NOTICE TO ALL MANUFACTURERS, WHOLESALERS, RETAILERS, AND IMPORTERS OF NON-IVD MEDICAL DEVICES IN ZAMBIA

MARKETING AUTHORISATION OF NON–IVD MEDICAL DEVICES

10th September 2024

The Zambia Medicines Regulatory Authority is established under the Medicines and Allied Substances Act (No.3) of 2013 to ensure that all allied substances, including Medical Devices, conform to the required standards for quality, safety, and efficacy throughout the chain of manufacture, importation, exportation, distribution, storage, and sale.

In the quest for the effective regulation of Medical Devices (Non-IVD) manufactured and imported into Zambia, ZAMRA wishes to inform all manufacturers and importers of the said medical devices including members of the public, that following the publication of the *Guidelines on the Grant of Marketing Authorisation of Non-In-Vitro Diagnostic Medical Devices*, the registration of Non-In-Vitro Diagnostic Medical Devices is in effect.

As mandated by the Medicines and Allied Substances Act (No.3) of 2013, medical devices being placed on the market must be granted Marketing Authorisation by the Authority. With the aforementioned, using a phased approach, the Authority is commencing the registration process starting with the registration of **Class A and Class B Non-IVD Medical Devices.**

Kindly be advised that only import controls will be applicable for all Non-IVD Medical Devices falling in Class C and Class D, and importers are advised to obtain import permits from the Authority until notification of the registration process.

Manufacturers, wholesalers, and importers of Non-IVD Medical Devices are advised to contact the Authority on the respective regulatory requirements to be met to ensure regulatory compliance.

You are further advised that Marketing Authorisation (registration) of Medical Devices is a legal requirement under the Medicines and Allied Substances Act (No.3) of 2013. Industry and the general public are advised to acquaint themselves with the prescribed regulatory requirements set out in the respective Guidelines available on our website at:
https://www.zamra.co.zm/wp-content/uploads/2024/07/GUIDELINES-ON-APPLICATION-FOR-GRANT-OF-MARKETING-AUTHORISATION-OF-NON-IVDS.pdf.

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