

FIELD SAFETY CORRECTIVE ACTION (FSCA) FORM



TMDA/DMD/MDV/F/005 Rev #:0 Page 1 of 2

A. ADMINISTRATIVE INFORMATION		
1. Date of the Report (dd/mm/yyyy):		
2. Reference number (by the manufactu	ırer):	
3. Identify to what other Competent Aut	horities this report was also sent:	
B. SUSPECTED MEDICAL DEVICE		
1. Brand Name:	2. Common Device Name:	
3. Manufacturer name:		
4. Authorized representative name:		
5. Type of Device (mark one only)		
	External defibrillators &	Patient hoists
Active implantable devices	pacemakers	Physiotherapy
Administration & giving sets	Feeding tubes	equipment
Anesthetic machines & monitors	Gloves	Radiotherapy equipment
Anesthetic & breathing masks	Guide wires	Radionuclide equipment
Autoclaves	Hearing aids	Resuscitators
Bath aids	Hypodermic Syringes &	Staples & staple
Beds & mattresses	needles	Stretchers
Blood pressure measurement	Implant materials	Surgical instruments
Breast implant	Infant incubators	Surgical powder
Cardiovascular implants &devices	Infusion pumps, syringe	Sutures
Commodes	drivers	Thermometers
Contact Lenses & care products	Insulin syringes	Ultrasound equipment
CT system	Intravenous catheters &	Urinary catheters
Dental materials & applications	cannulas	Ventilators
Dialysis equipment	Joint prostheses	Walking sticks/frames
Diathermy equipment &	Lasers & accessories	Wound drains
accessories	Magnetic resonance	X-ray equipment system
Dressings	equipment & accessories	& accessories
Endoscopes & accessories	Mobile x-ray systems	Others (Please specify)
Endotracheal & airways	Monitor & electrodes	
	Non-active implants	
	Ophthalmic equipment	
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/y	yyy):



FIELD SAFETY CORRECTIVE ACTION (FSCA) FORM



TMDA/DMD/MDV/F/005 Rev #:0 Page 2 of 2

C. SUBMITTER OF THE FSCA			
1. Reporting Firm			
Name:			
Address:			
City: Contact person name:			
Telephone/mobile: E- mail:			
D. DESCRIPTION OF FSCA			
i. Background information and reason for the FSCA:			
ii. Description of action taken: Recall Repair Replace Relabeling Notification Inspection Patient Monitoring Modification/Adjustment Other iii. Justification of the action taken: iv. Advice on actions to be taken by the distributor and the user: v. Attached please find: Field Safety Notice (FSN) in English Copy of related report sent to other Authorities (please specify) Others (please specify):			
vi. Time schedule for the implementation of the different actions:			
E. COMMENTS			

Send to:

The Director General,

Tanzania Medicines and Medical Devices Authority (TMDA),

P.O.Box 1253,

Dodoma, Tanzania

Tel: +255 (26) 2961989/2061990

Email: info@tmda.go.tz
Website: www.tmda.go.tz
Toll free number: 0800110084