SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

COMMUNICATION TO STAKEHOLDERS

Issue No.: MD01-2024/2025

5 June 2024

Contact details for Guideline SAHPGL-MD-03 Medical Device Vigilance: Adverse Events Reporting for License Holders

INTRODUCTION

This document is intended to provide contact details for communicating reportable adverse events, as per Guideline SAHPGL-MD-03, as well as contact details for any Recalls and Market actions for medical devices (including IVDs).

Reportable adverse events reports must be emailed to mdvigilance@sahpra.org.za and **copy (cc)** Puseletso.Mogano@shapra.org.za

IN CASE OF RECALLS AND MARKET ACTIONS

If the HCR / licensee is contemplating any of the following, the Regulatory Compliance Unit must be contacted for advice (SAHPGL-MD-03, Section 6).

- *correcting product on the market*
- *removing product from the market, or*
- *advising users of an issue with a medical device*

Stakeholders are hereby informed to communicate any recall or market action information to the following email address: recalls@sahpra.org.za and **copy (cc)** Maphutheho.Selikane@sahpra.org.za, Mokgadi.Fafudi@sahpra.org.za and kholofelo.maponya@sahpra.org.za.

Note: Recalls should not be communicated to the Vigilance Unit

Dr Boitumelo Semete-Makokotlela
SAHPRA Chief Executive Officer (CEO)