;

'**post-market surveillance'** means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;

'**putting into service'** means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;

'**risk**' means the combination of the probability of occurrence of harm and the severity of that harm;

'**serious incident'** means any incident that directly or indirectly led, might have led or might lead to any of the following:

- **a.** the death of a patient, user or other person,
- **b.** the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- **c.** a serious public health threat;

'serious public health threat' means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

'SRN' stands for single registration number – a registration number provided by the European electronic system through the national competent authority to manufacturers, authorised representatives and importers before placing a medical device on the market**;**

'System and procedure pack (SPP) producer' refers to the natural or legal person referred to in Article 22(1), 22(2) and 22(3) of the Medical Device Regulation

'Unique Device Identifier' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

'**user**' means any healthcare professional or lay person who uses a device;

'withdrawal' means any measure aimed at preventing a device in the supply chain from being further made available on the market.

Other definitions which shall apply to this document:

"cold chain" means a temperature-controlled supply chain. An unbroken cold chain consists of an uninterrupted series of storage and distribution activities which maintains a given temperature range, based on the manufacturer's recommended conditions for product stability integrity stated on the approved product packaging. A common temperature range for a cold chain is 2 to 8°C but this may vary depending on the product specifications;

"European Database on Medical Devices" (EUDAMED) means the European databank on medical devices. It is a secure, web-based portal which enables the exchange of information between National Competent Authorities and the European Commission;

"Medical Device Registered Person" (MDRP) means a person appointed by an economic operator and is registered with the Malta Medicines Authority who is responsible for ensuring regulatory compliance of medical devices made available on the Maltese market;

"Person Responsible for Regulatory Compliance" (PRRC) means a person with regulatory expertise who is appointed by a manufacturer or authorised representative to ensure compliance of medical devices with EU Regulations.

"**Standard Operating Procedures"** means documents that detail operating processes, including a description of the operations to be carried out, the precautions to be taken, and record keeping for the performance of the procedure;

CE: Conformitè Europëenne

FSCA: Field Safety Corrective Action

IVDR: InVitro Diagnostic Medical Device Regulation

MDR: Medical Device Regulation

MDRP: Medical Device Registered Person

MMA: Malta Medicines Authority

SPP: System Procedure Pack

UDI: Unique Device Identification

3. Legislation

Economic operators making medical devices available on the Maltese market shall be registered with the Malta Medicines Authority (MMA). These operators shall have available in their organisation at least one person responsible for regulatory compliance; a Medical Device Registered Person (MDRP), who is registered with the MMA and possesses the requisite knowledge and experience in the distribution and post-marketing activities concerning medical devices. Annex I outlines the qualifications, role and registration of an MDRP. Annex II includes the MDRP application form.

The Regulations clearly specify the distribution obligations applicable to the various operators. The general obligations of importers and distributors of medical devices are summarized in table 1 below (EU) 2017/745 and (EU) 2017/746:

Table 1. Importers' Obligations (*for full details of all importers' obligations please refer to the Regulations (EU) 2017/745 and (EU) 2017/746)*	
Section	**Obligations**
	MDR and IVDR Article 13 – General obligations of importers
Paragraph 1	Importers shall place on the Union market only devices that are in conformity with the Regulation.
Paragraph 2	In order to place a device on the market, importers shall verify that: (a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up; (b) a manufacturer is identified and that an authorised representative has been designated by the manufacturer in accordance with the Regulations; (c) the device is labelled in accordance with the Regulations and accompanied by the instructions for use; (d) where applicable, a UDI has been assigned by the manufacturer in accordance with the Regulations. Where an importer has reason to believe that a device is not in conformity with the requirements of the Regulations, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the importer is established.
Paragraph 3	Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trademark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
Paragraph 4	Importers shall verify that the device is registered in the electronic system and shall add their details to the registration in accordance with the Regulations.
Paragraph 5	Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and

	performance requirements set out in Annex I of the Regulations and shall comply with the conditions set by the manufacturer, where available.
Paragraph 6	Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.
Paragraph 7	Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with the Regulations shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate for the device in question in accordance with the Regulations, giving details, in particular, of the non-compliance and of any corrective action taken.
Paragraph 8	Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.
Paragraph 9	Importers shall, for the period referred to in the Regulations, keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with the Regulations.
Paragraph 10	Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.
	MDR Article 30 and IVDR Article 27 - Electronic system for registration of economic operators
Paragraph 1	The Commission, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) of the MDR and Article 28(2) of the IVDR and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be provided to that electronic system by the economic operators are laid down in Section 1 of Part A of Annex VI of the Regulations.
Paragraph 3	Within two weeks of placing a device, other than a custom-made device, on the market, importers shall verify that the manufacturer or authorised representative has provided to the electronic system the information referred to in paragraph 1. Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information referred to in paragraph 1 is not included or is incorrect. Importers shall add their details to the relevant entry/entries.

