**بسمه تعالی**

**شرکت تجهیزات پزشکی**

**پل سلامت ایرانیان**

واحد خدمات پس از فروش

فرم ویژه شرگت های تولید کننده (خارجی) وسایل پزشکی

Form A : for use by medical device manufacturers

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1 – Administrative Information | | | | | | | |
| Report Type (select one)  trend □ final □ follow-up □ intital □ | | | | | | | |
| Report Category  Serious Injury □ Other Death □ □serious Public Health Threat | | | | | | | |
|  | | | | | Date of Report (dd-mmm-yyyy) | | |
|  | | | | | Date of adverse event (dd-mmm-yyyy) | | |
|  | | | | | Date manufacture aware ( dd-mmm-yyyy ) | | |
|  | | | | | Date of next report ( dd-mmm-yyyy) | | |
| Person submitting this report | | | | | | | |
|  | | | | | | | Name |
|  | | | | | | | Company |
|  | | | | | | | Address |
|  | | Fax | |  | | | tel |
|  | | | | | | | E-mail |
| Identity of other Regulatory Authorities, Notified Bodies, etc, that this report was also sent.  1 –  2 –  3 – | | | | | | | |
| 2 – Clinical Event information | | | | | | | |
| Description of event or problem | | | | | | | |
| 3 – healthcare facility Information | | | | | | | |
|  | | | | | | Name | |
|  | | | | | | Address | |
|  | fax | |  | | | Tel | |
|  | | | | | | E-mail | |
|  | | | | | | Contact Name | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 4 – Device Information | | | | | | |
|  | | | | | | Name of  Device |
|  | | | | | | UMDNS Code |
|  | | | | | | Device  Classification |
|  | | | | | | Brand Name |
|  | | | | | | Model number |
|  | | | | | | Catalogue  Number |
|  | | | | | | Registration  number |
|  | | | (Serial number / lot number / batch number) | | | |
| ....../...../..... | | Date of  Installation | | ....../...../..... | Date of  manufacture | |
|  | | | | | Manufacture  Name | |
|  | | | | | Address | |
|  | Fax | | |  | Tel | |
|  | | | | | E-mail | |
|  | | | | | Contact Name | |
|  | | | | | Distributor/Authorized  representative | |
| Operator of Device at Event (select one)  □Not applicable Patient □ other Caregiver □ Healthcare Professional □ | | | | | | |
| Usage of Device  1 – Single use □  2 – Reuse of Reusable □  3 – Re-serviced / Refurbished □  4 – Implanted □ Date of implantation ……/…../…..  5 – other ……………………. | | | | | | |
| Current Location | | | | | | |
| 5 – Results of Manufacturers Device Investigation | | | | | | |
| Manufacturers device Analysis Results | | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Remedial Action/Corrective Action / Preventive Action  (Specify if/what action was taken for the reported specific event or for all similar type of events or products.)  repair □ patient monitoring □ relabeling □ recall □  inspection □ replace □ adjustment □ notification □  other ……………..  what action was taken to prevent recurrence?  Clarify the timeframe for completion of various action plans. | | | | | |
| 6 – Patient Information | | | | | |
|  | Wt(kg) |  | M/F |  | Age |
| Corrective action taken relevant to the care of the patient | | | | | |
| Patient outcome | | | | | |
| List of other devices involved in the event | | | | | |
| 7 – Other Information | | | | | |
| Manufacturer aware of other similar events: | | | | | |
| Countries where these similar adverse events occurred: | | | | | |
| Additional Comments | | | | | |