

## Section to be filled by Quanta System

Complaint Number

Received by

RMA Nr. (if any)

Received on

## COMPLAINANT DATA

Complainant (Distributor/Agent) name and address \*

Complainant case identification (i.e. internal report number):

Reported by (Distributor/Agent contact person)

Phone/email (Distributor/Agent)

## HOSPITAL / CLINIC DATA

Name and address of the hospital/clinic

Name of the initial reporter at the hospital/clinic

Phone of the hospital/clinic initial reporter

Event date (if available)

Date notified to the complainant (Distributor/Agent) \*

## PRODUCT AND PROBLEM DATA

Product Family

Product Model

Serial Number / Lot \*

Q.ty \*

Part Number

UDI

Software/hardware version

Error Code(s)

## Reported Issue (select one) \*

*Temporary Error**Minor anomalies not impacting on functionalities**Aesthetic defects / missing components**Wear damages**Product completely impossible to use**Functional / Performance impacting issues*

## Product Effect (select one) \*

*Product Impossible to use anymore**Component / Subsystem impossible to use anymore**Product usable but with reduced performance or usability**Product usable after component replacement**Product usable after technical intervention / service**Product normally usable, no performance or usability impact*

## Problem Description \*

## Timing of the Problem (select one) \*

☐ *As received from Quanta**During First Quality Control Incoming Inspection**Unknown / no timing reported*☐ *During demo without patient**During first installation**During maintenance*☐ *Patient there-just before treatment**During treatment on patient**Patient there- after treatment*

## Patient Involvement (select one) \*

*No involvement or consequences**Delay in AESTHETIC / DERMATOLOGIC treatment (without consequences)**Delay in SURGICAL 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**Unknown / no patient involvement reported**Other - Please Specify below*