**ATTACHMENT 1: INCIDENT REPORT FORM (to be completed for Adverse Events)**

**INCIDENT REPORT FORM**

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

For Emergency or Adverse Event Reporting, call the Americares Emergency Hotline 1-203-658-9658 and fax and/or email the completed Americares Incident Report Form to the Americares Adverse Event Reporting Team at 1-203-327-5200, or to adverseevents@americarse.org.

### 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 Problem
- [ ] Product Use Error

**B. Please describe the situation details below:**

- Location of incident:
- Date of incident:
- Number of people affected:
- Description of Patient(s) Affected (Include age, male/female, weight, etc): * Do not include actual patient names *
- Patient(s) Pre-Existing Medical Condition(s)
- Patient(s) Concomitant Medical Treatment(s)
- Detailed description of what occurred:
- Event Abated: After Use Stopped [ ] Yes [ ] No After Dose Reduced [ ] Yes [ ] No
- Supporting Lab Tests and Dates:

**C. Outcomes Attributed to Adverse Event: (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)

**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

**Do your sub-recipients have stocks of this item?**  
☐ Yes  ☐ No  ☐ Unknown

*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:

<table>
<thead>
<tr>
<th>Suspected Product Brand Name/Common Device Name:</th>
<th>Manufacturer Name:</th>
<th>City:</th>
<th>State:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model#</td>
<td>Lot#:</td>
<td>Serial#:</td>
<td>Catalogue#:</td>
</tr>
</tbody>
</table>

**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

**Do your sub-recipients have stocks of this item?**  
☐ Yes  ☐ No  ☐ Unknown

*If yes, please quarantine stocks at all locations and do not distribute additional items until this situation has been assessed.

### 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