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| MEDICAL DEVICE FIELD CORRECTIVE ACTIONREPORT FORMThis reporting form is to be used by establishment to report any field corrective action medical device in the market. This form and other related attachments must be completed and submitted to Medical Device Authority (MDA).MEDICAL DEVICE AUTHORITYMinistry of Health MalaysiaLevel 6, Prima 9, Prima Avenue II, Block 3547, Persiaran APEC, Cyberjaya, Selangor, MALAYSIA. Email : [Notice\_FCA@mda.gov.my](mailto:Notice_FCA@mda.gov.my) Tel: 03-8230 0300 Fax: 03-8230 0200 | | | | | | | |
| **FIELD CORRECTIVE ACTION REPORT FORM** | | | | | | | |
| Type of Field Corrective Action (FCA) | | * Return * Modification | * Exchange * Destruction | | * Specific Advice | | |
| Type of Report  (Report No.: ................................) | | * Initial/Preliminary * Follow Up | * Final | | | | |
| **Establishment Particulars** | | | | | | | |
| Name of company | |  | | | | | |
| Company address | |  | | | | | |
| Contact person name | |  | | | | | |
| Job title | |  | | | | | |
| Tel No. | |  | | Fax No. | |  | |
| Email Address | |  | | | | | |
| **Medical Device Details** | | | | | | | |
| Medical device name | |  | | | | | |
| Medical device intended use | |  | | | | | |
| MDA Registration No.  *(if device is registered)* | |  | | | | | |
| Model No. | |  | | | | | |
| Serial No. | |  | | | | | |
| Lot/Batch No. | |  | | | | | |
| Accessories/Associated medical devices affected *(if any)* | |  | | | | | |
| Manufacturer name | |  | | | | | |
| Manufacturer address | |  | | | | | |
| AR/Distributor/Importer and contact details | |  | | | | | |
| **FCA Information** | | | | | | | |
| Did the FCA arise due to an incident?  *(Please select only one)* | | * Yes * No | | | | | |
| If yes, what is the category of incident?  *(Please select all if applicable)* | | * Serious Public Health Threat * Death | | * Serious Injury * Non-serious Injury | | | |
| Did this incident occur in Malaysia? | | * Yes * No | | | | | |
| Has the incident been reported to MDA?  *(Please select only one)* | | * Yes (incident ref. no.: ........................) * No | | | | | |
| Evaluation of the risk associated with affected medical device (Health Hazard Evaluation Report) | |  | | | | | |
| Background information and reason for the FCA | |  | | | | | |
| FCA plan and action to be taken (corrective action) | |  | | | | | |
| Advice on actions to be taken by the distributor and the user | |  | | | | | |
| Has the FCA been  communicated to all consignees? | | * Yes (Date sent: ...........................(dd/mm/yyyy)) * No (Expected date to be sent: ..........................(dd/mm/yyyy)) | | | | | |
| Number and name of affected units supplied to each consignee | |  | | | | | |
| No. of affected units and the period that affected units are manufactured/imported/supplied  in Malaysia | | Manufactured in Malaysia: .............  Period: .................... (mm/yyyy) to ..................... (mm/yyyy) | | | | | |
| Imported into Malaysia: .................  Period: .................... (mm/yyyy) to ..................... (mm/yyyy) | | | | | |
| Supplied in Malaysia: .....................  Period: .................... (mm/yyyy) to ..................... (mm/yyyy) | | | | | |
| Expected shipments to Malaysia: ............  Expected date of arrival: .................... (mm/yyyy) | | | | | |
| Date of commencement of FCA by manufacturer | |  | | | | | |
| Date of commencement of FCA in Malaysia | |  | | | | | |
| Proposed date of completion of FCA in Malaysia | |  | | | | | |
| **Follow Up / Final report** | | | | | | | |
| FCA completed? | * Yes, Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_(dd/mm/yyyy) | | | | | | * No |
| Progress of FCA, together with reconciliation status and/or effectiveness check and  its method |  | | | | | | |
| Proposed action to prevent recurrence of the problem  (preventive action) |  | | | | | | |
| **Other Information** | | | | | | | |
|  | | | | | | | |

**I attest that the information submitted is true and correct.**

**Signature : ......................................................**

**Name of Reporting Person : ......................................................**

**Date of this report : ......................................................**

**Company stamp :**