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# MEDICAL DEVICE GUIDANCE DOCUMENT

# DISTRIBUTION RECORDS

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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## Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012; and

c) Medical Device (Duties and Obligation of Establishments) Regulations 2019.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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# DISTRIBUTION RECORDS

## 0 Introduction

It is necessary to protect public health and patient safety by ensuring that all medical devices in the Malaysian market meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

The Medical Devices (Duties and obligations of establishment) Regulations 2019 detailed out requirements for post-market surveillance and vigilance as provided in Chapter 3 of the Medical Devices Act 2012 (Act 737). These regulations are imposed to ensure licensees carry out their responsibilities to monitor and continuously ensure the safety and performance of their devices in the market. One of the requirements is to establish proper and effective procedure on managing and maintaining distribution records.

## 1 Objective

This document is made pursuant to Medical Device Act 2012 (Act 737) section 37 and Regulation 3 of Medical Device (Duties and Obligation of Establishments) Regulations 2019 to describe and define the framework on establishment and management of medical device distribution records by the establishment.

## 2 Scope and application

This guidance document specifies the requirements on distribution records that are to be established and maintained for all medical devices. This document is applicable to establishments including exporters dealing with medical devices.

## 3 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, and the regulations under it apply.

### 3.1 incident

An event that causes, or has a potential to cause, unexpected or unwanted effects involving the safety of any person who use a medical device or any person associated with the use of a medical device.

Note. Incident is referred to as adverse event in ASEAN Medical Device Directive.

### 3.2 user

Person using or operating a medical device on any person acquiring services in healthcare facilities or other facilities

## 4 General requirements

The distribution record shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market, where necessary.

### 4.1 Content of distribution records

**4.1.1** Distribution records shall contain the following:

a) postal address of the consignee(s) in a format that allows physical location to be established together with a telephone number;

b) the address of the place of storage of the medical device;

c) the identification of a medical device(s); make, class, model number or item description, part number, batch number, and quantity of the devices, including any medical device that is part of a medical device grouping as prescribed in Part II, Second Schedule of Medical Device Regulations 2012 (if applicable);

d) the details of the delivery and receipt of the medical device which are traceable to all shipping/delivery documentation information;

e) information and documentation on the disposal of the medical device (if applicable); and

f) any other information as may be required by the Authority.

**4.1.2** For implantable medical device, the distribution records shall contain the additional information as follows:

a) The details of healthcare facility where the implantable medical device is implanted including the department which conduct the implantation procedure;

b) The details of the patient on whom the implantable medical device is implanted or used if possible to get the information;

c) The date of implantation of the medical device; and

d) The details of removal of the implantable medical device, if applicable.

### 4.2 Maintaining the distribution records

**4.2.1** Records shall be maintained by the establishment in compliance with the requirements under Act 737 and its regulations. Establishment shall:

a) verify the record for adequacy;

b) update the record as necessary;

c) ensure all records remain eligible and identifiable; and

d) prevent the unintended use of obsolete records and apply suitable identification to them if they are retained for any purpose.

**4.2.2** The procedure on maintaining the distribution records shall be documented.

**4.2.3** The distribution record shall be retained as follows:

a) for 2 years after the date on which the medical device is supplied;

b) if the medical device is for export, for 2 years from the date the medical device is shipped out of Malaysia; or

c) if the medical device has a projected useful life, for the projected useful life of the medical device as determined by the manufacturer, whichever period is longer.

NOTE. The projected useful life of a medical device may be based on technical, legal, commercial or other considerations. Manufacturers may refer to ISO/TR 14969, *Medical devices – Quality management systems – Guidance on the application of ISO 13485:2003* for some of the considerations when defining the lifetime of their medical device.

**4.2.4** An establishment shall provide the distribution records to the Authority upon request.

## 5 Tracking of an Implantable medical device

**5.1** Establishment shall track all implantable medical device down to patient level in the case of any incident relating to the implantable medical device or FCA or recall is required to be conducted.

**5.2** If tracking is not possible at the patient level, the establishment shall:

a) track the implantable medical device tracking down to the healthcare facility level; or

b) keep track of the date of the medical device being put into service or implanted into a patient.

Examples of implants:

(i) mechanical heart valves;

(ii) implantable pacemakers, their electrodes and leads;

(iii) implantable defibrillators, their electrodes and leads;

(iv) implantable ventricular support systems; and

(v) implantable drug infusion systems.

# MEDICAL DEVICE AUTHORITY

## MINISTRY OF HEALTH, MALAYSIA

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