**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:** |