**Did any device related defects occur?** ❑ Yes

❑ No

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date deficiency was detected by site  (DD-MMM-YYYY): | Product Name: | Device ID: | Description of the deficiency: | \*Did the deficiency lead to a Serious Adverse Event? |
|  |  |  |  | ❑ Yes  ❑ No |
|  |  |  |  | ❑ Yes  ❑ No |
|  |  |  |  | ❑ Yes  ❑ No |
|  |  |  |  | ❑ Yes  ❑ No |
|  |  |  |  | ❑ Yes  ❑ No |
|  |  |  |  | ❑ Yes  ❑ No |
|  |  |  |  | ❑ Yes  ❑ No |
|  |  |  |  | ❑ Yes  ❑ No |

**\***If Yes, please report SAE under SAE reporting system.