**Please indicate if a Medical Device Deficiency report** □ **or a User Error report** □

|  |  |
| --- | --- |
| **Report details** | |
| Sponsor number: |  |
| Protocol title: |  |
| Centre number: |  |
| Country deficiency/user error occurred: |  |
| Participant number: |  |
| Device: |  |
| **Device details** | |
| Describe the nature of the device, its normal (label) applications and its application in the Clinical Investigation if different: | |
| **Event details** | |
| Date of deficiency/user error: |  |
| Description of deficiency/user error: | |
| Please indicate if the deficiency/user error is due to malfunction, use error or inadequate labelling. | |

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| For device deficiency only: please indicate if the deficiency concerns identity, quality, durability, reliability, safety or performance of the device. | |
| **Action taken** | |
|  | |
| **Additional information** | |
| Name and contact details of person reporting and their role: |  |
| Date of report: |  |
| PI signature: |  |
| Date received by Sponsor: |  |
| Action: | |