

醫療儀器的規管

*Regulation of*  
**Medical Devices**

**Guidance Notes for Listing of Importers of Medical Devices**

Guidance Notes: GN-07



中華人民共和國

香港特別行政區政府衛生署

Department of Health

The Government of the Hong Kong Special Administrative Region  
of the People's Republic of China

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## **1. Introduction**

Recognizing that importers of medical devices have an important role to play in the medical device vigilance system, the Medical Device Control Office (MDCO) maintains a List of Importers under the Medical Device Administrative Control System (MDACS). Importers of medical devices may apply to be included on the List, regardless of whether the devices they import are listed products or not. Application is entirely on a voluntary basis. The listed importer has vigilance related obligations to observe for the products that it imports, whether the products are listed or not.

## **2. Definitions**

For the purpose of this booklet, the definitions given in the Guidance Notes GN-00 (*Definitions and Abbreviations for Medical Device Administrative Control System*) apply, together with the following.

2.1 Importer means a legal or natural person who brings or causes to be brought into Hong Kong any medical devices falling within the scope of the MDACS<sup>1</sup> for distribution or use in Hong Kong but does not include any person who is employed or engaged by such person to carry such products into Hong Kong.

## **3. Application Procedures**

The applicant need only complete the application form MD-IP (Appendix 1) and send it to the MDCO together with the following documents:

- (i) Where the applicant is a body corporate or partnership, documentary proof of its body corporate or partnership status (a copy of a relevant business registration certificate is acceptable as such proof). Where the applicant is an individual, evidence of his/her identity, including a copy of the applicant's HKID card, or a copy of the main information page(s) of the applicant's passport.
- (ii) A copy of the documented procedures as required in Sec. 4.1.

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<sup>1</sup> See *Overview of the Medical Device Administrative Control System (Guidance Notes GN-01)*

Provided the application form is duly completed and all the required documents are submitted together with the application, it will take around 8 weeks to complete processing of the application. Please note that a listed importer must have a Hong Kong address and this address must be entered in the application form.

#### **4. Obligations of Listed Importers**

##### **4.1 Establishment of Procedures**

The listed importer shall maintain the distribution records for the products it imports. The distribution records shall be retained for a period of time at least equivalent to the service life of the said products as specified by the manufacturer, but not less than seven years from the date of distribution by the listed importer. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of distribution records. For the products that it imports with a view to distribution or use in Hong Kong, the listed importer shall establish in conjunction with the respective Local Responsible Persons (LRPs), or manufacturers if there is no LRP, the procedures (especially the procedures in respect of the interface between the listed importer and the LRP or manufacturer if there is no LRP) to follow in the following circumstances:

- (i) when the listed importer receives complaints about any of the products;
- (ii) when advisory notices (recall notices, hazard alerts, etc.) affecting any of the products are issued by manufacturers or LRPs;
- (iii) when a reportable or potentially reportable adverse incident as defined in Guidance Notes GN-00 (*Definitions and Abbreviations for Medical Device Administrative Control System*) involving any of the products has come to the attention of the listed importer. The listed importer is required to seek the consent of the reporting party to refer the reportable adverse incident to the Local Responsible Person (or the manufacturer and the MDCO if there is no LRP). If the reporting party does not consent, the listed importer should ask the reporting party to report the adverse incident directly to the Local Responsible Person (or the manufacturer and the MDCO if there is no LRP). Please refer to the

*Guidance Notes for Adverse Incident Reporting by Local Responsible Persons (GN-03)* for details about reportable adverse incidents.

A copy of the documented procedures shall be submitted together with the completed application form. A sample procedure is given in Appendix 2 for illustrative purpose only and the listed importer must establish its own procedures taking account of the workflow, operations, organization structure and needs of its own organization.

#### 4.2 Making Distribution Records etc. Available for Inspection

Upon the request from the MDCO, the listed importer shall make available to the MDCO for inspection the distribution records and other documents maintained by the listed importer.

#### 4.3 Requirements in Respect of Advertisement, Promotional Materials etc.

4.3.1 Where any document, statement, information, claim, advertisement, promotional material (or any other communication by any means) published to the public, customers or potential customers includes any representation that the importer is a listed importer, or that the importer is in compliance with the MDACS requirements on listed importers, it shall at the same time

- (1) include a statement to the effect that the listing of an importer carries no implication that its medical device products are listed, and
- (2) clearly state whether any of the medical devices presented in the same article are listed under the MDACS or not.