	MDR Article 31 and IVDR Article 28 - Registration of manufacturers, authorised representatives and importers
Paragraph 1	Before placing a device, other than a custom-made device, on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 30 of the MDR and Article 27 of the IVDR the information referred to in Section 1 of Part A of Annex VI, provided that they have not already registered in accordance with this Article. In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 52 of the MDR and Article 48 of the IVDR, the information referred to in Section 1 of Part A of Annex VI shall be provided to that electronic system before applying to the notified body.
Paragraph 4	Within one week of any change occurring in relation to the information referred to in paragraph 1 of this Article, the economic operator shall update the data in the electronic system referred to in Article 30 of the MDR and Article 27 of the IVDR.
Paragraph 5	Not later than one year after submission of the information in accordance with paragraph 1, and every second year thereafter, the economic operator shall confirm the accuracy of the data. In the event of a failure to do so within six months of those deadlines, any Member State may take appropriate corrective measures within its territory until that economic operator complies with that obligation.
Paragraph 6	Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex VI.
Paragraph 7	The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 30 of the MDR and Article 27 of the IVDR shall be accessible to the public.
Paragraph 8	The competent authority may use the data to charge the manufacturer, the authorised representative or the importer a fee pursuant to Article 111 of the MDR and Article 104 of the IVDR.

The general obligations of distributors of medical devices are summarized in table 2 below:

Table 2. Distributors' Obligations (*for full details of all distributors' obligations please refer to the Regulations (EU) 2017/745 and (EU) 2017/746)*	
Section	**Obligations**
	MDR and IVDR Article 14 – General obligations of distributors
Paragraph 1	When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.
Paragraph 2	Before making a device available on the market, distributors shall verify that all of the following requirements are met: (a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up; (b) the device is accompanied by the information to be supplied by the manufacturer in accordance with the Regulations;

	(c) for imported devices, the importer complied with the requirements set out in the Regulations; (d) that, where applicable, a UDI has been assigned by the manufacturer. In order to meet the requirements referred to in points (a), (b) and (d) the distributor may apply a sampling method that is representative of the devices supplied by that distributor. Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of the Regulations, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.
Paragraph 3	Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.
Paragraph 4	Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with the Regulations shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.
Paragraph 5	Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.
Paragraph 6	Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device. Distributors shall be considered to have fulfilled their obligation when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.
	MDR article 27 and IVDR Article 24 – Unique Device Identification system

Paragraph 8	Distributors shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to class III implantable devices or belong to one of the categories or groups of devices specified by the European Commission as requiring this traceability.
	MDR article 22 – Systems and procedure packs
	Reference should be made to Article 22 of the MDR which outlines the obligations of a system and procedure pack producer (SPP producer). More detail is outlined in Section 12 of this document.
	MDR Article 23 and IVDR Article 20 – Parts and components
Paragraph 1	The Regulations outline the obligations of economic operators intending to replace parts and components for devices that are defective or worn. An example of where this may apply is in the case of servicing and maintenance of medical devices in line with the manufacturer's guidelines. Repairs are permitted under the Regulations, however the requirements of Article 23 of the MDR and Article 20 of the IVDR on parts and components must be fulfilled.
Paragraph 2	Any natural or legal person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.
Paragraph 3	An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in the Regulation.
	MDR Article 30 and IVDR Article 27 - Electronic system for registration of economic operators
Paragraph 2	Distributors of devices which have been made available in the territory shall register as an Economic Operator with the Competent Authority (MMA).

Other obligations relating to economic operators and traceability of medical devices within supply chain are listed in table 3 below:

Table 3. Obligations regarding identification within supply chain (*for full details of all economic operators' obligations please refer to the Regulations (EU) 2017/745 and (EU) 2017/746)*

Section	**Obligations**
	MDR article 25 and IVDR Article 22 - Identification within the supply chain
Paragraph 1	Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

Paragraph 2	Economic operators shall be able to identify the following to the competent authority, for the period referred to in the Regulations: (a) any economic operator to whom they have directly supplied a device; (b) any economic operator who has directly supplied them with a device; (c) any health institution or healthcare professional to which they have directly supplied a device.

