

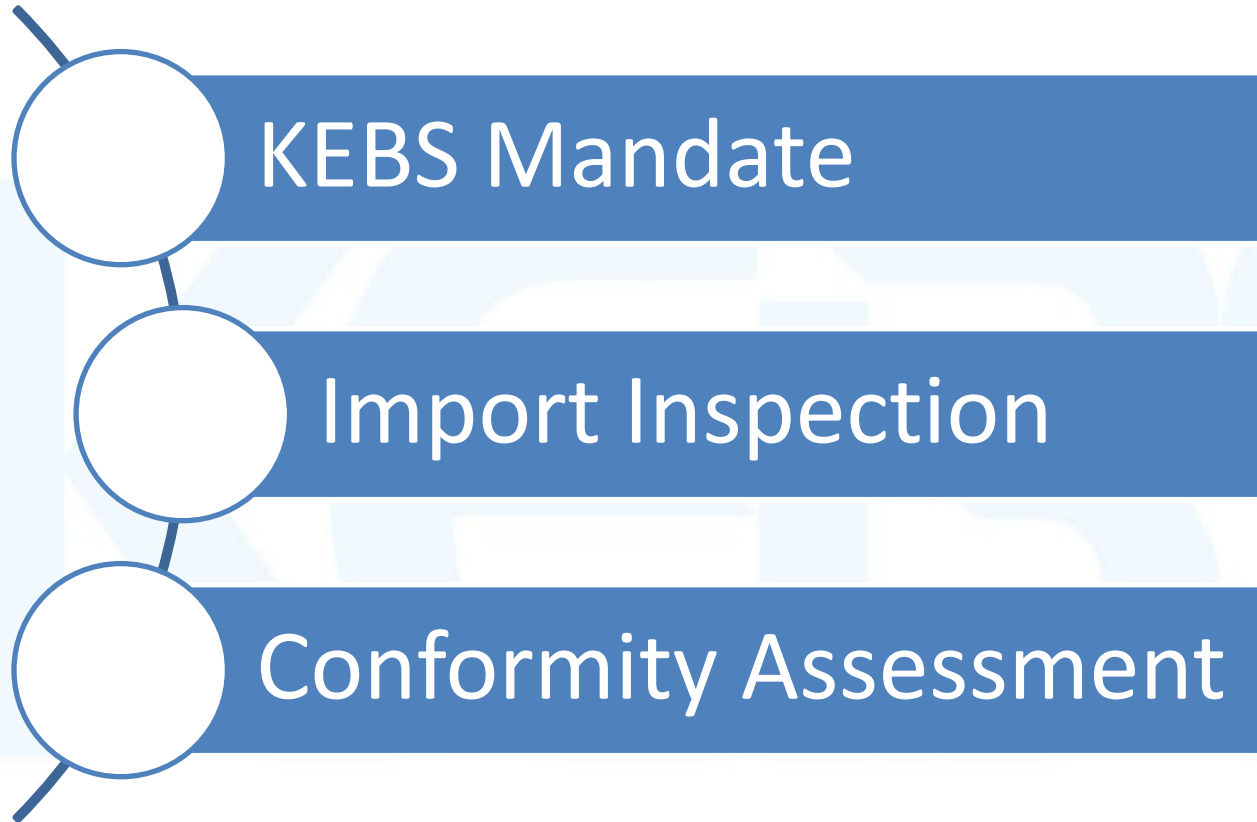


# Conformity Assessment Process in Kenya

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**MDRC - AMDRF - US FDA Workshop**

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- ❑ Established under Standards Act, Cap. 496 (July 1974)
- ❑ Under the Ministry of Investment, Trade, and Industry



**Ministry of Investments, Trade and Industry**  
**State Department for Industry**

## **Standardization Services**

- Development/harmonization of Standards
- Maintenance of Measurement Standards (Metrology)

## **Conformity Assessment Services**

- Inspection
- Quality Assurance and Market Surveillance
- Product Certification
- Testing and calibration services