4.3.2 Where the representation that the importer is a listed importer, or that the importer is in compliance with the MDACS requirements on listed importers, is in writing, then the statements required by 4.3.1(1) and (2) above shall be in the same format (in terms of font size, colour, etc) as the aforesaid representation.

### **5. Other Obligations**

Both during the application process and after its application is approved, the applicant/listed importer shall notify the MDCO of any changes to the information submitted. The MDCO has the discretion to request the applicant/listed importer to

produce documentary evidence of the change so notified. The applicant/listed Importer shall answer MDCO's enquiries as soon as possible, but no later than three working days.

## **6. Administrative Provisions**

### **6.1 Validity of Approval**

If an application for inclusion on the List of Importers is approved, (subject to section 6.4 below) the applicant will be included on the List for two years. The listed importer may apply for renewal of his current inclusion on the List of Importers not less than three months before the expiry of its current inclusion on the List of Importers. If its current inclusion on the List of Importers expires prior to the MDCO's determination of its application for renewal, its current inclusion shall remain in effect until the determination of its renewal application by the MDCO.

### **6.2 Fees**

No fee will be charged by the Government for the application or in relation to the inclusion of an importer's name on the List of Importers.

### **6.3 Undertaking by Applicant**

The applicant shall, on the terms set out in the Undertaking in the Application Form, undertake inter alia to indemnify the Government of the Hong Kong Special Administrative Region against any loss or claim that flows from any of the following: any act or default of the applicant, any defective design of the medical device products of the applicant, any defect in such products, and any information supplied by the applicant to the Government. The MDCO will only proceed with the processing of the application if, and only if, the Undertaking in the application form has been duly completed and signed by or on behalf of the applicant.

### **6.4 Delisting of Importers**

An importer on the List of Importers may be delisted or removed from the List if any of the following circumstances arises:

- (i) (in case the listed importer is a body corporate or a partnership) the listed importer has been wound up, dissolved or otherwise has ceased to exist, or (in case the listed Importer is an individual) the listed importer has died;

- (ii) the delisting is requested by the listed importer;
- (iii) the listed importer fails to comply with the MDACS requirements including but not limited to those stipulated in Sections 4 and 5;
- (iv) the listed importer does not address or adequately address a situation that gives rise or that might give rise to a hazard of its medical device products or to a public health or public safety concern; or
- (v) the MDCO considers the delisting necessary for the public health or safety considerations.

#### 6.5 The List of Importers

For each listed importer the entries on the List may include:

- (i) the name, telephone number and address of the importer.
- (ii) the Listed Importer Number assigned to the importer

The List of Importers will be publicly accessible.

#### 6.6 Exclusion

A person who imports medical devices for use exclusively in the treatment or care of himself, his immediate family members, relatives or dependents is excluded from the scope of these listing provisions.

#### 6.7 Appeal against Rejection of an Application or Decision to Delist a Listed Importer

Any appeal against a decision to reject of an application for inclusion or renewal of inclusion on the List of Importers or to delist a listed importer must be lodged by the applicant/listed Importer within 4 weeks of receiving the notification of decision. To lodge the appeal the applicant/listed importer must write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Control Office, stating its grounds of appeal. An appeal lodged after the time limit will not be considered.

### **7. Points to Note**

The inclusion of an individual, person, company or partnership on the List of Importers is not endorsement in support or any recommendation whatsoever of that individual, person, company or partnership as an importer of medical devices by the Department of Health. Nor does the inclusion imply that the import of medical devices by that individual, person, company or partnership is in compliance with

the applicable laws or has the necessary regulatory approvals. The responsibility for ensuring the legality of the import rests with the importer.

## **8. Enquiries**

Enquiries concerning this booklet and the MDACS should be directed to:

Medical Device Control Office,  
Department of Health.

