REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

FULL IMPLEMENTATION OF THE GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES

REGISTRATION OF CLASS C AND D MEDICAL DEVICES

The Pharmacy and Poisons Board is implementing Guidelines on Submission of Documentation for Registration of Medical Devices including Invitro-Diagnostics starting January 2019.

The Board wishes to inform the applicants to prepare product registration application for marketing authoriztion of Class C and D using the Common Submission Dossier Template (CSDT) and Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices and IVDs (STED) for medical devices and IVDs respectively. Class A and B will be listed as has been the case.

All applications shall be submitted through the Pharmacy and Poisons Board online portal**:** **products.pharmacyboardkenya.org**

Chief Executive Officer

Pharmacy and Poisons Board