MDA/GD/0012

October 2026

Draft Public Comment (3-18 NOV 2026)

Second Edition

PUBLIC COMMENT 3- 18 NOV 2026

MEDICAL DEVICE GUIDANCE DOCUMENT

DISTRIBUTION RECORDS

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents

	Page
Preface	4
1 Introduction	5
2 Scope and application	5
3 Terms and definitions	6
4 General requirements	7
4.1 Content of distribution records	8
4.2 Maintaining the distribution records	9
4.3 Retention of Distribution Records	9
4.4 Controls of Distribution Records	9
Tracking of an Implantable medical device	10
4.5 Distribution Records and Tracking of Implantable Medical Devices	10
5 Obligations of establishments	10
Annex A (normative) Contents required for Distribution Records	12

PUBLIC COMMENT 3- 18 NOV 2026

REVISION HISTORY

No.	Section/Clause	Changes	Date
1		1st Edition	June 2020
2	1. Introduction	Rephrased to include distribution-related risks, Good Distribution Practice for Medical Devices (GDPMD), and the importance of distribution records in preventing faulty and counterfeit medical devices.	Public comment
	2. Scope and Application	Rephrased to include requirements for the development, maintenance and retention of distribution records for all medical devices placed on the market.	
	3. Terms and Definition	Added new definitions for distributor; establishment; Field Corrective Action (FCA); implantable medical devices; Unique Device Identification (UDI); and licensee.	
	4. General Requirements	Clarified requirements for distribution records, traceability and record controls	
	4.1 Contents of distribution records	Further specified distribution records requirements, including traceability, medical device identification, delivery and receipt, Software as Medical Device (SaMD), disposal and supporting documents required by the Authority.	
	4.2 Maintaining the distribution records	Clarified requirements for maintaining, updating and controlling distribution records.	
	4.3 Retention of distribution records	Added provisions of Medical Device (Duties and Obligations of Establishments) Regulations 2019.	
	4.4 Controls of distribution records	Added requirements for control, security, retention and provision of distribution records to the Authority.	
	4.5 Distribution records and tracking of implantable medical devices	Further specified the requirements for traceability of implantable medical devices up to the healthcare facility and patient level.	
	5. Obligations of establishments	Added obligations of establishments in establishing and complying with the distribution records.	
	Annex A Contents required for the distribution records	Added the minimum distribution records required to be maintained by establishments	

PUBLIC COMMENT UP TO 18 NOV 2026

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.

PUBLIC COMMENT 3- 18 NOV 2026

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website:mda.gov.

DISTRIBUTION RECORDS

1 Introduction

Protecting public health and patient safety is paramount. This requires ensuring all medical devices in the Malaysian market consistently meet appropriate standards of safety, quality, performance, and effectiveness, and are used safely. The integrity of medical devices, including their quality, safety, and performance, can be compromised after they leave the manufacturer due to various factors in the distribution process, such as inadequate storage conditions, inappropriate warehouse environments, poor handling, suboptimal transportation, improper installation, lack of servicing, extended storage duration, and insufficient user training.

To continuously ensure the safety and performance of devices in the market, the Medical Devices (Duties and Obligations of Establishment) Regulations 2019 impose specific requirements for post-market surveillance and vigilance, as detailed in Chapter 3 of the Medical Devices Act 2012 (Act 737). A fundamental requirement of these regulations is for licensees to establish proper and effective procedures for managing and maintaining comprehensive distribution records.

Furthermore, widespread adoption and rigorous implementation of Good Distribution Practice for Medical Devices (GDPMD) across the medical device supply chain are critical to preventing the distribution and use of substandard (faulty) and falsified (counterfeit) medical devices.

This document describes and defines the framework for establishing and managing medical device distribution records by establishments, in accordance with Section 37 of the Medical Device Act 2012 (Act 737) and Regulation 3 of the Medical Device (Duties and Obligation of Establishments) Regulations 2019. It aims to provide guidance to establishments on establishing and implementing proper record-keeping procedures throughout the medical device supply chain, and to Conformity Assessment Bodies (CABs) for carrying out conformity assessment activities.

2 Scope and application

This document outlines the requirements and procedures for the development, maintenance, and retention of distribution records for all medical devices placed on the market by an establishment.

The scope of this document applies to establishments involved in the supply chain activities including import, export and placement in the market of medical devices. Compliance with these requirements is essential to ensure the traceability of medical devices, facilitate timely field corrective actions (FCA) or recall, and meet all applicable regulatory requirements as defined by the Authority.

PUBLIC COMMENT 5 18 NOV 2025

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 distribution

The activities of pre (release), placement (delivery) and postdelivery of medical devices conducted by the establishment

SOURCE: Good Distribution Practise of Medical Device (GDPMD)

3.2 distributor

Any natural or legal person in the supply-chain who, on his own behalf, places a medical device on the market and further the availability of the medical device to the end user including persons in the supply-chain involved in activities such as storage and transport on behalf of the authorized representative, importer or distributor.