Facsimile number: 3157 1286

Telephone number: 2961 8788

E-mail address: [mdco@dh.gov.hk](mailto:mdco@dh.gov.hk)



**Medical Device Control Office  
Department of Health**

**Medical Device Administrative Control System -  
Application for Inclusion on the List of Importers**

*For official use only*

Date Received: \_\_\_\_\_ Application No.: \_\_\_\_\_ Officer: \_\_\_\_\_

Date Approved/Rejected: \_\_\_\_\_ Importer No. \_\_\_\_\_

Remarks: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Particulars of Applicant			Encl.
1001	Name	<i>in English</i>	
		<i>in Chinese</i>	
1002	Business Name (if any) (see Note 1)	<i>in English</i>	
		<i>in Chinese</i>	
1003	Address in Hong Kong	<i>in English</i>	
		<i>in Chinese</i>	
1004	Status and Identity (Please provide documentary proof; see Note 2)	<input type="checkbox"/> Body corporate <input type="checkbox"/> Partnership <input type="checkbox"/> Individual (Please give below your HKID Card no. or, if you do not hold a HKID Card, your passport no.) <input type="checkbox"/> HKID Card No. _____ <input type="checkbox"/> Passport No. _____	(A1) <input type="checkbox"/>
1005	Contact Information	Contact Person (Name a contact person unless applicant is an individual)	
		Name	
		Position	
		Telephone	
		Fax	
		E-mail	
	Website		

<b>Applicant's Intent to Import Medical Devices</b>		
2001	<p><i>Please tick against the description that applies to your case:</i></p> <p><input type="checkbox"/> The import intended or envisaged will be in the name of or for the purpose of a business that the applicant carries on. The business has been registered with the business registration number _____ _____.</p> <p><i>(Please enclose a copy of the business registration certificate. If your business name as appears on the certificate (see Note 1) is not the same as your name given in item 1001, please provide documentary evidence that you carry on that business, (e.g. an extract of the relevant information from the business register). If your application is successful, you will be listed on the List of Importers by your business name as appears on the business registration certificate.)</i></p> <p><input type="checkbox"/> The applicant is a body corporate not carrying on a business and has intent to import medical devices.</p> <p><input type="checkbox"/> The applicant is an individual with intent to import medical devices otherwise than for the purpose of a business he/she carries on. It is not the intention of the applicant that the devices are for use exclusively in the treatment or care of himself/herself, his/her immediate family members, relatives or dependents (see Clause 6.6 of the Guidance Notes GN-07 on Exclusion)</p>	(A2) <input type="checkbox"/>
2002	<p>Medical devices intended to be imported fall within the following categories:</p> <p><input type="checkbox"/> devices for general medical use</p> <p><input type="checkbox"/> devices for use in the medical specialties of _____ _____</p>	
2003	<p>Medical devices intended to be imported are of the following countries of origin: _____ _____</p>	

<b>Quality Management and Vigilance Practices</b>		
3001	<p>The applicant's established procedures in respect of medical devices that it imports include documented procedures on:</p> <p><input type="checkbox"/> complaint handling</p> <p><input type="checkbox"/> adverse incident handling</p> <p><input type="checkbox"/> handling advisory notices (recall notices, hazard alerts etc.) issued by manufacturers and Local Responsible Persons</p> <p><input type="checkbox"/> maintenance of distribution records</p>	<p><b>(A3)</b></p> <input type="checkbox"/>
3002	<p>The applicant has in place</p> <p><input type="checkbox"/> a quality management system having been certified by a third party certification body, namely, _____, _____, and which has incorporated all/part of the established procedures above mentioned (Please enclose a copy of the certificate with the completed application form).</p> <p><input type="checkbox"/> a quality management system incorporating all/part of the established procedures above mentioned. The system has not been independently certified.</p> <p><input type="checkbox"/> no quality management system yet.</p>	<p><b>(A4)</b></p> <input type="checkbox"/>
<b>Notes</b>		
<ol style="list-style-type: none"> <li>The business name given in item 1002 must be the same as the Name of Business that appears on your business registration certificate.</li> <li>An applicant who is a body corporate or a partnership must provide documentary proof of its body corporate or partnership status (a copy of a relevant business registration certificate is acceptable as such proof). If the applicant is an individual, the documentary proof must include (if the applicant holds a HKID card) a copy of the applicant's HKID card or (if the applicant does not hold a HKID card) a copy of the main information page(s) of the applicant's passport.</li> </ol>		

## Undertaking by Applicant

Date: \_\_\_\_\_

To the Government of the Hong Kong Special Administrative Region (hereinafter “the Government”):

I/We have read the latest editions of the Guidance Notes GN-01 (with all appendices) and GN-07 (with all appendices) issued by the Department of Health in relation to the Medical Device Administration Control System (MDACS) and the listing of importers of medical devices thereunder.

