**ATTACHMENT 1: INCIDENT REPORT FORM**

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| **▪ INCIDENT REPORT FORM ▪**

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| Date Completed:       |
| Date Received by Americares:       |
| Americares Case Number:       |

 | 88 Hamilton Avenue, Stamford, CT 06902(800) 486-4357 ▪ Fax (203) 327-5200 ▪ [www.Americares.org](http://www.americares.org) |

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| For Emergency or Adverse Event Reporting, call the Americares Adverse Event Hotline 203-658-9658 and fax and/or email the completed Americares Incident Report Form to the Americares Adverse Event Reporting Team at 203-327-5200, or adverseevents@americares.org  |

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| **I. Organization Contact Information Section** |
| **Organization Name:**       |
| **Address** | Street / PO Box:       |
| City:       | State/Province:       |
| Postal Code:       | Country:       |
| **Phone:**       | **Fax:**       |
| **Primary Contact Name:**       | **Title:**       |
| **Email Address:**       |
| **Phone:** | Home:       | Work:       | Mobile:       |
| **Alternate Contact Name:**       | **Title:**       |
| **Email Address:**       |
| **Phone:** | Home:       | Work:       | Mobile:       |
|  |  |
| **II. Product Incident Description Section** |
| **A.** | **Please identify what type of incident occurred:** |  |
|  | **[ ]** Adverse event  | [ ]  Product Quality Issue | [ ]  Product Use Error |  |
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| **B.** | **Please describe the situation details below:** |  |
|  | **Location of incident:** |  |
|  | **Date of incident:** | **Number of people affected:**  |  |
|  | **Description of Person(s) Affected (Include age, male/female, weight, etc):** \* Do not include actual names \*      |  |
|  | **Person(s) Pre-Existing Medical Condition(s):**       | **Person(s) Concomitant Medical Treatment(s):**       |  |
|  | **Detailed description of what occurred:**       |  |
|  | **Event Abated: After Use Stopped?** [ ]  Yes [ ]  No **After Dose Reduced?** [ ]  Yes [ ]  No [ ]  N/A |  |
|  | **Supporting Lab Tests and Dates:**       |  |
|  |  |  |
| **C.** | **Outcomes Attributed to Incident:** (Select all that apply) |  |
|  | [ ]  Congenital Anomaly / Birth Defect | [ ]  Hospitalization (initial or prolonged) |  |
|  | [ ]  Death (date – mm/dd/yy):       | [ ]  Life-threatening |  |
|  | [ ]  Disability or Permanent Damage | [ ]  Other Serious (Important Medical Events) |  |
|  | [ ]  Required Intervention to Prevent Permanent Impairment/Damage (Device) | [ ]  Illness/Symptoms |  |
|  |  |  |
| **D.** | **Please complete the following information regarding the product:** |  |
|  | **Suspected Product Name:** |  |  |
|  | **NDC Number (if available):** |  |  |
|  | **Product Dosage:** | **Dose:       Frequency:       Route:** |  |
|  | **Indication:**  |  |  |
| **Product Lot #:** |  |  |
|  | **Product Expiration Date:** |  |  |
|  | **Do you still have additional stocks of this item?**  | [ ]  Yes [ ]  No [ ]  Unknown [ ]  N/A |  |
|  | **Do your sub-recipients have stocks of this item?** | [ ]  Yes [ ]  No [ ]  Unknown [ ]  N/A |  |
|  | **\*If yes, please quarantine stocks at all locations and do not distribute additional items until this situation has been assessed.** |
| **E.** | **If Medical Device event, please complete the following information regarding the product:** |  |  |
|  | **Suspected Product Brand Name/Common Device Name:** |  |
|  | **Manufacturer Name:** | **City:** | **State:** |  |
| **Model# :       Lot# :       Serial# :       Catalogue# :       Expiration Date:** |  |
| **Operator of Device:** [ ]  Health Professional [ ]  Lay User/Patient [ ]  Other: (please explain)  |  |
| **If implanted, provide date:** |  |
| **Do you still have additional stocks of this item?** [ ]  Yes [ ]  No [ ]  Unknown [ ]  N/A |  |
| **Do your sub-recipients have stocks of this item?** [ ]  Yes [ ]  No [ ]  Unknown [ ]  N/A |  |
| **\*If yes, please quarantine stocks at all locations and do not distribute additional items until this situation has been assessed.** |  |
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| **III. Other Incidents Section** |  |
| Please identify the incident type and complete the information below, where applicable: |
| **[ ]  Customs Clearance Problem** (Select all that apply below) |  |  |
|  | [ ]  Paperwork delay |  |
|  | [ ]  Change in regulations |  |
|  | [ ]  Demurrage Fees accumulating - Fees incurred to date: | $       | (USD) |  |
|  | [ ]  Fees will be paid | [ ]  Exemption being sought for fees | [ ]  Unable to pay fees |  |
|  | Please explain the above selection(s) and describe next steps to be taken:  |  |
|  |       |  |
|  |  |
| **[ ]  Product Diversion** |  |
|  | Please describe the location where product diversion was discovered and steps being taken to address the issue: |  |
|  |       |  |
|  |  |  |
| **[ ]  Warehouse Theft** |  |
|  | Please describe the incident and items stolen: |  |
|  |       |  |
|  |  |
| **[ ]  Negative Media Report(s)** |  |
|  | [ ]  Print Media | [ ]  Television Report | [ ]  Internet Report |  |
|  | Please attach a copy of the article or describe the report:  |  |
|  |       |  |
|  |  |
| **[ ]  Legal Action being taken against organization** |  |
|  | Please describe the situation and next steps: |  |
|  |       |  |
|  |  |  |  |
| **[ ]  Other (Explain Below):** |  |  |
|  | Please describe situation: |  |
|  |       |  |
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|  |  |  |
| **Name/Title of Person Completing Form** |  | **Date** |  | **Signature** |  |