SOURCE: Good Distribution Practise of Medical Device (GDPMD)

3.3 establishment

As defined in Section 2 of Act 737

3.4 Field corrective action

a corrective action taken by a manufacturer or its authorised representative to minimize or prevent the risk of death or serious deterioration in the state of health of a person associated with the use of a medical device.

[SOURCE: Medical Device (Duties and Obligations of Establishments) Regulations 2019]

3.5 incident

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

[SOURCE: Medical Device (Duties and Obligations of Establishments) Regulations 2019]

NOTE: In the ASEAN Medical Device Directive (AMDD), this incident is termed an "adverse event."

3.6 implantable medical device

any medical device, including one that is partially or wholly absorbed or which is intended to be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by surgical intervention and which is intended to remain in place after the procedure or any medical device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least thirty days is also considered an implantable device.

[SOURCE: Medical Device Regulations 2012]

3.7 licensee

Any person who obtains and holds establishment license under Act 737.

PUBLIC COMMENT 3- 18 NOV 2026

SOURCE: Medical Device Regulations 2012

3.8 Unique Device Identifier (UDI)

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI.

NOTE: The word "Unique" does not imply serialization of individual production units.

[SOURCE: Unique Device Identification (UDI) System Application Guide (IMDRF/UDI WG/N48 FINAL:2019) 21 March 2019]

3.9 user

The person, either professional or lay, who uses a medical device.

4 General requirements

The establishment shall document all activities relating to the distribution of medical devices including all applicable receipts, storage, delivery and disposal.

The establishment shall maintain detailed records of all distribution activities related to medical devices. This includes receipts (purchase invoices, proof of delivery), storage conditions (temperature, humidity, and any other specific requirements for device integrity), delivery records (tracking shipments to healthcare facilities, distributors, or end-users), and disposal records (for expired, damaged, or recalled products) to provide evidence of conformity to requirements and of the effective operation of the quality management system.

Records shall ensure traceability of the medical device throughout the supply chain, from the manufacturer or Authorised Representative (AR) to the end user.

Measures shall be established to maintain traceability across all distribution channels, including the manufacturer, AR, importer, distributor, and where applicable, healthcare facilities, retailers, and patients.

The distribution record shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market, where necessary. The establishments shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

CAB may perform inspection or audit to the distribution records maintained by the establishments. Failure to maintain a distribution record as required under Section 37 of the Act 737 shall be considered as an offense and can be compounded under Medical Device (Compounding of Offences) Regulations 2024.

4.1 Content of distribution records

Complete distribution records are critical to support effective implementation of a Field Corrective Action (FCA). Where an FCA requires the recall or withdrawal of a specific batch or lot, inadequate batch/lot traceability may result in the need to extend the recall to all affected products.

Distribution records shall contain the following:

PUBLIC COMMENT 8 NOV 2026

a) the name, address, telephone number and email of the consignee(s);

b) the name, address, email address (if applicable), and telephone number of the storage facility where the medical device is kept, and the final location at which the medical device was supplied for use by the patient or user;

NOTE: Importers and distributors are required to maintain records of storage facilities, including warehouses, used for the storage of medical devices prior to distribution to customers.

c) the identification of a medical device(s); medical device name, proprietary (brand) name, UDI, and quantity of the devices (including number of medical devices received (from the importer, in case from foreign manufacturers) and distributed to the retailer/healthcare institutions), 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);

NOTE: For medical devices without a UDI, records shall include the model or version number and the batch or lot number, where applicable. The MDA registration number and registration validity period shall also be included.

d) or in the case of Software as Medical Device (SaMD): installation configuration management; identification, delivery method and target audience.

e) the details of the delivery and receipt of the medical device which are traceable to all shipping/delivery documentation information, including date of shipped and PO and DO number, information of customers (e.g. healthcare institutions or retailers), including the latest contact details**;**

f) information and documentation on the disposal of the medical device (if applicable depending on the types of the device);

NOTE: For medical devices with a short shelf life, establishments should consider the potential for increased disposal due to product expiry.

g) other supporting documents that must be maintained by the establishments such as copies of invoices related to the receipt and supply of medical devices; copies of purchase orders and sales orders; a current list of establishments, including details of the relevant medical device supplied, LoA; and

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

PUBLIC COMMENT 3- 17 NOV 2020

4.2 Maintaining the distribution records

The establishment shall maintain the distribution record through a documented procedure.

In maintaining the distribution record, establishment shall:

a) verify the record for adequacy;

b) update the record as necessary. Changes to a record shall remain identifiable;

c) ensure all records remain legible, identifiable and retrievable; and

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

4.3 Retention of Distribution Records

The establishment shall establish and maintain distribution records for the period specified under the Medical Device (Duties and Obligations of Establishments) Regulations 2019.

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.

4.4 Controls of Distribution Records

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

Records (including, but not limited to, those listed in Appendix 1) shall be established and maintained to provide evidence of conformity to the requirements and the effective implementation of the procedures.

The listed distributor shall document the procedures to define the controls needed for the identification, storage, security and integrity, retention time and disposition of records.

