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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. Av. Galvarino #7640, Quilicura, Santiago, Chile. |  |  | Clinica Alemana Santiago, Vitacura 5951, Santiago, Chile. |
|  |  |  |  |
| **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* |
| 33 |  |  |  |
| **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 Fernández |  |  |  |
| **Phone/email (Distributor/Agent)** |  |  | **Incident date** |
| *Telefono/email (distributore/agente)* |  |  | *Data dell’evento* |
| +56976720543 jfernandez@cencomex.cl |  |  |  |
| **Date notified to the complainant (Distributor/Agent)** |  |  |  |
| *Data di notifica del reclamo (distributore/agente)* |  |  |  |
| 05-01-2022 |  |  |  |
|  |  |  |  |
| **Product and Problem Data** |
| **Product Family** *Famiglia di prodotto* |  |  | **Product Model** *Modello prodotto* |
| Laser |  |  | Cyber HO 100 |
| **Serial Number/Lot** *Numero Seriale/Lotto* |  |  | **Kite Part Number** *Codice Kite* |
| CYH 0628-0421 |  |  |  |
| **UDI** *UDI* |  |  |  |
|  |
| **Software/hardware version** *Versione software/hardware* |  |  | **Error Code(s)** *Codice/i errore* |
|  |  |  |  |
| **Problem Description** *Descrizione del problema* |  |  |  |
| The Laser system shutted down during a procidure. Afte this every time the system is powered on we can only see the white loading circle in the screen ,after tha the screen stays black. Nothing else gets powered on,even the chillers  |
| **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* |[ ]  *No involvement or consequences* |[x]  *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*  |
|  |