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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* |
| CencomexAv. Galvarino 7640 – Parque Industrial Aconcagua –Quilicura- Santiago- Chile |  |  | Hospital San Pablo de Coquimbo |
|  |  |  |  |
| **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* |
| 00010 |  |  | Andres Yañez |
| **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* |
| Andres Yañez |  |  | +56964496402 |
| **Phone/email (Distributor/Agent)** |  |  | **Incident date** |
| *Telefono/email (distributore/agente)* |  |  | *Data dell’evento* |
| ayanez@cencomex.cll |  |  |  |
| **Date notified to the complainant (Distributor/Agent)** |  |  |  |
| *Data di notifica del reclamo (distributore/agente)* |  |  |  |
| 21-08-2019 |  |  |  |
|  |  |  |  |
| **Product and Problem Data** |
| **Product Family** *Famiglia di prodotto* |  |  | **Product Model** *Modello prodotto* |
| Laser |  |  | CYBER TM |
| **Serial Number/Lot** *Numero Seriale/Lotto* |  |  | **Kite Part Number** *Codice Kite* |
| CYT0102-0119 |  |  |  |
| **UDI** *UDI* |  |  |  |
|  |
| **Software/hardware version** *Versione software/hardware* |  |  | **Error Code(s)** *Codice/i errore* |
|  |  |  |  |
| **Problem Description** *Descrizione del problema* |  |  |  |
| Input seccion of optical fiber got overheated and melted. Plastic protector of the optical fiber used during the surgery was also melted.  |
| **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* |[ ]  *On Product Delivery from Quanta* |[ ]  *During First Incoming Inspection*  |
|[ ]  *During demo without patient* |[ ]  *During installation/re-installation* |[ ]  *During maintenance* |  |  |
|[ ]  *Patient there-just before treatment* |[x]  *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.* |[ ]  *Trivial impairment or damage to a body structure or**function.* |
| [ ]  | *Permanent irreversible impairment of a body function or permanent damage to a body structure.* |[ ]  *Life threatening Injury-Illness.* |[ ]  *Medical or surgical intervention needed to preclude**permanent impairment of a body function or damage to a body structure.* |
|  |  |[ ]  *Death.* |[ ]  *Other - Please specify below.* |
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