4.5 Distribution Records and Tracking of Implantable Medical Devices

For implantable medical devices, the distribution records shall contain the information specified in 4.1 and the following additional information:

a) Details of the healthcare facility where the implantable medical device is implanted, including the department that conducted the implantation procedure;
b) Details of the patient on whom the implantable medical device is implanted or used;
c) The date of implantation of the medical device; and
d) Details of removal of the implantable medical device, including the date on which the device was permanently explanted from the patient, where applicable.

PUBLIC COMMENT 5-18 NOV 2026

Establishments shall maintain accurate, complete and readily retrievable distribution and traceability records up to the patient level.

For assessment by the Authority or CAB, establishments shall ensure that the distribution records are traceable up to the healthcare facility level. CABs shall assess the effectiveness of the establishment's traceability and tracking system based on the distribution records and provide a clear conclusion on compliance in the audit report.

Establishments shall ensure that implantable medical devices can be further traced to the patient level through their maintained records. Patient-level information shall be made available to the Authority when required, including but not limited to post-market incident investigations, Field Corrective Actions (FCA) and recalls.

5 Obligations of establishments

Table 1 outlines the regulatory obligations of manufacturers, Authorised Representatives (AR), importers and distributors throughout the medical device supply chain. The obligations are intended to ensure compliance with applicable regulatory requirements and to support the proper storage, transportation, traceability and post-market activities of medical devices.

PUBLIC COMMENT 3- 18 NOV 2026

Table 1: Regulatory Responsibilities of Establishments in the Medical Device Supply Chain

Obligations	Manufacturer	AR	Importer	Distributor
General requirements	Responsible to register the medical device with MDA,		Shall only import registered medical devices with MDA, or medical devices that are explicitly exempted from registration requirements by the Authority.	Shall only distribute registered medical device with MDA, or medical devices that are explicitly exempted from registration requirements by the Authority
Storage and transport	Establish the instructions for storage and transport	Communicate the instructions to the distributors and importers.	According to manufacturer's instructions	
Traceability of medical devices	All establishments shall: ● shall establish measures to ensure traceability of the medical device throughout distribution channels from the manufacturer or AR, to the importer (if applicable), to the customer and to the patient. [SOURCE: Clause 26.1 (iv) in the Good Distribution Practise of Medical Devices] ● cooperate to maintain a high level of medical device traceability. ● be able to identify and provide to the MDA, upon request and for the applicable retention period: ○ the delivery or supply details to the customer or patient; and ○ the recipient details (Customer or patient) ○ records shall be maintained to ensure traceability of the medical device throughout the supply chain, from the manufacturer or authorised representative (AR) to the customer or end user (if applicable). ● able to identify, throughout the retention period, the following data for each activity related to each medical device: the date of the action, the name of the medical device, the name and address of the supplier, the name and address of the customer (except for direct sales to private individuals), the serial or batch number and the expiry date.			
Cooperation within the supply chain	Request and obtain relevant information from importers, distributors, healthcare facilities,		Distributor shall share the	Importers shall share the information of

PUBLIC COMMENT 3-18 NOV 2026

on the investigation of complaints	or other parties involved to support the manufacturer's investigation.	information of distribution records to the manufacturer or AR for post market obligations.	distribution records to the manufacturer or AR for post market obligations.

PUBLIC COMMENT 3- 18 NOV 2026

Annex A
(normative)

Contents required for Distribution Records

This annex specifies the minimum distribution records required to be maintained by establishments to ensure traceability of medical devices throughout the supply chain.

Details of the consignee:

- Name of consignee
- Address
- Telephone number
- Email address

Details specifications of the medical device

- Medical device name
- Proprietary (brand) name
- UDI (where applicable)
- Class of device
- Quantity (received and distributed)
- MDA registration number
- Registration validity period

For devices without UDI, the following shall be recorded:

- Model/version number
- Batch/lot number

For Software as Medical Devices (SaMD):

- Installation/configuration management details
- Device identification

Details of the medical device's storage

- Name of storage facility (including warehouse, if applicable)
- Address of storage facility
- Email address (if applicable)
- Telephone number
- Final location where the medical device is supplied for use by the patient or user

Details about the delivery of medical device

- Date of delivery by the distributor or importer
- Quantity delivered
- Remarks (if applicable)

Details about the receipt of medical device

- Date of receipt by consignee
- Quantity received
- Remarks (if applicable)

PUBLIC COMMENT 5- 18 NOV 2026

Details about the disposal of medical devices (if applicable)

- Device disposed (Yes/No)
- Reason for disposal (e.g. expiry, damage, low shelf life)
- Date of disposal
- Method of disposal

Supporting Documents

Establishments shall retain including but not limited to the list of information required for investigation purposes:

- Copies of invoices (receipt and supply)
- Purchase orders and sales orders
- List of establishments in the distribution chain
- Letter of Authorisation (LoA), where applicable
- Any other relevant supporting documents

PUBLIC COMMENT 3- 18 NOV 2026

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

PUBLIC COMMENT 3- 18 NOV 2026

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website:mda.gov.my