**Adverse Event (AE) Report Form**

**Date: Institution Name:**

**Address: Contact: Tel:**

**AE Location:** □China □Outside China

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| 1. **Product information** | | |
| **Name:** | | |
| **Model#:** | **Specification:** | |
| **Lot#: Product ID:**  **Unique identifier (UDI)#:** | | |
| **Production date:** | **Use by date:** | |
| 1. **Use details** | | |
| **Intended use or function:** | | |
| **Date of use:**  **Site of use:** □Medical institution □Home  □Other settings, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Site name:** | | |
| **Describe the process of use:** | | |
| **Combination medication/medical device:** | | |
| 1. **Adverse event(s) information** | | |
| **Onset date:** | | |
| **Discovery/Report date:** | | |
| **Outcome attributed to adverse event:** (*Check all that apply*)  □Death □Serious injury  □Other outcomes, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Describe the AE outcome:** | | |
| **Patient name:** | | **Date of birth:** |
| **Age:** | | **Gender:** |
| **Medical record No.:** | | |
| **Past medical history:** | | |