MHRA ADVERSE INCIDENT REPORT FORM

Please tick (✓) the appropriate boxes

**Origin of report:**
- Reporting Body: 
- Address: 
- Reporter: 
- Position: 
- Telephone number: 
- Consultant-in-charge (if known): 

This report confirms a telephone report ☐ a fax report ☐ neither ☐

**Type of device: (tick one only)**
- ☐ Active implantable devices
- ☐ Administration & giving sets
- ☐ Anaesthetic machines & monitors
- ☐ Anaesthetic & breathing masks
- ☐ Autoclaves
- ☐ Bath aids
- ☐ Beds & mattresses
- ☐ Blood pressure measurement
- ☐ Breast implants
- ☐ Cardiovascular implants & devices
- ☐ Commodities
- ☐ Contact lenses & care products
- ☐ CT systems
- ☐ Dental materials & appliances
- ☐ Dialysis equipment
- ☐ Diathermy equipment & accessories
- ☐ Dressings
- ☐ Endoscopes & accessories
- ☐ Endotracheal tubes & airways
- ☐ Enteral feeding systems

☐ External defibrillators & pacemakers
☐ Feeding tubes
☐ Gloves
☐ Guidewires
☐ Hearing aids
☐ Hypodermic syringes & needles
☐ Implant materials
☐ Infusion pumps, syringe drivers
☐ Intravenous catheters & cannulae
☐ Lasers & accessories
☐ Magnetic resonance equipment & accessories
☐ Mobile x-ray systems
☐ Monitors & electrodes
☐ Non-active implants
☐ Ophthalmic equipment
☐ Patient hoists
☐ Patient monitoring equipment

☐ Radiotherapy equipment
☐ Radionuclide equipment
☐ Resuscitators
☐ Staples & staple guns
☐ Stretchers
☐ Surgical instruments
☐ Sutures
☐ Thermometers
☐ Ultrasound equipment
☐ Ventilators

☐ Physiotherapy equipment
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- ☐ Product
- ☐ Manufacturer
- ☐ Model
- ☐ Telephone no:
- ☐ Supplier
- ☐ Batch No
- ☐ Date of mfr

☐ Is there a CE-mark? YES ☐ NO ☐
☐ If YES, was the manufacturer or supplier contacted? YES ☐ NO ☐
☐ Was there a fatality? YES ☐ NO ☐
☐ Was an injury caused? YES ☐ NO ☐

**Injury details:**
- Nature of defect / details of incident:
- Contact name for further details:
- Telephone number:

**Action taken by staff / manufacturer / supplier:**

PLEASE NOTE IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST.

If you still have the incident device please retain it and await further instructions from the MHRA.

Signed: ..................................................... Date: ..............................

Further details can be given on additional sheets if necessary.

Please send completed form to: Medicines & Healthcare products Regulatory Agency Adverse Incident Centre, 2nd Floor, Market Towers, 1 Nine Elms Lane, London, SW8 5NQ, Fax 0207 084 3109, e-mail: aic@mhra.gsi.gov.uk

FORMGEN (March 2003)