**ATTACHMENT 1: INCIDENT REPORT FORM**

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| **▪ INCIDENT REPORT FORM ▪**   |  | | --- | | 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](mailto: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: | | | | | | | |
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| **II. Product Incident Description Section** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **A.** | | **Please identify what type of incident occurred:** | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
|  | | Adverse event | | | | | | | Product Quality Issue | | | | | | | | | | | | | Product Use Error | | | | | | | |  |
|  | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
| **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:** | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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| **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 | | | | | | | | | | | |  |
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| **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: | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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| **Product Diversion** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
|  | | Please describe the location where product diversion was discovered and steps being taken to address the issue: | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
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| **Warehouse Theft** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
|  | | Please describe the incident and items stolen: | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
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| **Negative Media Report(s)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
|  | | Print Media | | | Television Report | | | | | | | Internet Report | | | | | | | | | | | | | | | | | |  |
|  | | Please attach a copy of the article or describe the report: | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
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| **Legal Action being taken against organization** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
|  | | Please describe the situation and next steps: | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
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| **Other (Explain Below):** | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | |  |
|  | | Please describe situation: | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
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| **Name/Title of Person Completing Form** | | | | | | | |  | | **Date** | | | | | | |  | | | **Signature** | | | | | | | | | |  |