Other obligations of manufacturers that apply to importers, distributors or other persons are listed in table 4 below:

Table 4. Obligations of manufacturers that apply to importers, distributors or other persons (*for full details of all economic operators' obligations please refer to the Regulations (EU) 2017/745 and (EU) 2017/746)*	
Section	**Obligations**
	MDR and IVDR Article 16 – Cases in which obligations of manufacturers apply to importers, distributors or other persons
Paragraph 1	A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following: a) Makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation; b) Changes the intended purpose of a device already placed on the market or put into service; c) Modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected; The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in point (30) of Article 2, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.
Paragraph 2	For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements: (a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State; (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of

	devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.
Paragraph 3	A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established. Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, inter alia, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.
Paragraph 4	At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributor or importer complies with the requirements laid down in paragraph 3.

4. Organisational Requirements

Economic operators that make available medical devices on the local market shall operate an effective quality system appropriate to the nature and scale of their activities. The appointed Medical Device Registered Person (MDRP) shall be responsible to ensure that an organisation's quality system is properly administered and can consistently support the fulfillment of all legal requirements. The organisational set-up must ensure that all medical devices and associated services have been evaluated and that any non-compliant or otherwise unacceptable devices may be detected. Detailed documentation and record-keeping systems

shall facilitate traceability of all devices to allow for prompt recall or withdrawal of any unsuitable devices from the market.

Quality system

An organisation shall document a quality system, clearly defining its medical device distribution activity, and oversee its effective implementation. The organisation shall:

- set out a Quality Policy with clear quality objectives;
- determine clearly defined processes needed and their application throughout the organisation (determining the sequence and interaction of all the functions);
- establish criteria and clear methodology for all tasks – relevant, up-to-date standard operating procedures (SOPs) to be issued to staff concerned;
- justify and validate any critical steps in the process;
- allocate the resources necessary for efficient implementation;
- exercise control by maintaining accurate records of all procedures;
- monitor and periodically review the process to ensure compliance;
- maintain documentation of reviews and any recommendations which are duly implemented;
- retain suitable records of all transactions with third parties to enable tracking of all devices placed on the market.

The operation of an effective quality system for the distribution of medical devices shall support the integrity of the supply chain, in line with manufacturers' recommendations, and ensure patient safety.

Quality management

Senior management is responsible for active leadership of the organisation to attain the set quality objectives. Managerial responsibilities are to be clearly specified. Active engagement and commitment to highest standards is required by staff at all levels within the organisation, by the organisation's suppliers and by any subcontractors involved in the operations.

Distributors may refer to ISO 13485 for more information on quality management systems for suppliers of medical devices.

5. Personnel

The implementation of a satisfactory distribution operation for medical devices relies upon qualified and trained personnel. Individual responsibilities for the various tasks involved should be clearly understood. Procedures should be in place to provide staff with the necessary skills and knowledge to ensure the maintenance of the quality, safety and security of the medical devices stored and handled. Personnel should be trained to perform assigned duties at an acceptable level, to observe personal and general hygiene and to abide by Occupational Health and Safety Regulations.

Training records shall be kept for all personnel and training should be repeated or reinforced at appropriate intervals.

6. Documentation

An essential element of a quality system is the keeping of good documentation and the various types and media used should be fully defined. The documents required to manage a compliant distribution system include instructions, reports and records and suitable controls should be implemented to ensure accuracy, integrity and availability of documents. Management should ensure that only the latest approved versions of SOPs are available in the relevant stations and any outdated or superseded versions are archived.
The Regulations stipulate the obligations of economic operators to maintain an appropriate level of identification and traceability of the medical devices they distribute. Adequate records will enable distributors to inform the competent authority, upon request, of any information required about specific devices.

Distributors and importers should keep detailed records of suppliers and customers, all devices received as well as all the devices supplied. The records should be designed to include, but not be limited to, medical device name, classification, code, batch or lot number and traceability records of all transactions carried out. In the event that any devices need to be officially discarded, a certificate of destruction would need to be recorded. All records should be kept for a period of 10 years (or 15 years in the case of implantable devices).

