Botswana Medicines Regulatory Authority
BOMRA/PCT/PV/P10/F01
Issue No. 1.1

BoMRA Use Only (Received Stamp)

MDAE number:

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM FOR HEALTH CARE PROFESSIONALS AND USERS

I. PATIENT INFORMATION *(if applicable)*:

*Patient initials: Patient reference no.: *Gender: ☐ M ☐ F Weight (kgs):_____

*Date of Birth:_ _ /_ _ / _ _ _ _ **OR** *Age_ _ Years _ _ Months _ _ _ Days
OR *Age group ☐ < 1Year ☐ 1 to 5Years ☐ >5 to 18years ☐ 18 to 60years ☐ >60years

II. REPORTER:

*Name:_____ *Designation & Department:_____

Institution:_____

*Contact Number: _____ Email address:_____

*Address:_____

*Date patient notified event to health system:_ _ /_ _ / _ _ _ _ *Today's date:_ _ /_ _ / _ _ _ _

*Event reported to manufacturer: ☐ Yes ☐ No	Medical device available for evaluation: ☐ Yes ☐ No

III. SUSPECTED MEDICAL DEVICE(S) / IVD DETAILS:

*Brand Name of device:

*Manufacturer (*name and location*):

*Name of local supplier:

*Model number	*Batch/Lot number	*Serial number	Catalogue number	Software Version (*If applicable*)	*Expiration date _ _ / _ _/ _ _ _ _

***Operator of Device:** ☐ Healthcare Professional ☐Patient ☐ Other *(specify)*:_____
☐ Problem noted prior to use/ near miss event

MD Use duration: MD Start/ Implant Date : _ _/ _ _/ _ _ _ _ MD Stop/Explant date: _ _/ _ _/ _ _ _

**Implant & Explant dates refer to Implanted medical devices ONLY *(pacemakers, metal-on-metal hip Implants, etc)*

IV. OTHER MEDICAL DEVICE(S) / IVD USED AT THE TIME OF EVENT

Brand name	**Manufacturer**	**Start Date:**	**Stop Date:**

V. ADVERSE EVENT(S) EXPERIENCED/OBSERVED:

*Date event occurred:	Event Subsided after Suspected Device use discontinuation: ☐ Yes ☐ No	Rechallenge: ☐ Yes ☐ No

***Type of event :** ☐ User experienced adverse event ☐ Incorrect device use
☐ Defects / Malfunction of device ☐ Other

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Description of Adverse Event** ***(Include as many details as possible):
***Current location of Device:** ☐ Destroyed ☐ Remains implanted in patient ☐ Returned to manufacturer ☐ Within the healthcare facility ☐ At patient home ☐Others, Specify:_____
***Serious:** ☐No ☐Yes , **IF** Yes , ☐ Life threatening ☐ Hospitalized ☐ Congenital anomaly/birth defect ☐Disabling/incapacitating ☐ Death, *date: (_ _ /_ _ /_ _ _ _).* ☐ Other important medical event, *Specify*_____
***Outcome:** ☐ Recovered ☐ Recovering ☐ Not Recovered ☐ Fatal ☐ Recovered with sequelae ☐ Unknown
Pre-existing medical conditions and concurrent medication (E.g. Chronic conditions, Allergies, Pregnancy, Smoking, Alcohol, Hepatic/Renal Dysfunction, etc.).
Additional relevant Information (use *additional sheets if needed*) -

VI. FIRST DECISION MAKING LEVEL:	
Investigation needed: ☐ Yes ☐ No	If Yes, date investigation planned : _ _ /_ _ /_ _ _ _
VII. CAUSALITY ASSESSMENT. To Be Completed By BoMRA:	
Date report received: _ _ / _ _ /_ _ _ _	BoMRA MDAE ID :_____ International MDAE ID:_____
Comments:	

Confidentiality: Patient confidentiality is fully held in strict confidence and protected. Submission of the report does not constitute an admission that the medical personnel, manufacturer, or the product caused or contributed to the adverse event/ problem. Submission of the MDAE report does not have any legal implication on the reporter.

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MEDICAL DEVICE ADVERSE EVENT REPORTING GUIDE

How to complete this form:

***ALL FIELDS MUST BE COMPLETED**

"N/A" IF NOT APPLICABLE TO THE EVENT OR "UNKNOWN WHEN THE DATA IS NOT AVAILABLE.*

I. **Patient Information** – Reference number (Case No./Patient No/File No. for your facility DO NOT USE NATIONAL ID NO.) **Age group**-used as alternative if date of birth and age at onset is unknown.

II. **Reporter** – Your contact details may be required in case of follow up to clarify information.
Date patient notified event to health system can be a different from the date when the report was compiled.

III. **Suspected medical device details**- including any health-related kit, test, tool or piece of equipment (e.g. pacemakers, hearing aids, diabetes glucose test kits, breast pumps etc.)

IV. **Other Medical Device(s)** used at time of reaction.

I. **Adverse Event Experienced/Observed** – Description of the events in chronological order. Please provide as much details as possible. Relevant tests/ Laboratory data (if available) - numerical results should be written with units of measurement. **Additional relevant Information** - Please add additional details that will help with processing this report. Please include other documents as attachments, if necessary.

V. **First Decision Making level-**Indicate if an investigation for the MDAE needs to be done and the date.

VI. **Causality Assessment**: To be completed by BoMRA.

- Fill in as much information as possible and send form even if you do not have all the information.
- You may include or attach a picture of the medical device with the name visible.
- Items marked with an asterisk **(*)** represent minimum information required to process the MDAE report.

Use separate page for additional information*

WHERE TO REPORT? Duly filled Medical Device Adverse Event (MDAE) reporting form can be sent to;

Botswana Medicine Regulatory Authority,
Private Bag 2,
Gaborone Station
Botswana.

OR

E-mail: reportmdae@bomra.co.bw
Tel No: (+267) 3731727
Fax No: (+267) 3186254
Toll Free: 0800 600 216