In consideration of the promise of the Government in the Guidance Notes GN-07 to proceed with the processing of this application under the MDACS, I/we\* \_\_\_\_\_

[name and address of the Applicant], undertake, acknowledge and agree in favour of the Government as follows:

1. To the maximum extent permitted by law I/we agree to exempt, relieve, exonerate, indemnify and hold harmless, and to keep indemnified and harmless, as the case may be, the Government from and/or against any and all losses, claims, demands and proceedings (including but not limited to all costs, charges and expenses) whatsoever and howsoever suffered or incurred by, or made or issued against, the Government, as the case may be, by any third party in respect of any loss of or damage to any property or injury to or death of any person arising out of and/or relating and/or incidental to:
  - a. any act, neglect or default on my/our part or on the part of my/our employees or agents;
  - b. any defect in the design, material, workmanship or installation in relation to my/our medical device product or products;
  - c. any use of any of the information supplied by me/us or my/our employees or agents in relation to this application or to my/our medical device product or products, whether or not such information has materially contributed to the inclusion of the applicant on the List of Importers or the inclusion of any of my/our product or products on the List of Medical Devices and whether or not such information is misleading, wrong or inaccurate.
2. I/We also agree and accept that:
  - a. the Government, its employees or agents shall not be liable to me/us for any loss of or damage to property caused by the act, default or neglect of the Government or its employees or agents in the processing of my/our application, the inclusion or non-inclusion of any of my/our information and/or product or products on the Lists being maintained under the MDACS (including but not limited to the List of Importers and the List of Medical Devices) or any cause whatsoever arising out of or in connection with the implementation and management of the MDACS;
  - b. neither the Government nor any of its employees or agents makes any representation, statement, warranty or guarantee, express or implied, that any of my/our products (including any spares or replacement parts), whether or not they are included on the List of Medical Devices, are of merchantable quality or are fit for the purposes for which they are commonly bought, used and/or applied and that the spares or replacement parts are readily available.
3. I/We undertake that the information contained in my/our application is true and correct and that my/our medical device product or products (including any spares or replacement parts) are of merchantable quality and are fit for the purposes for which they are commonly bought, used and/or applied.
4. I/We fully understand and agree that any future changes or additions to the requirements of the MDACS can be imposed by the Department of Health without prior notice. I/We hereby undertake to comply with the latest requirements of the MDACS that are in force.
5. I/We undertake that I/we have neither amended any wording in this form, nor otherwise altered the form in any material manner, apart from filling in the appropriate blanks / boxes.

Each of the provisions of this Undertaking is severable and distinct from the others and, if one or more of such provisions or any part thereof is or becomes illegal, invalid or unenforceable, the legality and enforceability of the remainder of this Undertaking shall not be affected or impaired in any way.

The Government shall be entitled to enforce any or all of its rights under this Undertaking.

Form MD-IP (2007 Edition)

This Undertaking shall be governed by and construed according to the laws of Hong Kong and the parties irrevocably submit to the non-exclusive jurisdiction of the Courts of Hong Kong.

As witness whereof, this Undertaking has been entered into the day, month and year first above written

SIGNED BY )  
 )  
\_\_\_\_\_ (name of Applicant or its representative\*) )  
\_\_\_\_\_ (position) )  
 )  
[for and on behalf of )  
 )  
\_\_\_\_\_ (name of Applicant) )  
(who hereby warrant(s) that the signatory above has )  
the authority to bind the above firm and the partners )  
therein for the time being / the above company\* to )  
this Undertaking)]# )  
 )  
in the presence of )  
 )  
\_\_\_\_\_ (name) )  
 )  
\_\_\_\_\_ (address) )

\* Delete where appropriate

# Delete if the applicant is an individual

## **Personal Data (Privacy) Ordinance**

### **Statement of Purposes**

1. Purpose of Collection

The personal data that you provide the Department of Health (“the Department”) in connection with the Medical Device Administrative Control System (MDACS) or with this application in particular will be used by the Department for the management and implementation of the MDACS.

2. Class of Transferees

The personal data are mainly for use by the Department, but may also be disclosed to other Government bureaux/departments or other parties for the purpose stated in para. 1 above or for the purpose of a related matter. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where it is allowed under the Personal Data (Privacy) Ordinance.

3. Access to Personal Data

You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

4. Enquiries

Enquiries in relation to the personal data, including requests for making access or corrections to the data, should be addressed to the Medical Device Control Office, Department of Health (facsimile number 3157 1286; telephone number 2961 8788, e-mail address: mdco@dh.gov.hk). Please quote your application number when you make the enquiries.