7. Premises and Equipment

Premises and equipment shall be designed, constructed and adapted to suit the operations to be carried out. Layout should aim at minimising risk of errors and any equipment installed should be in such a way that it can permit effective cleaning and maintenance.

Lighting, temperature, humidity and ventilation shall not adversely affect the quality of the products or the accurate functioning of monitoring equipment. Maintenance procedures should not present any hazard to the quality of the products.

Storage areas should be of sufficient capacity to allow orderly storage of various categories of products. Such areas shall be designed to provide good storage conditions – they should be clean and dry and maintained within acceptable ambient limits. In the case of special storage requirements (e.g. temperature, humidity, etc.) specific areas shall be suitably equipped, constantly monitored and tracking records kept. Refrigerated areas and cabinets must be regularly cleaned to prevent the growth of mould. Environmental recording and control equipment should be calibrated and routinely checked at defined intervals by appropriate methods. Records of such activities should be maintained. Specific segregated areas, clearly marked, should be provided for the storage of products in quarantine, rejected, returned or recalled.

Spill kits should be adequately located within the storage area and any spills cleaned up promptly such that working spaces are rendered safe as soon as possible. If hazardous materials are being stored, written procedures and relevant training of responsible staff must be in place for dealing with handling and spillage.

Receiving and dispatch bays should protect products from weather and reception areas should be designed to allow products to be assessed, recorded and cleaned before going into storage. Passage ways should be kept clear and tidy at all times. Maintenance workshops, tool rooms and ancillary areas for rest and refreshment should be separate from the other areas.

Written, detailed procedures shall be in place for regular cleaning of all areas in the premises (records are to be kept of cleaning tasks carried out) and precautions shall be taken to protect against entry of insects, rodents and other animals in the premises. Periodic pest control certification shall be carried out and records of inspections and follow-ups are to be documented.

8. Product Handling and Inventory Control

Policies and procedures should be in place to provide for proper product handling and inventory control to prevent damage to packaging, deterioration of the products or confusion of goods to be distributed. A specific procedure for recognition and prompt handling of devices that require any special conditions is recommended, where applicable.

All stocks received at the warehouse should be checked against their delivery documentation to ensure:

- correct items and correct quantities are received;
- expiry dates are acceptable (according to the specific products);
- there is no damage or evidence of tampering;
- products have not been mishandled or exposed to adverse storage conditions during transport and at air/seaports; (*Particular attention to be given to the integrity of seals, especially of packs of sterile goods and any special handling and storage instructions as indicated by the manufacturer.)*
- products are in conformity with legislation:
    - presence of CE Mark followed by Notified Body number, where applicable;
    - EU declaration of conformity;
    - manufacturer information and, where applicable, authorised representative details;
    - a UDI has been assigned by the manufacturer, where applicable;
    - devices are labelled in accordance with legislation and accompanied by the required information for use;

    (In cases of bulk supplies, a sampling method representative of the devices being supplied, should be effected and this must be well documented.)

Special instructions for importers of products to be placed on the EU market. Importers shall:

- apply for an SRN number through EUDAMED actor registration module, as referred to in Article 31 of the MDR and Article 28 of the IVDR;
- indicate on the device or on its packaging or in a document accompanying the device the importer's name, registered trade name or registered trademark, their registered place of business and address at which they can be contacted; (*The additional information shall not obscure any information on the label provided by the manufacturer*.)

- verify that the device is registered in EUDAMED and shall add their details to the registration;
- keep copies of EU declarations of conformity and any other relevant documentation, including any amendments and supplements for a period of at least 10 years (at least 15 years in case of implantable devices) after the devices are placed on the market.

Medical devices which may be rejected because of error, damage, leakage or any other fault should be placed in quarantine and brought to the attention of the MDRP for reporting and proper disposal.
Storage should be organised to enable segregation and identification of the various materials and products stored. An adequate system of stock rotation must be in place with regular checks on expiry dates. Devices bearing an expiry date should not be received or supplied after the said expiry date and any such devices inadvertently received must be quarantined pending proper disposal.

All medical devices, accessories and spare parts are to be maintained in a clean, dry and orderly condition to comply with conditions set by the manufacturer. Devices are to be stored off the floor (e.g. shelving or pallets) to help facilitate cleaning and to reduce exposure to dust and moisture.

