

# **Kenya Bureau of Standards**

# PRODUCT REGISTRATION GUIDELINES

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### 1. Overview

Pursuant to the amendments of legal Notice 78 of 28th April 2020 through Legal Notice 212 of 18th December, 2020, introducing product registration aspect, KEBS has developed an administrative structure to implement the provisions of the regulations.

Importers interested in having their products registered are required to notify the Bureau before importing any such product into Kenya and provide proof that the products meet requirements of relevant Kenya standards, approved specifications and other applicable regulations as Provided for under Legal Notice No. 78 of 28th April 2020 clause 5(2).

Under the Framework, registered products will not be subjected to PVOC requirements, but instead will undergo destination inspection (DI) and/or testing before being allowed on the Kenya market. Continuous quality monitoring of registered products already placed on the market shall be conducted by the Bureau's Market Surveillance Directorate. Importers shall be responsible for the quality of registered products placed on the market.

### 2. Scope

The Product Registration Process applies to all Regulated Products as per Legal Notice No. 78 of 28th April 2020. However, products listed in Appendix A are not eligible for Registration.

### 3. References

- 3.1. The Standards Act Cap 496, Laws of Kenya
- 3.2. Legal Notice Number 78 of 28th April 2020
- 3.3. Legal Notice Number 212 of 18th December 2020
- 3.4. Legal Notice Number 53 of 22nd April 2021
- 3.5. CPR 173: Inspection Process Document
- 3.6. PVOC Program Manual
- 3.7. ISO/IEC 17020 Conformity assessment Requirements for the operation of various types of bodies performing inspection

- 3.8. ISO/IEC 17000 Conformity assessment Vocabulary and general principles
- 3.9. ISO 9001- Quality Management Systems-requirements
- 3.10.ISO 9000 Quality management systems -- Fundamentals and vocabulary

### 4. Abbreviations

- 4.1. PRF-Product Registration Application Form
- 4.2. KENTRADE Kenya Trade Network Agency
- 4.3. KESWS Kenya Electronic Single Window System
- 4.4. CD Consignment Document
- 4.5. PVOC Pre Export Verification of Conformity
- 4.6. MD Managing Director, KEBS
- 4.7. DI Destination Inspection
- 4.8. UCR Unique Consignment Reference
- 4.9. IDF Import Declaration Form
- 4.10.KRA Kenya Revenue Authority
- 4.11.CIF Cost Insurance and Freight (Customs Value).
- 4.12.FOB- Freight on Board
- 4.13.IEC-International Electro Technical Commission
- 4.14.IECEE-IEC system of conformity Assessment Scheme Electro Technical Equipment and Components
- 4.15.CBTLs- Certification Body Testing Laboratories

### 5. **Definitions**

- 5.1. **Certification:** third-party attestation (issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated) related to an object of conformity assessment.
- 5.2. **Destination inspection** is the process of verification of import documents, Physical Inspection and /or testing of goods before acceptance into the country.
- 5.3. **Importer:** -is the legal person who brings product(s) into Kenya for sale and is responsible for the quality of the said product while on the market in Kenya,
- 5.4. **Manufacturer:** -is the legal person with responsibility for the design, manufacture, packaging and labelling of a device or product before it is placed on the market under its own name.
- 5.5. **Product Recall: -**Any measure aimed at achieving removal from the market of non-complying product after discovery of safety issues or product defects that might endanger the consumer.
- 5.6. **Product Registration:** -is the process of listing a product for purposes of placement on the market through technical evaluation of its conformity to the applicable standards and statutory regulations.
- 5.7. **Destination inspection** is the process of verification of import documents, Physical Inspection and /or testing of goods before acceptance into the country.
- 5.8. **Recognized Laboratory:** is a laboratory with necessary competence to conduct tests specified in approved Standards. For the purpose of this guidelines, recognized laboratory, include;
  - 5.7.1.A laboratory with testing facilities duly accredited to ISO/IEC 17025
  - 5.7.2. Certification Body Testing Laboratories (CBTLs) under IEC Scheme
- 5.9. **Risk profiling:** is the process of analysing rules associated with a product and instituting appropriate intervention.

### 6. Framework for Product Registration

- 6.1. KEBS shall register products based on the following certifications:
  - 6.1.1. Certification issued under internationally recognized conformity assessment schemes.
  - 6.1.2. Certification issued based on test reports from laboratories accredited to ISO/IEC 17025.
  - 6.1.3. Certification issued by National Standards Body in the country of origin in line with the requirements of ISO/IEC 17065.

### 6.2. Products eligible for Registration

All Regulated Products as per Legal Notice No. 78 of 28th April 2020. However, products listed in **Appendix A** are not eligible for Registration.