### A Sample Procedure of An Importer's Vigilance System

#### 1. Purpose

The purpose of this document is to set out the procedures to follow in the following circumstances:

- (a) when a complaint is received about a medical device product imported by this Company;
- (b) when it has come to the attention of this Company that an adverse incident involving one or more medical device products imported by this Company has happened;
- (c) when the manufacturer of a medical device product imported by this Company, or the Local Responsible Person that the manufacturer designates, has issued an advisory notice in respect of the product.

#### 2. Scope

The procedures apply to all medical device products imported by this Company. The models of these products are listed in Annex 1.

#### 3. Reference Documents

- 3.1 Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.
- 3.2 Guidance Notes for Adverse Incident Reporting by Local Responsible Persons. Guidance Notes GN-03.
- 3.3 Guidance Notes for Listing of Importers of Medical Devices. Guidance Notes GN-07.
- 3.4 SOP-15 – General Procedures for Handling Complaints
- 3.5 SOP-16 – Handling of Customer Properties

#### 4. Definitions and Abbreviations

- 4.1 **Advisory notice.** It is a notice which the manufacturer of a medical device product or the Local Responsible Person that it designates issues after the product is placed on market, in order to convey supplementary or updated information about the product (supplementary advice regarding use of the product, warning about a hazard, etc.) or notify actions that should be taken in relation to the product (recall, field modifications, destruction, etc.).

4.2 **Reportable adverse incident.** An incident which is reportable to the Medical Device Control Office under the Medical Device Administrative Control System. The reportability criteria have been set out in sections 4 and 5 of the Reference Document 3.2. For example, subject to certain exceptions, an incident involving one or more listed medical device products is reportable if the incident involves deaths or serious injuries, or although no death or serious injury has occurred, death or serious injury will ensue if the incident recurs.

4.3 **Listed products.** The products listed under the Medical Device Administrative Control System.

4.4 **MDACS** is the acronym for “Medical Device Administrative Control System”.

4.5 **MDCO** is the acronym for “Medical Device Administrative Control System”.

4.6 **LRP** is the acronym for “Local Responsible Person”.

## 5. **Responsibilities**

5.1 The Manager (Medical Products) must ensure compliance with these procedures.

5.2 The Manager (Medical Products), in consultation with the Head of the Technical Services Department, may agree with the originator of an advisory notice (a manufacturer or an LRP) that certain actions related to the notice will be taken by this Company on behalf of the originator.

5.3 Where the Manager (Medical Products) agrees with the originator of an advisory notice that certain actions related to the notice will be taken by this Company on behalf of the originator, the Head of the Technical Services Department will be responsible for the taking of those actions.

## 6. **Procedures**

### 6.1 Handling of Complaints About Medical Device Products

The complaints must be handled in accordance with SOP-15 (Reference Document 3.4). (1) to (6) below are specific requirements that the staff handling complaints about medical device products must observe, in addition to the requirements of SOP-15:

- (1) Details of the complaints, including any correspondence related to the complaints, must be filed or recorded on the File MD001.3 (“Medical Device Product Related Complaints and Incidents”).
- (2) The staff member who receives the complaint must, as quickly as possible (within 2 working days unless with justifications) and as far as he/she can, gather the following information, record it on the form CH001 and file the form onto the File MD001.3:
  - (a) Date and time of the complaint
  - (b) Name of the complainant
  - (c) Contact information of the complainant (if this information is not on the Central Address Book of Customers)
  - (d) Make, model, serial number, batch number, and other identifiers (if any), of the product
  - (e) Where the product is used. Who its user is.
  - (f) What the complaint is about (e.g. any concerns regarding product quality or design, details of any observed failure or malfunction of the product, any adverse consequences or possible adverse consequences of the failure or malfunction, any concerns regarding inadequacy of information given in the product labeling, etc.) Where the complaint discloses an adverse incident involving the product, see also (3) below.
  - (g) Any suggestions or requests by the complainant
- (3) Where the complaint discloses an adverse incident, the staff member must gather and record information according to section 6.2(2). The completed MD001 form (the pink form) must then be attached to and filed together with the CH001 form.
- (4) Care must be taken not to make any unauthorized disclosure of confidential patient information to any party. The general principle is that such confidential information must not be disclosed to any outside party, except where the written, voluntary and informed consent of the patient (if he or she is an adult with capacity to give the consent) or his/her personal representative (guardian, parent, or other person authorized to make medical decisions for the patient) has been obtained.

