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| MEDICAL DEVICE RECALL REPORT FORMThis reporting form is to be used by medical device manufacturers, authorised representatives, or distributors, to report any recalled medical device in the market. This form must be completed and submitted to Medical Device Authority (MDA).MEDICAL DEVICE AUTHORITY, Ministry of Health Malaysia, Level 6, Prima 9, Prima Avenue II, Block 3547, Persiaran APEC, 63000 Cyberjaya, Selangor, MALAYSIA. Email : recall\_enquiry@mdb.gov.my Tel: 03-8230 0300Fax: 03-8230 0200 |

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| Medical Device Recall Report Form |

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| MDA Recall Reference Number | |  | | | | | | | |
| Type of Recall | | Voluntary Recall Mandatory Recall | | | | | | | |
| Type of Report | | Notification Preliminary Report (Report no. :\_\_\_\_\_\_) Final Report | | | | | | | |
| Establishment Details | | | | | | | | | |
| Name of establishment | |  | | | | | | | |
| Establishment address | |  | | | | | | | |
| MDA Establishment License No. | |  | | | | | | | |
| Contact person name | |  | | | | | | | |
| Job title | |  | | | | | | | |
| Tel No. | |  | | | | Fax No. | |  | |
| Email Address | |  | | | | | | | |
| Device Details | | | | | | | | | |
| Affected Device Name | |  | | | | | | | |
| Device intended use | |  | | | | | | | |
| Device category | | Non-invasive device Invasive device Active device | | | Implantable device IVD device Other (specify): | | | | |
| MDA Device Registration No. | |  | | | | | | | |
| Table of Device Details | | | | | | | | | |
| Product Number/ Catalogue Number | Lot/Serial Number | | Manufacturing/  Distribution Date | Expiration Date | | | UDI Code  *(if applicable)* | | Quantity |
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| (If the list is more, please provide an attachment) | | | | | | | | | |
| Accessories/Associated Devices affected *(if any)* | |  | | | | | | | |
| Manufacturer Name | |  | | | | | | | |
| Manufacturer Address | |  | | | | | | | |
| Manufacturer contact details | |  | | | | | | | |
| Notification Report Section: Recall Information | | | | | | | | | |
| Did the Recall arise due to an adverse incident?*(Please select only one)* | | Yes  No | | | | | | | |
| If yes, what is the category of adverse incident?*(Please select all applicable)* | | Serious Public Health Threat Death Serious Injury Non-serious Injury | | | | | | | |
| Did this adverse incident occur in Malaysia? | | Yes  No | | | | | | | |
| Has the adverse event been reported to MDA?(Please select only one) | | Yes (Adverse Incident ref. no.: \_\_\_\_\_\_\_\_) No | | | | | | | |
| Reason for Recall | |  | | | | | | | |
| Risk to Health | |  | | | | | | | |
| Recall Class | | Class I : High Risk Class II : Moderate Risk Class III : Low Risk | | | | | | | |
| Recall Strategy and action to be taken | |  | | | | | | | |
| Action to be taken by the Customer/User | |  | | | | | | | |
| Date of Recall initiation*(Expected date of first notification will be sent to all affected customers)* | |  | | | | | | | |
| Expected date to submit preliminary report to MDA | |  | | | | | | | |
| Attachments | | A copy of the Recall communication to affected customers Table of affected device details Device brochure A copy of Recall procedure | | | | | | | |

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| Preliminary Report Section: Follow-up Recall Information | |
| Do Recall communication has been sent to all consignees? | Yes (Date sent: \_\_\_\_\_\_\_\_\_\_\_\_\_(dd/mm/yyyy)) No (Expected date to be sent: \_\_\_\_\_\_\_\_\_\_\_\_\_(dd/mm/yyyy)) |
| Total number of affected units supplied to each consignee |  |
| No. of affected units and the period that affected units are manufactured/imported/distributed in Malaysia | Manufactured in Malaysia: \_\_\_\_\_\_unitsPeriod: \_\_\_\_\_\_\_\_ (mm/yyyy) to \_\_\_\_\_\_\_\_ (mm/yyyy) |
| Imported into Malaysia: \_\_\_\_\_\_\_unitsPeriod: \_\_\_\_\_\_\_\_ (mm/yyyy) to \_\_\_\_\_\_\_\_ (mm/yyyy) |
| Supplied in Malaysia: \_\_\_\_\_\_\_unitsPeriod: \_\_\_\_\_\_\_\_ (mm/yyyy) to \_\_\_\_\_\_\_\_ (mm/yyyy) |
| Expected shipments to Malaysia: \_\_\_\_\_\_unitsExpected date of arrival: \_\_\_\_\_\_\_\_\_\_(mm/yyyy) |
| Countries to which this Recall has been reported *(if any)* |  |
| Date of commencement of Recall by Manufacturer(dd/mm/yyyy) |  |
| Date of commencement of Recall in Malaysia(dd/mm/yyyy) |  |
| Proposed date of completion of Recall in Malaysia(dd/mm/yyyy) |  |
| Expected date to submit final report to MDA |  |
| The method of quarantine and segregation for the recalled products |  |
| Attachments | List of hospital/customer/user with number of affected device in their storage Copy of acknowledgment receipt on the product recall by the affected customers Shipment history of the affected device into Malaysia Picture of quarantine/segregation area and tagging *(if applicable)* |
| Final Report Section: Final Recall Information | |
| Do Recall exercise completed? | Yes (Date : \_\_\_\_\_\_\_\_\_\_\_\_\_(dd/mm/yyyy)) No, *(justification)*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Summary results of the recall effectiveness check and its method |  |
| Status of the device | Return all the affected stocks to the manufacturer(Date sent: \_\_\_\_\_\_\_\_\_\_(dd/mm/yyyy)) Disposal (Date disposed: \_\_\_\_\_\_\_\_\_\_\_\_\_(dd/mm/yyyy)) Totally consumed Totally unidentified *(justify)*:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Other *(specify)*:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| The method of disposal for the recalled products |  |
| Final risk evaluation  *(if different from the initial risk evaluation)* |  |
| Proposed action(s) to prevent recurrence of the problem |  |

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| **Table of Final Device Status** | | | | | | | | |
| Product / Catalogue Number | Lot/ Serial Number | Total affected unit | Quantity remaining in warehouse | Quantity distributed to customer | Quantity Recalled | Quantity consumed by customer | Quantity unidentified | Quantity returned to manufacturer or disposed |
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| (If the list is more, please provide an attachment) | | | | | | | | |
| Justification on total quantity of unidentified device *(if applicable)* | | |  | | | | | |
| Attachments | | | Table of Final Device Status  Health Risk Assessment Report  Report on action(s) to prevent recurrence of the problem *(if applicable)*  Evidence of returning affected device to the manufacturer *(if applicable)*  Evidence of disposal process *(if applicable)* | | | | | |
| Attestation | | | | | | | | |
| I attest that the information submitted is true and correct.  Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Reporting Person : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of this report : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (dd/mm/yyyy)  Company stamp : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | |