**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

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| 1 – Administrative Information |
| Report Type (select one)trend □ final □ follow-up □ intital □ |
| Report CategorySerious 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 |

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| 4 – Device Information |
|  | Name ofDevice |
|  | UMDNS Code |
|  | DeviceClassification |
|  | Brand Name |
|  | Model number |
|  | CatalogueNumber |
|  | Registrationnumber |
|  | (Serial number / lot number / batch number) |
| ....../...../..... | Date of Installation | ....../...../..... | Date of manufacture |
|  | ManufactureName |
|  | Address |
|  | Fax |  | Tel |
|  | E-mail |
|  | Contact Name |
|  | Distributor/Authorizedrepresentative |
| Operator of Device at Event (select one)□Not applicable Patient □ other Caregiver □ Healthcare Professional □ |
| Usage of Device1 – 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 |

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| 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 |