Transportation procedures should be in place to ensure adequate methods of transportation, within the right conditions specified by manufacturer, to achieve safe, secure and timely delivery of all devices from the warehouse to their destination. Product receipts are to be endorsed by the authorised receiver, confirming that goods are received in good order within the required transportation conditions. Temperature recorders or other logging or tracking equipment, when required, should be ongoing up to confirmation and sign off by the authorised receiver. A system must be in place for collection and storage of the signed receipts and tracking equipment obtained in paper or electronic format.

Delivery vehicles are to be kept clean, regularly serviced and all vital components (e.g. ventilation and cooling systems) kept in good working order.

If deliveries are performed by subcontracted delivery companies, products must be packed in a manner to ensure adequate protection from damage or deterioration of the devices. Delivery personnel must be well briefed and supervised to carry out all the essential functions required.

9. Non-Compliant and Counterfeit Medical Devices

The possible presence of non-compliant and counterfeit medical devices in the market is a constant threat to health and safety of users, patients and the public. Non-compliant devices may carry false or misleading claims with respect to performance, compliance with legislation or fitness for purpose. Counterfeit devices infringe on intellectual property rights of the registered owner and in most cases such devices are found to be sub-standard, non-compliant and defective. Accessories, components and replacement parts for medical devices may also be counterfeit and/or non-compliant and may result in damage to equipment, invalidating its compliance, resulting in poor performance and reliability issues of devices which may be detrimental to health and safety.

Economic operators need to have robust systems in place to verify the sources of the medical devices and related products which are being distributed and to ensure the legitimacy of their suppliers. Each organisation should maintain a list of approved suppliers and be familiar with the stages of the supply chain for the medical devices received. Procurement of devices should only be made directly from the approved suppliers.

If there is any suspicion that a medical device which has been received is not legitimate, the MMA should be immediately informed via the Medical Devices and Pharmaceutical Collaboration Directorate email on devices.medicinesauthority@gov.mt. Suspect devices are to be immediately quarantined and removed from saleable stock. Verification of the authenticity and compliance of these devices may be required. Any medical devices which are suspected or confirmed as being counterfeit and/or non-compliant should not be returned to the supplier without the authorisation of the MMA.

10.System and Procedure Packs

Reference should be made to Article 22 of the MDR, which outlines the obligations of a system and procedure pack producer (SPP producer).

A distributor will be considered a SPP producer if they combine devices bearing the CE marking with the following other devices or products, in a manner that is compatible with their intended purpose and within the limits of use specified by their manufacturers, in order to place the system or procedure on the market:

(a) other devices bearing the CE marking;

(b) in vitro diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;

(c) other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.

The SPP producer must draw up a statement that needs to be kept available for the national competent authority (MMA) after the system or procedure pack has been put together, for the period that is applicable under Article 10(8) of the MDR to the devices that have been combined (10 or 15 years). Where those periods differ, the longest period shall apply.

In the statement, the SPP producer concerned shall declare that:

(a) they verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;

(b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

Any SPP producer who sterilises systems or procedure packs for the purpose of placing them on the market shall, at their choice, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI of the MDR. The application of those procedures and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged. The SPP producer shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions, the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure pursuant to Article 52 of the MDR. The SPP producer shall assume the obligations incumbent on manufacturers.

The systems or procedure packs shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trademark of the SPP producer as well as the address at which that person can be contacted, so that the person's location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 23 of Annex I of the MDR.

11.Management of Returns

Medical device distributors should have policies and procedures in place to deal with products returned from customers. Product returns may occur for a number of reasons, including errors in orders from clients (e.g. wrong product codes quoted), errors in distribution (e.g. supply of incorrect device), logistical reasons (e.g. delayed delivery).

A product which has left the warehouse and is returned for any reason should be documented and placed in quarantine until it has been examined and assessed by the MDRP or a duly authorised person. A thorough examination of the suitability of any returned medical device should be made and documented to verify that the quality of the product has not been compromised in any way. The assessment should ensure that products:

- have originally been dispatched from the warehouse; (*Original invoice with all product details should be available together with a signed Returns Note with relevant details.)*
- are in original containers with intact labels, packaging and a valid expiry date;
- have not been subject to adverse conditions during the period outside the distributor’s control;
- have not been tampered with or contaminated.