## **Training and Education**

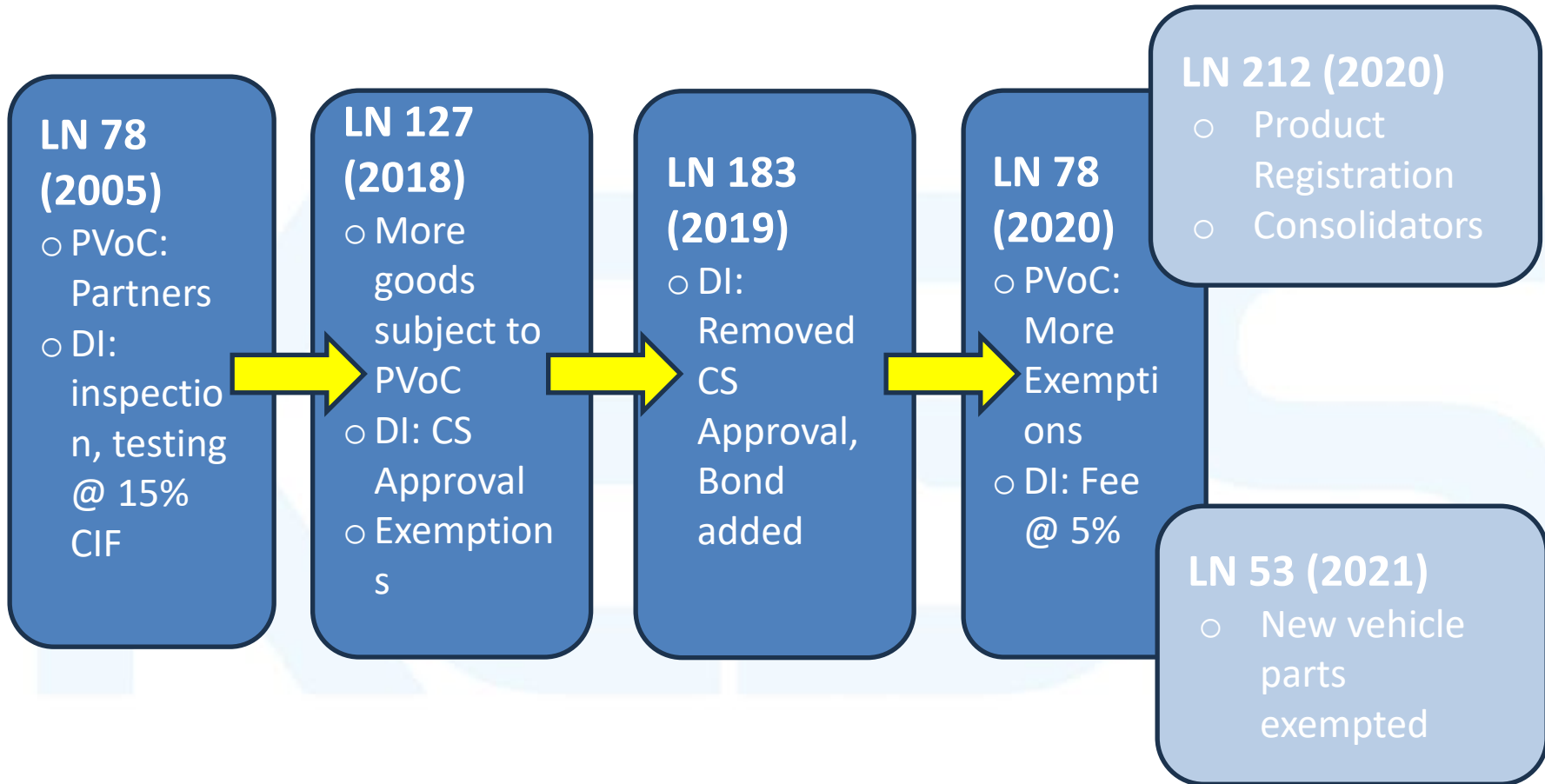
## **Information Services** (Standards and WTO)

# Import Inspection

☐ Has two components:-

- Pre-Export Verification of Conformity (PVoC)
- Destination Inspection (DI)

# Import Inspection Regulation



# PVOC (General Goods)



Kenya Bureau of  
Standards

Standards for quality life

- ❑ Conformity assessment program applied to products at the country of supply
- ❑ Administered by contracted inspection agents:

