SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

Issue No.: MD04-2026/27

24 June 2026

Contact Details for Guideline No. SAHPGL-MD-03 Medical Device vigilance: Adverse Events Reporting for Licence Holders

1. INTRODUCTION

This document provides contact details for reporting adverse events in accordance with the latest version of Guideline No. SAHPGL-MD-03 accessible on SAHPRA Website, Field Safety Corrective Actions. It also includes contact information for medical devices recalls, including In vitro diagnostics (IVDs).

2. IN CASE OF FIELD SAFETY CORRECTIVE ACTIONS

The Holder of the Certificate of Registration (HCR) or licensee is required to submit a Field Safety Corrective Action report to the Medical Device Unit when undertaking any of the following actions: if they are undertaking one of the following activities:

(a) correcting product that is already on the market

(b) removing product/s from the market to facilitate necessary corrections

(c) advising users of an issue relating to a medical device

All reportable adverse events and Field Safety Corrective Action notifications must be submitted to the following address: mdvigilance@sahpra.org.za.

Furthermore, stakeholders are requested to communicate any recalls to the following email address: recalls@sahpra.org.za.

NOTE: Please note that recalls MUST NOT be communicated to the Medical Device Unit. Recalls must be communicated to the Regulatory Compliance Unit on the email address above.

Boitumelo Semete-Makokotlela

24/06/2026 07:31:04(UTC+00:00) SIGNIFLOW

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SAHPRA Chief Executive Officer (CEO)