Doc Number: GLF-MD-11A	Medical Device Adverse Event Reporting Form	SAHPRA South African Health Products Regulatory Authority
Revision: 1.0		Effective date: 20 November 2023

	☐ Initial Report ☐ Follow Up Report ☐ Final Report SAHPRA MD AE Ref No.	Authorised Representative Name: AR Contact Details: Tel: Email: Establishment Name: Establishment Licence No.:

NOTE: **Only 1 device may be reported per adverse event form.**

Adverse Event Classification

☐Death/Serious Injury ☐ Minor Injury ☐Quality issue ☐Near adverse event ☐Other

If other specify:

(if the AE is related to a SAHPRA Pre-Market Clinical or Post-Market Clinical study, answer YES) ☐ Yes ☐ No

If yes, name of Clinical Trial and Study ID #:

Patient Information

Patient Age at Time of Event: (number) **Age Unit: Years or Days**	**Is patient/user under 18?** ☐ Yes ☐ No ☐ N/A
Patient Name or Identifier:	**Patient Weight:** ☐Kg or ☐Grams
Patient Date of Birth: (dd/mmm/yyyy)	**Patient Gender:**
Patient Sex: ☐ M ☐ F ☐ Unknown **Patient Race:**	**Anatomy location:**

Adverse Event Reporter Information

Reporter Name: First name, last name)	**Reporter Phone:**
Healthcare Professional? ☐ Yes ☐ No	**Reporter Email Address :**
Reporter Occupation:	**HCP Phone:**
Name / Address of location where AE occurred:	**Name of contact person:**
Has the original Manufacturer been notified of AE ☐ Yes ☐ No Notification date:	**Name of original Manufacturer**

Adverse Event Information

Type of Report: Adverse Event ☐ **Product Quality Problem** ☐

Date Adverse Event Occurred:	**Date Adverse Event Submitted to SAHPRA:**

Type of adverse event and/or health impact: check all that apply

	Change in Therapeutic Response		Recognised Device or Procedural Complication
	Death		Reduction in Life Expectancy
	Brain Death		Sedation
	Delay to Diagnosis		Rehabilitation
	Delay to Treatment / Therapy		Surgical Intervention
	Disruption of Subsequent Medical Procedure		Serious Public Health Threat
	Exacerbation of Existing Condition		Unexpected Deterioration
	Hospitalization or Prolonged Hospitalization		Unexpected Diagnostic Intervention
	Foetal Harm		Unexpected Medical Intervention
	Inadequate / Inappropriate Treatment or Diagnostic Exposure		Insufficient Information
	Minor Injury / Illness / Impairment		Unanticipated Adverse Device Effect
	Serious Injury / Illness / Impairment		No Health Consequences or Impact
	Misdiagnosis / Misclassification		No Patient Involvement
	Prolonged Episode of Care		Appropriate Term / Code Not Available

☐ **Death** **Date of Death**	

Describe the adverse event. No patient names should be included in the adverse event description.
Refer to table 1 to include the anatomy of the minimum clinical signs, symptoms, conditions of the adverse event:

Relevant Lab Tests / Results:

Relevant History, Including Preexisting Medical Conditions (e.g. allergies, pregnancy, liver/kidney problems, smoking etc,)

Interventions taken to care for the patient?	
Suspected Medical Device	
UDI: If available	**GMDN Code**
Product name or description:	
Medical Device Registration number:	
Model number:	**Serial number:**
Batch/Lot/Serial #: (if not known, enter UNKNOWN)	
Is this a single use device? ☐ Yes ☐ No	**Re-sterilized?** or **Reprocessed?** ☐ Yes ☐ No ☐ Unknown ☐ N/A
Used past expiry date? ☐ Yes ☐ No ☐ N/A	
If reprocessed and used on patient, enter reprocessor's name and address:	
Is this device implantable: ☐ Yes ☐ No	**Implant Date:**
Product Explanted ☐ Yes ☐ No	**Explant Date:**
Is product returned to manufacturer? Yes ☐ No ☐ Disposed ☐ Implanted ☐ Retained ☐ N/A ☐ Other – specify	
Other medical devices involved in this event?	
Similar events?	
Manufacturers Investigations	
Statement by the HCR or Establishment Licence on similar adverse events submitted to other regulatory authorities: ***(Where available; include date of reports, number of similar events, number of devices involved, incident rate of similar events, list relevant CAPAs in other countries opened as a results of similar adverse events)***	
Manufacturer device analysis results: refer to table 2 for describing the parts and components which were involved in, or affected by, the medical device adverse event/incident.	
Remedial Action / Corrective Action / Preventative Actions Taken:	
Completed Actions:	**Planned Actions:**