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| --- | --- |
| **Section to be filled by Quanta System** | *Sezione da compilare a cura di Quanta System* |
|  | **Complaint Number** |  |  | **Received by** |  |  |
|  | *Numero Reclamo* |  |  | *Ricevuto da* |  |  |
|  | **RMA Number (if any)** |  |  | **Received on** |  |  |
|  | *Numero RMA (se presente)* |  |  | *Ricevuto il* |  |  |
| **Complainant Data** |  |  | **Hospital/Clinic Data** |
| **Complainant (Distributor/Agent ) name and address** |  |  | **Name and address of the hospital/clinic** |
| *Azienda ed indirizzo di chi presenta reclamo (distributore/agente)* |  |  | *Nome ed indirizzo dell’ospedale o clinica* |
| Cencomex, avenida galvarino 7640, quilicura, santiago, chile |  |  | Clinica Indisa, Av. Sta. María 1810, Santiago, Providencia, Región Metropolitana |
|  |  |  |  |
| **Complainant case identification (i.e. internal report number):** |  |  | **Name of the initial reporter at the hospital/clinic** |
| *Identificazione del reclamo (es. numero di rapporto interno)* |  |  | *Nome del contatto presso l’ospedale o clinica* |
| 0029 |  |  |  |
| **Reported by (Distributor/Agent contact person)** |  |  | **Phone of the hospital/clinic initial reporter** |
| *Riportato da (persona di contatto distributore/agente)* |  |  | *Telefono del contatto presso l’ospedale o clinica* |
| Jorge fernandez |  |  |  |
| **Phone/email (Distributor/Agent)** |  |  | **Incident date** |
| *Telefono/email (distributore/agente)* |  |  | *Data dell’evento* |
| +569 76720543 jfernandez@cencomex.cl |  |  | 12/11/2021 |
| **Date notified to the complainant (Distributor/Agent)** |  |  |  |
| *Data di notifica del reclamo (distributore/agente)* |  |  |  |
| 15/11/2021 |  |  |  |
|  |  |  |  |
| **Product and Problem Data** |
| **Product Family** *Famiglia di prodotto* |  |  | **Product Model** *Modello prodotto* |
| LASER |  |  | Fiber Dust |
| **Serial Number/Lot** *Numero Seriale/Lotto* |  |  | **Kite Part Number** *Codice Kite* |
| TFL 0333-0321 |  |  |  |
| **UDI** *UDI* |  |  |  |
|  |
| **Software/hardware version** *Versione software/hardware* |  |  | **Error Code(s)** *Codice/i errore* |
|  |  |  |  |
| **Problem Description** *Descrizione del problema* |  |  |  |
| Client in hospital informed us that the system had a low energy error message. We retrieve the system to our labs to check it and the system now shows “laser source error” message every time when we try to do firing test. |
| **Kind of treatment (select one)***Tipo di trattamento* |[ ]  *Aesthetic/Dermatologic* |[x]  *Surgical* |[ ]  *Not Applicable* |
| **Timing of the problem (select one)***Quando è accaduto il problema* |[ ]  *As Received from Quanta* |[ ]  *During First Quality Control Incoming Inspection*  |
|[ ]  *During demo without patient* |[ ]  *During installation* |[ ]  *During maintenance* |  |  |
|[x]  *Patient there-just before treatment* |[ ]  *During treatment on patient* |[ ]  *Patient there-after treatment* |[ ]  *Unknown* |
| **Patient involvement (select one)***Coinvolgimento paziente* |[x]  *No involvement or consequences* |[ ]  *Delay in treatment (without clinical consequences).* |
|[ ]  *Limited/trivial damages that would heal within short timing* |[ ]  *Reversible cosmetic damage* |[ ]  *New or prolonged hospitalization of the patient* |
| [ ]  | *Trivial impairment or damage to a body structure or function* |[ ]  *Medical or surgical intervention needed to preclude permanent impairment of a body function or damage to a body structure* |[ ]  *Permanent irreversible impairment of a body function or permanent damage to a body structure* |
|[ ]  *Life threatening Injury-Illness* |[ ]  *Death* |[ ]  *Other - Please specify below* [ ]  *Unkwown*  |
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