|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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  Av. 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](mailto: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* | | | | | |  | *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* | | |  | *During treatment on patient* | | | | | |  | *Patient there-after treatment* | |  | *Unknown* | |
| **Patient involvement (select one)**  *Coinvolgimento paziente* | | | | |  | *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.* | | | | |
|  | | | | | | | | | | | | | | | | | |