Products which fail to meet any of the above criteria or show any other sign of non-conformity are not to be returned to saleable stock and should be retained in quarantine/reject area pending proper disposal.

Particular attention must be given to the return of sterile medical devices and devices requiring storage at specific temperature ranges. Distributors should only return to saleable stock those sterile products where there is no reasonable possibility that sterility of the product has been compromised – in case of any doubt such products must be rejected. With regards to temperature sensitive products, distributors must have documented evidence confirming that the device was maintained within the desired temperature range for the entire time that the product was out of the warehouse. In the absence of such evidence the products must be rejected.

Distribution staff must be informed of the danger of falsified medical devices entering the supply chain through the returns process and the importance of due diligence.

12.Field Safety Corrective Actions (FSCA)

To ensure that devices manufactured in series production continue to be in conformity with the requirements of the Regulations, manufacturers should establish a system for risk management and a system for reporting of incidents and field safety corrective actions.

In order to better protect health and safety regarding devices on the market, serious incidents and field safety corrective actions should be reported on a central portal at Union level.

According to Article 27 of the MDR and Article 24 of the IVDR, the UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87 of the MDR and Article 82 of the IVDR.

Distributors should have a system in place for handling FSCAs notified by the manufacturer. The system established should allow the distributor to report FSCAs where the distributor is responsible for initiating or reporting an FSCA. The obligations related to the planning, conducting and reporting of the corrective action taken should be well documented. In addition, the MMA should be notified before any FSCA is undertaken and/or communicated onward.

13.Medical Device Recalls

Policies and procedures should be in place to provide for actions to be taken in the event of a recall of defective medical devices. Essential elements for recall procedures should include:

- the role of the MDRP as the person responsible for coordination of the recall action;
- contact details (mobile number and email address) for the MDRP and other designated company officials;
- contact details (contact number and email address) of the Medical Devices and Pharmaceutical Collaboration Directorate at the MMA

- the requirement of communication with the manufacturer and the Medical Devices and Pharmaceutical Collaboration Directorate and devising appropriate action and communication plans to customers, healthcare providers and users;
- the requirement of full description of the defective device, including: UDI / Batch / Lot / Model numbers / risk classification;
- the listing of all customers supplied in the local market and templates of a communique regarding the exercising of a recall and product return forms;
- the requirement of a schedule for collection of the devices and return forms (including any promotional samples maintained by sales representatives);
- handling of recalled products in the warehouse – segregation from saleable stock;
- the requirement for arrangements for appropriate disposal of goods/returns to manufacturer;
- reconciliations and reporting requirements to Medical Devices and Pharmaceutical Collaboration Directorate and the manufacturer.

The effectiveness of the recall procedure and the ability of the organisation to trace all customers of a specific batch of a medical device and reconciling quantities of the product held in stock and those distributed to customers should be tested on a regular basis (e.g. carrying out of a mock recall).

References

European & Local legislation accessible from the following link:
https://medicinesauthority.gov.mt/medicaldevices

Signatures on File

Annex I Role and Eligibility Criteria of a Medical Device Registered Person (MDRP)

Role

Wholesale distributors and importers shall have available within their organisation at least one Medical Device Registered Person (MDRP) who possesses the requisite expertise in the field of medical devices. The MDRP is responsible to ensure that local distributors and importers adhere to all applicable legislation and guidance documents with regards to making available on the market medical devices and in-vitro diagnostic medical devices. The MDRP must be registered with the MMA. Responsibilities of the MDRP include:

- Ensuring that medical devices placed on the market comply with the legislation
- Keeping a copy of the EU declaration of conformity (DoC), instructions for use (IFU) and labelling of the device, and, if applicable, a copy of any relevant certificate, including any amendments and supplements in accordance with the Regulations
- Verifying that the device is registered with the European databank (Eudamed) and notified in the national medical device database
- Ensuring that an organisation's quality system is developed, properly administered and can consistently support the fulfilment of all legal requirements
- Ensuring that while a device is under their responsibility, storage and transport conditions comply with the general safety and performance requirements found in the legislation as well as the conditions set by the manufacturer
- Ensuring that an appropriate level of traceability of devices is kept by means of detailed documentation and record-keeping systems
- Ensuring complaints and incident reports from Healthcare Professionals, patients or users will be forwarded to the manufacturer, and his authorised representative if applicable, as well as the national competent authority
- Liaising with manufacturers in collecting information and dealing with preventive, corrective and field safety corrective action
- Informing the national competent authority if a device is believed to present serious risk or is suspected to be falsified
- Coordinating recalls
- Keeping a register of complaints, of non-conforming devices, recalls and withdrawals