- (5) The staff member who receives the complaint must promptly bring it to the attention of the Manager (Medical Products) without having to wait for the completion of the form CH001 (and the MD001 if the complaint discloses an adverse incident). The complaint may raise issues relevant, and/or issues not relevant, to the manufacturer. The Manager (Medical Products) must review all relevant information to identify those issues. The Manager (Medical Products) must follow up the issues as follows:

Issues	Actions
Issue of relevance to the manufacturer. (N.B. Where the complaint discloses an adverse incident, the incident must always be treated as an issue of relevance to the manufacturer.)	<ul style="list-style-type: none"> <li>● The Manager (Medical Products) must promptly in writing refer the issues to the LRP (if the product is a listed product), or to the manufacturer (if otherwise) and, where necessary, follow up with the manufacturer or the LRP. Depending on the urgency of the complaint he may, at his discretion, refer the issues to the manufacturer or LRP only after the completed CH001 form (and the completed MD001 form if the complaint discloses an adverse incident) has been made available to him. To the extent that confidentiality is not breached (see also (4) above), the Manager (Medical Products) must provide the manufacturer or LRP with as much information about the complaint as possible, with a view to enabling the manufacturer or LRP to pursue an investigation of the complaint.</li> <li>● Where the complaint discloses an adverse incident, the procedures in section 6.2 also apply.</li> </ul>
Issue of no relevance to the manufacturer (e.g. mishandling on the part of this Company's contractor in the course of the transportation of the product from this Company's warehouse to the end-users)	The Manager (Medical Products) must follow up the issues in accordance with SOP-15 (Reference Document 3.4). If he would have the manufacturer to assist in handling one of those issues he may also approach the manufacturer or the LRP accordingly.

- (6) Any staff member who handles customer properties in the course of the above procedures must ensure compliance with SOP-16.

## 6.2 Handling of Adverse Incidents

- (1) The general principle is that, once it has come to the attention of this Company, an adverse incident involving a medical device product imported by this Company must be promptly referred to the LRP (if the product is a listed product) or to the manufacturer (if otherwise), unless (i) it is clear that the LRP or manufacturer is fully aware of the incident and (ii) the incident is not the subject or part of the subject of a complaint. The principle applies regardless whether the incident is reportable under the MDACS, or whether it is not certain the product has actually contributed to the incident. When referring the incident to the manufacturer or LRP, care must be taken not to make any unauthorized disclosure of confidential patient information to the manufacturer or LRP. In general, such confidential information must not be disclosed to any outside party, except where the written, voluntary and informed consent of the patient (if he or she is an adult with capacity to give the consent) or his/her personal representative (guardian, parent, or other person authorized to make medical decisions for the patient) has been obtained.
- (2) A complaint may disclose an adverse incident. But an adverse incident may also come to the attention of this Company in other ways. On becoming aware of an adverse incident involving a medical device product imported by this Company, a staff member must gather information and bring the incident to the attention of the Manager (Medical Products) in accordance with the procedures (3) and (4) below.
- (3) The staff member who becomes aware of an adverse incident must, as quickly as possible (within 2 working days unless with justifications) and as far as he/she can, gather the following information, record it on the form MD001 (the pink form) and file the form onto the File MD001.3:
  - (a) Date and time of the incident
  - (b) Make, model, serial number, batch number, and other identifiers (if any), of the product involved
  - (c) Where the product was used and who its user was at the time of the incident.
  - (d) Contact information of the clinicians, healthcare facilities, or organizations who used the product
  - (e) Contact information of whomever the manufacturer or the LRP may contact for further information of the incident

