➢ ACRONYMS

AFRO: African Region

AHWP: Asian Harmonization Working Party.

AIDS: Acquired Immunodeficiency Syndrome

ASEAN: Association of Southeast Asian Nations.

ASLM: African Society for Laboratory Medicine.

CAB: Conformity Assessment Body

CAPA: Corrective and Preventive Action

CBER: Center for Biologics Evaluation and Research (USFDA)

CDC: Centers for Disease Control and Prevention (USA)

CDRH: Center for Devices and Radiological Health (USFDA)

CE: Conformité Européenne

CFR: Code of Federal Regulations

CLIA: Clinical Laboratory Improvement Amendments of 1988

CLSI: Clinical and Laboratory Standards Institute

CRF: Circulating Recombinant Form (HIV)

Dx: Diagnostic

EAC: Eastern African Community.

EIA/ELISA: Enzyme Immunoassay/ Enzyme Linked Immunoassay/

EU: European Union

FDA: US Food and Drug Administration

FD&C: Food Drug and Cosmetic Act (USA)

FSCA: Field Safety Corrective Action

FSN: Field Safety Notice (or Notification)

GHTF: Global Harmonization Task Force.

GLP: Good Laboratory Practice

GMP: Good Manufacturing Practice

HHS: Health and Human Services (USA)

HIV: Human Immunodeficiency Virus

IDE: Investigational Device Exemption

IEC: International Electrotechnical Commission

IFA: Immunofluorescence Assay

IFU: Instructions For Use

IMDFR: International Medical Device Regulators Forum

IRB: Institutional Review Board

ISO: International Organization for Standardization

IVD: In Vitro Diagnostic

MDG: Millennium Development Goal

MDSAP: Medical Device Single Audit Program

MoH: Ministry of Health

MRA: Mature Regulatory Authority.

NAT/NAAT: Nucleic Acid Test/ Nucleic Acid Amplification Test

NEPAD: New Partnership for Africa's Development

NPV: Negative Predictive Value

NRA: National Regulatory Authority.

OBRR: Office of Blood Research and Review (USFDA)

PAHWP: Pan African Harmonization Working Party on Medical Devices and Diagnostics

PEPFAR: *U.S*. President's Emergency Plan for AIDS Relief

PMA: Premarket Authorization

PMS: Post-Marketing Surveillance

PPV: Positive Predictive Value

PQ: Pre-Qualification

QC/QA: Quality Control/Quality Assurance

QMS: Quality Management System

QSR: Quality Systems Regulation

SADC: Southern African Development Community

SOP: Standard Operation Procedure

STED: Summary Technical Documentation

TGA: Therapeutic Goods Administration (Australia)

ToC: Table of Content

UHC: Universal Health Coverage

USAID: United States Agency for International Development

WHA: World Health Authority

WHO: World Health Organization

➢ GLOSSARY

'Authorized Representative' means any natural or legal person established within the jurisdiction who has received a written mandate from the overseas manufacturer to act on his behalf for specified tasks, including the obligation to represent the manufacturer in its dealings with the NRA.

'CLIA-Waived' means a lab test for which the Food and Drug Administration (FDA) has determined to be so simple that there is little risk of error when used by an untrained user in a non-laboratory setting.

'Conformity assessment' means the systematic examination of evidence generated, and procedures undertaken, by the manufacturer, under requirements established in the Medical Devices Regulation, to determine that a medical device complies with all relevant requirements.

'Conformity Assessment Body (CAB)' means an independent body designated and monitored by the NRA to undertake specified conformity assessment activities to determine whether a manufacturer fulfils the relevant requirements of the Medical Devices Regulation.

'Distributor' means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

'Efficacy' means the ability of a medicinal product to produce a desired effect.

'Field safety corrective action (FSCA)' means an action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.

'GHTF Founding Members' are Australia, Canada, EU, Japan and USA.

'Healthcare facility' is any party within the country providing healthcare services.

'Importer' means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another country, available in this jurisdiction.

'Instructions for use' means information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.

'Intended use / purpose' means the objective intent of the manufacturer regarding the use of a medical device, process or service as reflected in the specifications, instructions for use and information provided by the manufacturer.

'Investigational Device' means a device, including a transitional device , that is an object of investigation prior to approval for the intended use by the regulatory authority?????.

‘Investigational Device Exemption’ allows a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device.

‘In vitro Diagnostic Medical Device’ are those reagents, instruments and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health in order to cure, mitigate or prevent disease.

‘Labelling’ means the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

‘Licensing’ means the process whereby the NRA issues a license to a party which permits the party to undertake one of the following activities:

- importing a medical device subject to the provisions of the Medical Devices Regulation;
- distributing a medical device subject to the provisions of the Medical Devices Regulation;
- acting on behalf of the manufacturer within the jurisdiction.

‘Life-cycle’ means all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.

‘Local manufacturer’ means a manufacturer established within the country.

‘Manufacturer’ means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the device available for use, under his name; whether or not such a device is designed and/or manufactured by that person himself or on his behalf by another person(s).

‘Placing on the market’ means the first making available of an individual medical device in return for payment or free of charge, with a view to distribution and/or use within the jurisdiction.

‘Premarket approval (PMA)’ means any application for a Class III device including all information submitted with or incorporated by references therein.

‘Post-market surveillance’ means the active, systematic, scientifically valid collection, analysis and interpretation of data or other information about a marketed device.

‘Putting into service’ means the stage at which an individual medical device has been made available to the final user as being ready for use for the first time in the jurisdiction for its intended purpose.

‘Quality management system (QMS)’ means the organizational structure, responsibilities, procedures, processes and resources for implementing quality management, including both the establishment and maintenance of the system.

‘Quality System Regulation (QSR)’ refers to requirements that govern methods used in and the facilities, controls, used for the design, manufacture, packaging, labelling, storage, installation and servicing of all finished devices intended for human use.

‘Risk’ means the combination of the probability of occurrence of harm and the severity of that harm.

‘Supply Chain’ means different elements of the distribution activities of a medical device occurring between it being available for importation into the jurisdiction and it being put into service.

‘User’ means the person, either professional, lay or a patient, who uses a medical device.