Eligibility Criteria

Applicants applying for the MDRP role, should meet the following criteria:

a) Applicant is either an EU citizen (providing proof through a valid passport or identity card document) or if a non-EU citizen has a permanent Maltese residence and a Maltese working permit (providing relevant documentation);

b) One of the following criteria related to qualifications / experience:

   i. in possession of one of the following qualifications: a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by Malta, in law, medicine, pharmacy, engineering or another relevant scientific discipline, **and** at least one (1) year of professional experience in regulatory affairs or in quality management systems related to medical devices;

   ii. two (2) years of professional experience in regulatory affairs or in quality management systems related to medical devices;

c) A course recognised by the MMA related to medical devices.

For any queries or clarifications, please send an email on: devices.medicinesauthority@gov.mt

Applications for MDRP registration are downloadable from the MMA website: https://medicinesauthority.gov.mt/medicaldevices .

Annex II MDRP Application Form

For office use only: MDRP Registration Form received on: ___ / ___ / _____

MDRP Registration Form Reference No.: _____

MDRP Reference No.: _____

MT-MDF11

Application Form for Medical Device Registered Person (MDRP)

The application is valid when submitted with the relevant documents and fees.
Refer to the *GL-MDS01 Guidance for Good Distribution Practice in relation to Medical Devices* and *GL-MDF07 Guidance on fees in relation to Medical Devices*. Guidance documents and Application Form are available on the Malta Medicines Authority website: https://medicinesauthority.gov.mt/medicaldevices.

Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

info.medicinesauthority@gov.mt | (+356) 23 439 000

www.medicinesauthority.gov.mt

Section A.1 Applicant details

Surname:

Name:

Home address

Name/ No.:

Street:

Locality:

Country:

Post code:

Email address:

Telephone number:

Mobile number:

Section A.2 Application Type

☐ First application

☐ Revision of submitted details for MT-MDF11 Application Form for Medical Device Registered Person (MDRP)

☐ Amend MDRP details

☐ Withdraw application for MDRP

Application Reference:

Section B Eligibility Criteria

i) Citizenship - Tick as applicable, providing relevant documentation.

EU citizen

☐ Valid Passport/Identity Card document

Non-EU citizen

☐ Permanent Maltese residence

☐ Maltese Working Permit

ii) Qualifications/Experience

Experience and qualifications will be assessed from the Curriculum Vitae provided.

iii) Medical Device Course certificate

Provide the name and certificate of the relevant course attended in relation to medical devices.

Section C Details of Payment

☐ Proof of Payment attached (Standard fee)

☐ Proof of Payment attached (Fast-track fee)

Section D Additional Documents

☐ Citizenship document/s

☐ Europass Curriculum Vitae

☐ Medical Device Course certificate

☐ 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.

Consent for the publication of personal data on the Malta Medicines Authority website

As the regulatory Authority for Medical Devices the Malta Medicines Authority is the controller of your personal data as a Medical Device Registered Person, namely your name, address, email address, telephone number. The Malta Medicines Authority stores this information in accordance with applicable record retention requirements.

I, _____, holder of identity card/passport number _____ hereby consent to the publication of my email address on the Malta Medicines Authority website. I understand and agree that my email address will be made publicly accessible on the website for the purpose of facilitating communication between stakeholders.

I acknowledge that the publication of my email address is voluntary and that I have the right to withdraw this consent at any time by contacting the Medical Devices and Pharmaceutical Collaboration Directorate at Life Science Park, Sir Temi Żammit, San Ġwann 3000 or by phone and email at devices.medicinesauthority@gov.mt.

I understand that the Malta Medicines Authority will take all reasonable measures to protect my personal information in accordance with applicable data protection laws, including the General Data Protection Regulation (GDPR).

By signing this consent form, I confirm that I have read and understood the above information, and I freely give my consent to the publication of my name, surname and email address on the Malta Medicines Authority website.

Signature: _____

Date: _____

[Please fill out and return this form to authorise the publication of your email address on the MMA website.]

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.

Name & Surname: Click here to enter text.

Position: Click here to enter text.

Signature: _____

Date: Click to enter a date.