

DESTINATION:

1. Competent Authority

Address:

2. Reporting firm name:

a) Manufacturer Authorised representative within EEA

b) Address:

c) Contact person name:

d) Telephone number:

e) Telefax number:

f) Report date:

3. Manufacturer (if not already provided in point 2)

a) Name:

b) Address:

4. Information about incident

a) Medical device commercial name:

b) (*) Kind of device (e.g. pacemaker, diathermy machine):

c) Model or catalogue number:

d) Serial number(s) or lot number(s):

e) Accessories/associated devices (if applicable):

f) Software version (if applicable):

g) Identification number of Notified Body involved in conformity assessment (if applicable):

h) Reporting firm is aware of other similar incidents having an impact on the current report

Yes No

i) If yes, the countries to which these have been reported, and the report reference numbers are listed below:

j) Incident reported by (user or other source):

Address:

Telephone number:

Date reported:

k) Incident date:

l) Incident description:

m) Outcome: (e.g. death, deterioration in health):

n) Manufacturer's preliminary comments:

o) Current location of device (if known):

p) Expected date of follow-up report:

q) Corrective action (if any):

r) Projected timing:

Note: submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the competent authority that the content of this report is complete or accurate, that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

(*) Please also include nomenclature id. and which nomenclature system used if known (e.g. UMDNS)