

# HEALTH SCIENCES AUTHORITY

## REGULATORY GUIDANCE

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# MEDICAL DEVICE GUIDANCE

GN-06: Guidance on Distribution Records for  
Medical Devices

Revision 2.2



**CONTENTS**

PREFACE .....	3
1. INTRODUCTION .....	4
1.1. Purpose .....	4
1.2. Background.....	4
1.3. Scope.....	4
1.4. Definitions .....	4
2. WHO IS RESPONSIBLE FOR KEEPING DISTRIBUTION RECORDS? ..	5
3. WHY KEEP DISTRIBUTION RECORDS? .....	5
4. WHAT IS THE INFORMATION REQUIRED? .....	5
5. HOW LONG TO KEEP RECORDS? .....	7
6. HOW TO KEEP RECORDS? .....	7
7. RECORDS OF IMPLANT .....	7

## PREFACE

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## CONTACT INFORMATION

Email (post-market submissions): [hsa\\_medical\\_device@hsa.gov.sg](mailto:hsa_medical_device@hsa.gov.sg)

## REVISION HISTORY

<u>Guidance Version (Publish Date) [3 latest revisions]</u>	<u>Revision</u>
GN-06: Revision 1 (October 2008)	R1
<b>R2</b> ► GN-06: Revision 2 (September 2013)	R2
<b>R2.1</b> ► GN-06: Revision 2.1 (July 2015)	R2.1
<b>R2.2</b> ► GN-06: Revision 2.2 (01 November 2017)	R2.2

*\*Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

## **1. INTRODUCTION**

### **1.1. Purpose**

This document provides guidance for keeping of distribution records related to medical devices.

### **1.2. Background**

Traceability is not only a requirement of an effective quality system but also the requirement of regulatory bodies around the world. Keeping proper and appropriate distribution records is an important component of ensuring traceability of products in the market.

### **1.3. Scope**

This document is applicable to all persons who register, manufacture, import and supply by wholesale medical devices in Singapore.

### **1.4. Definitions**

Nil.

## **2. WHO IS RESPONSIBLE FOR KEEPING DISTRIBUTION RECORDS?**

The registrant, manufacturers, importers, wholesalers (including exporters) are each required to:-

- establish and implement documented procedures for distribution records;
- maintain a distribution record of each medical device.

Distribution records are to be maintained for all medical devices, including low risk medical devices that are exempted from product registration.

## **3. WHY KEEP DISTRIBUTION RECORDS?**

Keeping distribution records will facilitate the accountability and traceability of a medical device. This ensures that the medical device distribution channels in Singapore, including medical device exports from Singapore, are identifiable.

Distribution records of the medical devices are required to:-

- expedite any recalls of batches of the medical devices;
- identify the manufacturer of each batch of the medical devices;
- identify where each batch of the medical devices is supplied.

## **4. WHAT IS THE INFORMATION REQUIRED?**

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

Information may include:-

- name and address of initial consignee;
- identification and quantity of medical devices shipped;
- date shipped;

- any control number(s) used, including lot / batch / serial number of the medical device.

## **5. HOW LONG TO KEEP RECORDS?**

The distribution record maintained with respect of a medical device should be retained for the longer of one of the following:-

- the projected useful life<sup>1</sup> of the medical device as determined by the product owner;
- two years after the medical device is shipped.

For medical devices that are imported for export only, it is two years after the date the medical device is shipped out of Singapore.

## **6. HOW TO KEEP RECORDS?**

Distribution records should be maintained in a manner that will allow their timely retrieval.

## **7. RECORDS OF IMPLANT**

The distribution record maintained should also contain a record of the information of the implant when supplied by a healthcare facility.

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<sup>1</sup> The projected useful life of a medical device may be based on technical, legal, commercial or other considerations. Product owners 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.

# HEALTH SCIENCES AUTHORITY

Health Products Regulation Group  
Blood Services Group  
Applied Sciences Group

[www.hsa.gov.sg](http://www.hsa.gov.sg)

## Contact Officers:

Medical Devices Branch  
Pre-marketing Cluster  
Health Products Regulation Group  
Health Sciences Authority

11 Biopolis Way, #11-03 Helios  
Singapore 138667  
[www.hsa.gov.sg](http://www.hsa.gov.sg)  
**Email:** [hsa\\_md\\_info@hsa.gov.sg](mailto:hsa_md_info@hsa.gov.sg)

