Medical Device Report

THIS FORM IS INTEDEND TO BE USED BY PUBLIC, AR, HCF TO REPORT AN ADVERSE EVENT OR COMPLAINT TO NHRA MDR TEAM

Report type: ☐ Initial ☐ Follow up ☐ Final

SECTION 1: Reporter Details			
Type of Reporter	☐ Individual	☐ AR/ Supplier	☐ Healthcare Facility
Name			
Position/Job Title			
Mobile No.			
Email Address			
Report Date	/ /		

SECTION 2: Medical Device Details **If more than one device (Attach List)**			
Device Name			
No. of Devices involved			
Model No.			
Serial No.			
Lot / Batch No.			
Date of installation	/ /	**Last PPM**	/ /
Device location / Dept	☐ Surgery ☐ Orthopedic ☐ Pediatric ☐ Laboratory ☐ Pharmacy ☐ OPD ☐ Rehabilitation ☐ Radiology ☐ O&G ☐ ICU ☐ CCU ☐ Emergency ☐ Dialysis ☐ Ophthalmology ☐ Dental ☐ Andrology ☐ Endoscopy ☐ Respiratory ☐ Audiology ☐ Cardiology ☐ Oncology ☐ Others: …… ☐ Anesthesia ☐ Dermatology		

nhra BAHRAIN

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

HealthCare Facility Information	
HCF Name	
Address	
Contact Person Name	
Position/ Job Title	
Mobile No.	
Email Address	

Adverse Event Details	
Adverse Event Classification	☐ Death ☐ Serious Injury ☐ Other Reportable event.
Description	
Immediate action taken	
Supportive Documents	**Attach (pictures, reports…etc)**

Staff Involved Details If more than one Person (Attach List)	
Name	
Position/ Job Title	
Mobile No.	
Email Address	

SECTION 5: Authorized Representative Details	
Name	
Email Address	
Telephone No.	
Date of report awareness	/ /
Corrective Action Taken	

SECTION 6: Manufacturer Information	
Name	
Country of Origin	
Contact Person Name	
Email Address	
Date of Awareness	/ /
Action Recommended	

SECTION 7: NHRA	
Date of Receiving	/ /
NHRA Ref No.	
Responsible person	
Position/Job title	
Signature	
Report Status	☐ Open ☐ Closed ☐ Other:

Please send the report to medical _devices@nhra.bh

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.