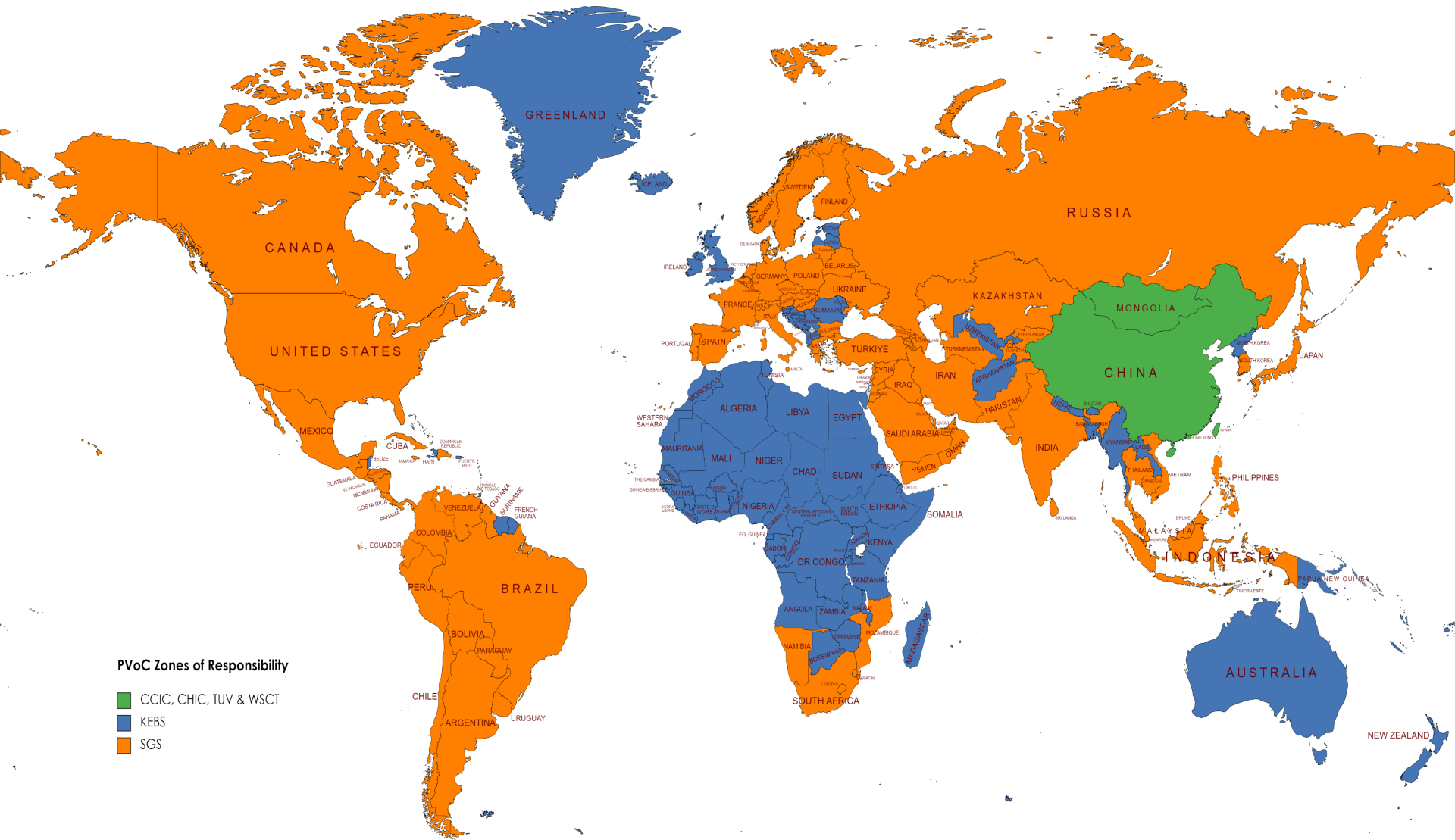
The logo for SGS, consisting of the letters 'SGS' in a bold, grey, sans-serif font. A thin orange vertical line is positioned to the right of the 'S', and a thin orange horizontal line is positioned below the 'S'.



The logo for WSCT, featuring the letters 'WSCT' in a bold, white, italicized sans-serif font on a blue rectangular background. A thin orange horizontal line is positioned below the blue background.

The logo for TÜV AUSTRIA, with 'TUV' in a bold, black, sans-serif font and 'AUSTRIA' in a smaller, black, sans-serif font below it. A red checkmark is integrated into the 'V'.





