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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. 5855 **12 February 2025**

EXEMPTION OF MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS OF CLASS A MEDICAL DEVICES AND IN VITRO DIAGNOSTICS FROM THE OPERATION OF THE PROVISIONS OF SECTION 22C (1) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (Act No. 101 of 1965)

The Minister of Health has, in terms of section 36 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and in consultation with the South African Health Products Regulatory Authority (SAHPRA), that establishments which requires a Medical Devices and In Vitro diagnostics establishment license in terms of section 22C of the Medicines and Related Substances Act for only Class A medical device including IVDs that do not have measuring properties/characteristics and /or are non-sterile" are exempted for the period of three years to possess an establishment license.

Repeal

The exemption of manaufacturers, wholesalers and distributors of class A medical and In Vitro diagnostics from the operation of the provisions of section 22C of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as published under Government Notice No.4406 in Government Gazette No.50164 of 23 February 2024 is hereby repealed.

DR PAKISHE AARON MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 4/2/2025

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