- (f) What happened in the incident. Where appropriate, get hold of photos of the product, its fault-log, evidence of its settings at the time of the incident, etc., (especially if the information might help the manufacturer or LRP pursue its investigation) and file them as attachments to the form MD001
  - (g) Any other information that might help the manufacturer or LRP pursue its investigation
- (4) The staff member who becomes aware of an adverse incident involving a medical device product imported by this Company must promptly bring it to the attention of the Manager (Medical Products) without having to wait for the completion of the MD001 form. The Manager (Medical Products) must promptly in writing refer the incident to the LRP (if the product is a listed product), or to the manufacturer (if otherwise), except if (i) he is sure that the LRP or the manufacturer is fully aware of the incident and (ii) the incident is not a subject or part of a subject of a complaint. The Manager (Medical Products) must try to be as helpful to the manufacturer or LRP as possible. To the extent that confidentiality is not breached, the Manager (Medical Products) should share the information he has about the incident with the manufacturer or LRP, with a view to enabling the manufacturer or LRP to pursue an investigation of the incident. Depending on the criticality of the incident and/or its implications the Manager (Medical Products) may, at his discretion, refer the incident to the manufacturer or LRP only after the completed MD001 form has been made available to him. It will be incumbent upon the LRP or the manufacturer to decide, taking account of the relevant regulations, whether the incident is to be reported to a regulatory authority. Where necessary, the Manager (Medical Products) must, after referral of the incident, follow up with the manufacturer or the LRP, or provide them with further assistance, especially in liaison with this Company's customers.
- (5) Any staff member who handles customer properties in the course of the above procedures must ensure compliance with SOP-16.

### 6.3 Handling of Advisory Notices

- (1) Staff members who have enquiries about advisory notices affecting products imported by this Company may direct their enquiries to the respective LRPs or manufacturers. The medical device products imported by this Company, as well as the corresponding manufacturers and LRPs, are listed in Annex 1. The contact information of these manufacturers and LRPs is given in Annex 2.

(2) On receiving an advisory notice from its originator (either a manufacturer or an LRP) the Manager (Medical Products) must:

- (a) have the notice faxed to the MDCO (fax. no. 3157 1286); and
- (b) arrange dissemination of the notice to this Company's customers as intended by the originator. The distribution records being kept in the file MD001.1 ("Distribution Records for Medical Device Products") may be useful for this purpose.

On completion of (a) and (b) the Manager (Medical Products) must notify the originator of the notice accordingly.

(3) Where the originator of the notice and the Manager (Medical Products) agrees that this Company is to take certain actions related to the notice on behalf of the originator, the Manager (Medical Products) must arrange with the Head of the Technical Services Department for the Department to take the actions. If the actions entail any handling of customer properties, this must conform to the requirements in SOP-16. The Head of the Technical Services Department must keep the Manager (Medical Products) and the originator of the notice updated of the progress of the actions.

(4) All records related to advisory notices must be filed onto MD001.4.

## 7. Records

Records related to	Must be Filed in	Retention Period
medical device product related complaints and adverse incidents	MD001.3	Records relating to a complaint or an incident must be retained for at least the lifetime of the device in question (as defined by its manufacturer) and in any case for not less than six years from the date of the last record relating to that complaint or incident
advisory notices	MD001.4	Records relating to an advisory notice must be retained for the lifetime of the device in question (as defined by its manufacturer) and in any case for not less than six years from the date of the last record relating to that advisory notice

## 8. Annexes

Annex 1 List of Medical Device Products Imported

Annex 2 Contact Information of Medical Device Manufacturers and LRPs

**Annex 1**

**Medical Device Products Imported**

	Make	Model	Product Description	Manufacturer	Listed Product?	LRP
1.	RATH	12	Infusion pump, general purpose	RATH Inc.	Yes	ABC Ltd
2.	RATH	13A	Infusion pump, general purpose	RATH Inc.	Yes	ABC Ltd
3.	KAN	8891	Infusion pump, general purpose	KAN Co. Ltd	No	-

**Annex 2**

**Contact Information of Medical Device Manufacturers and Local Responsible Persons**

Company	Manufacturer?	LRP?	Contact information
ABC Ltd	No	Yes	Mr T.M. Chan, Manager, ABC Ltd., 79/F, 23 Merry Road, Central, Hong Kong Tel. (852) 555 5555 Fax. (852) 555 6666 e-mail: smchan@abcltd.com.hk
KAN Co. Ltd	Yes	No	Mr S.M. Chan, Quality Manager, KAN Co. Ltd., 80/F, 23 Merry Road, Central, Hong Kong Tel. (852) 5555 5533 Fax. (852) 5555 6699 e-mail: sm.chan@kanco.com.hk
RATH Inc.	Yes	No	Mr David Smith, Quality Assurance Manager, RATH Inc., 1123 Temple Avenue., Goodsburg, MD 22222, USA Tel. +1 555 555 5555 Fax. +1 555 555 6666 e-mail: david.smith@rathinc.com