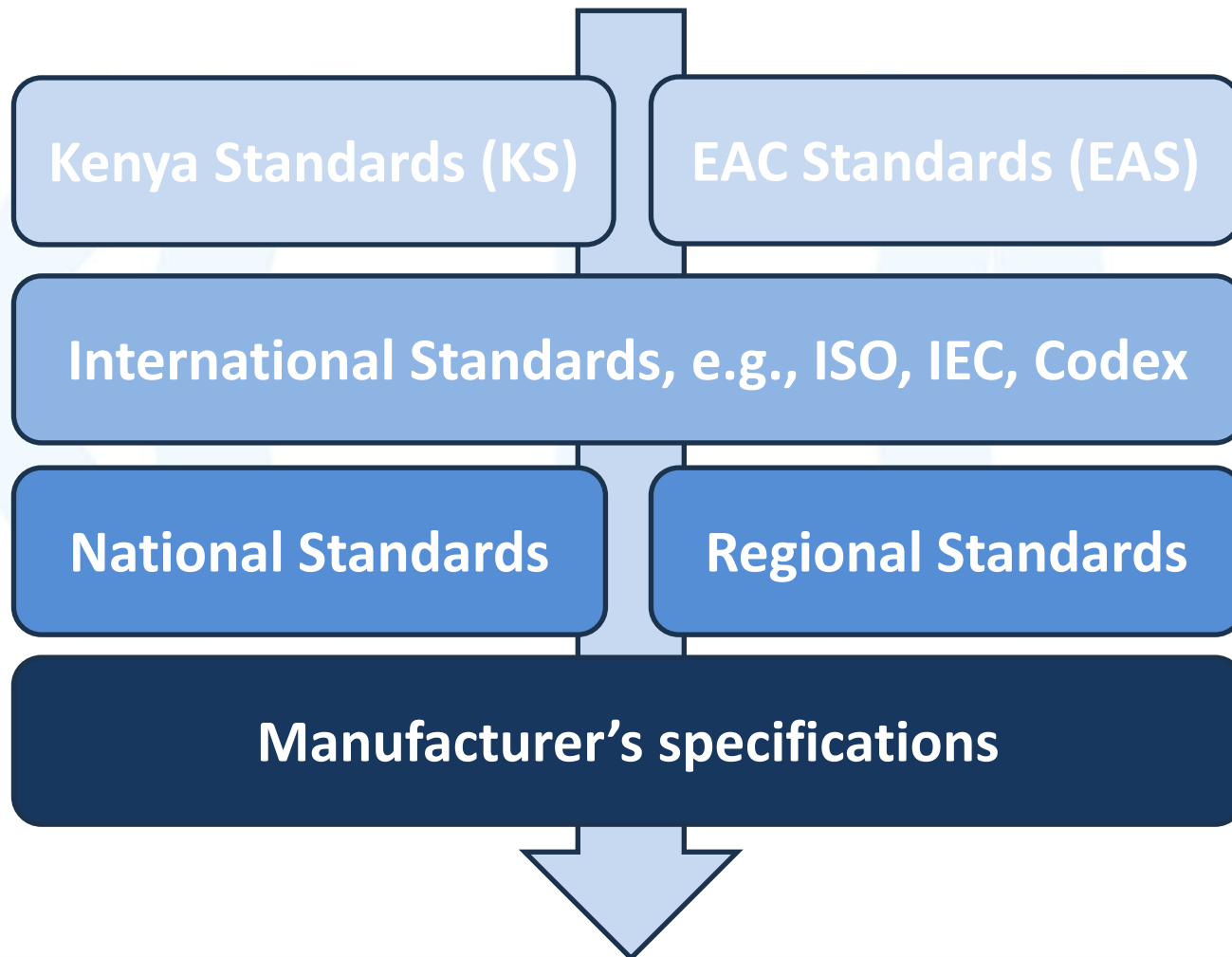
**PVoC Zones of Responsibility**

- CCIC, CHIC, TUV & WSCT
- KEBS
- SGS



# Conformity Assessment (Basis)

**Standards** - Conformity assessment is based on standards and applicable regulations



# Conformity Assessment (Basis)

- ❑ **Testing:** Recognized test reports considered during certification



- ❑ **Medical equipment:** accepts test reports from ISO 13485 accredited firms, IECEE CB Scheme

# Certification Routes

Routes designed to provide maximum flexibility to exporters and importers during importation

## Route A

- Consignment-based certification
- inspection
- Testing

## Route B

- Product Registration
- One (1) Year Registration Validity
- Importers/Exporters of homogenous goods

## Route C

- Product Licensing
- For Manufacturers
- License valid for 3 years

**Compliant Goods** – Certificate of Conformity (CoC)

**Non-compliant Goods** – Non-Conformity Report (NCR)

# Benefits of PVOC



- Blocking importation of substandard and counterfeit goods
- A reduction in rejected goods - less destructions and reshipments.
- Reduced turnaround time for clearance of goods at the port of entry

# Destination Inspection (DI)

- Goods with CoCs, Exemptions - testing/inspection not mandatory
- Goods without certifications are inspected and tested before release
- Conditional release for provided in LN 78
- Goods not meeting requirements are rejected

# Exemptions and Waivers



- ❑ Exemptions are provided for in LN 78 (2020):
  - **Clause 4(1):** schedule of exempted products and the documents required.
  - **Clause 10:** gives powers to the Cabinet Secretary to exempt any product for the requirements of PVOC on advice of the NSC.

- ❑ More information: PVoC Operations Manual
- ❑ KEBS Website: [www.kebs.org](http://www.kebs.org)
- ❑ Monitoring and reviewing periodically to address the challenges and improving the schemes and programs.



# Thank you!

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