



FIELD SAFETY CORRECTIVE ACTION (FSCA) FORM

A. ADMINISTRATIVE INFORMATION		
1. Date of the Report (dd/mm/yyyy):		
2. Reference number (by the manufacturer):		
3. Identify to what other Competent Authorities this report was also sent:		
B. SUSPECTED MEDICAL DEVICE		
1. Brand Name:		2. Common Device Name:
3. Manufacturer name:		
4. Authorized representative name:		
5. <u>Type of Device (mark one only)</u>		
<input type="checkbox"/> Active implantable devices <input type="checkbox"/> Administration & giving sets <input type="checkbox"/> Anesthetic machines & monitors <input type="checkbox"/> Anesthetic & breathing masks <input type="checkbox"/> Autoclaves <input type="checkbox"/> Bath aids <input type="checkbox"/> Beds & mattresses <input type="checkbox"/> Blood pressure measurement <input type="checkbox"/> Breast implant <input type="checkbox"/> Cardiovascular implants & devices <input type="checkbox"/> Commodes <input type="checkbox"/> Contact Lenses & care products <input type="checkbox"/> CT system <input type="checkbox"/> Dental materials & applications <input type="checkbox"/> Dialysis equipment <input type="checkbox"/> Diathermy equipment & accessories <input type="checkbox"/> Dressings <input type="checkbox"/> Endoscopes & accessories <input type="checkbox"/> Endotracheal & airways	<input type="checkbox"/> External defibrillators & pacemakers <input type="checkbox"/> Feeding tubes <input type="checkbox"/> Gloves <input type="checkbox"/> Guide wires <input type="checkbox"/> Hearing aids <input type="checkbox"/> Hypodermic Syringes & needles <input type="checkbox"/> Implant materials <input type="checkbox"/> Infant incubators <input type="checkbox"/> Infusion pumps, syringe drivers <input type="checkbox"/> Insulin syringes <input type="checkbox"/> Intravenous catheters & cannulas <input type="checkbox"/> Joint prostheses <input type="checkbox"/> Lasers & accessories <input type="checkbox"/> Magnetic resonance equipment & accessories <input type="checkbox"/> Mobile x-ray systems <input type="checkbox"/> Monitor & electrodes <input type="checkbox"/> Non-active implants <input type="checkbox"/> Ophthalmic equipment	<input type="checkbox"/> Patient hoists <input type="checkbox"/> Physiotherapy equipment <input type="checkbox"/> Radiotherapy equipment <input type="checkbox"/> Radionuclide equipment <input type="checkbox"/> Resuscitators <input type="checkbox"/> Staples & staple <input type="checkbox"/> Stretchers <input type="checkbox"/> Surgical instruments <input type="checkbox"/> Surgical powder <input type="checkbox"/> Sutures <input type="checkbox"/> Thermometers <input type="checkbox"/> Ultrasound equipment <input type="checkbox"/> Urinary catheters <input type="checkbox"/> Ventilators <input type="checkbox"/> Walking sticks/frames <input type="checkbox"/> Wound drains <input type="checkbox"/> X-ray equipment system & accessories <input type="checkbox"/> Others (Please specify)
6. Batch No:		7. Serial No:
8. Model No:		9. Catalog No:
10. Software version number (if applicable):		
11. Mfg. Date (dd/mm/yyyy):		12. Exp Date (dd/mm/yyyy):