### 6.3. Documents to be submitted by Applicants

Applicant shall register and apply for product registration via the link: <a href="https://www.productregistration.kebs.org">www.productregistration.kebs.org</a>, and submit the following documents:

- i. Business registration certificate
- ii. KRA pin certificate.
- iii. Test Certificates for IECEE Scheme for electrical and electronic products as listed in Appendix G.
- **iv.** Test Report(s) issued against applicable Kenya or equivalent International standard by a recognized laboratory.
- v. Valid Manufacturer's QMS certificates and/or valid manufacturer's food safety management system certificate (FSSC/FSMS) for food products and/or valid product certification issued by national standardization body of the respective country of manufacture.
- vi. Colored photographs to cover all product information and demonstrate compliance with the labelling requirements.
- vii. Product samples (where applicable).
- viii. Material Safety Datasheets for products, where applicable.
- ix. Operation/Instruction Manual for appliances and machines, where applicable.
- **x.** Distributorship/Dealership agreements if applicant is not the brand owner
- **xi.** Manufacturer's warranty, where applicable
- **xii.** Product type approval, where applicable
- xiii. Regulatory permits, where applicable
- xiv. Declaration of conformity containing information as detailed in Appendix H (mandatory)
- xv. Product Recall procedure
- xvi. Proof of payment of the application fee (MPESA transaction code)-mandatory. Payment to be made via Mpesa pay bill No.804700 A/C No. 10165.

### 6.4. Preliminary Evaluation

The following criteria shall be applied during preliminary evaluation:

- i. Eligibility of the product for registration
- ii. Verification of submitted documents
- iii. Test reports and test certificate shall be validated as per Appendix F
- iv. Proof of payment

### 6.5. Technical Evaluation

The following criteria shall be applied during technical evaluation:

- i. Test Reports and photographs shall be evaluated for conformity of the product to the relevant standard.
- ii. Compliance to other applicable regulatory requirements.
- iii. Evaluation of type approvals and external product certifications for adequacy in meeting applicable requirements.
- iv. Review the Management system documentation submitted to establish the manufacturer's ability to consistently supply quality goods.
- v. Technical evaluation may also involve comparison of the photographs with the samples submitted. Where applicable, testing may be done to ascertain compliance to the requirement of the standards at the cost of the applicant.

### 6.6. Registration Fees

An applicant whose product(s) meet the criteria for registration as outlined in 6.4 above shall be required to pay the registration fee at the rate of Ksh 7500 per product.

### 6.7. Certificate of Registration

A certificate of registration (see Appendix E) shall be issued in respect of all applications that meet the evaluation criteria. The Certificate shall contain:

- i. A schedule of products for which the registration is applicable
- ii. Terms and conditions for use of the registration
- **iii.** The validity period of the certificate, subject to compliance with the set terms and conditions

The registration certificate shall be valid for a period of one year.

### 7. Clearance of Registered Goods

- 7.1. Notification of importation An importer of a registered product shall notify KEBS by submitting a KEBS CD and attach the registration certificate through the Kenya National Electronic Single Window System, before arrival of the registered products.
- 7.2. The importer of the registered goods shall pay destination inspection fee at a rate of **0.6%** of the approved customs value subject to a minimum of **USD 265** and a maximum of **USD 2,700** excluding sampling and testing fees. Sampling and testing fees shall be charged on a case by case basis.
- 7.3. Issuance of Local CoC for clearance of registered products shall be based on a valid registration status and compliance with destination inspection surveillance plan.

### 8. Monitoring of Registered Products

8.1. KEBS shall establish a surveillance plan and risk profiling criteria for registered products which shall be implemented at the port of entry and in the market

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8.2. Monitoring shall involve physical inspection and/or testing

- 8.3. The results of monitoring shall be communicated to the importer and shall be used to determine the status of the registration.
- 8.4. KEBS may also undertake factory audits where applicable

### 9. Renewal of Registration

- 9.1. Applications for renewal should be received at least two (2) months before expiry of registration.
- 9.2. KEBS shall not be responsible for any consequences of submitting the application late.
- 9.3. Renewal of registration shall be done by submitting the documents in accordance with clause 6.2. & 6.3
- 9.4. Renewal of application will be based on results of monitoring.

# 10. Responsibilities of the Registration holders (Importers) and handling of non-compliant products 10.1.Importers responsibilities

- 10.1.1. The registered importer shall have full responsibility for quality of registered products.
- 10.1.2. The importer of the registered products shall provide guidance to the downstream of the supply chain on handling requirements for registered products to ensure preservation of quality.
- 10.1.3. The importer shall maintain records of (first customer) sales records for registered products with clear mechanism of batch/lot identification and the same shall be provided for verification to KEBS inspectors on demand
- 10.1.4. The importer of the registered products shall have a documented procedure for removal from market of non-compliant registered products (Product Recall procedure).
- 10.1.5. The importer shall undertake product recall if demanded by KEBS at his/her cost.

### 10.2. Handling of non-compliant registered products

- 10.2.1. Where a registered product in the market has been established to be non-compliant with standard requirements, the importer shall ensure that immediate actions are undertaken to isolate the product to prevent exposure to consumers.
- 10.2.2. Institute withdrawal of the non-compliant products for corrective action or destruction as may be required in view of health, safety and environmental consideration.
- 10.2.3. All recalls and market withdrawals shall be notified to KEBS in a format prescribed in Appendix C - Product Recall Notification Form.
- 10.2.4. This provision does not prevent KEBS from undertaking any legal measures it deems necessary to protect the consumers or the public from harmful products.

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### 10.3. Consumer Complaints Register

Importers shall maintain a register of complaints received related to the Registered Product (Appendix D). Complaints shall be investigated and where valid, addressed and resolved.

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### 11. Suspension of Registrations

- 11.1.Registered products shall be suspended due to failure to adhere to terms and conditions of registration.
- 11.2. The suspended product shall be withdrawn from the certificate of registration.
- 11.3. The Registered Importer shall be informed about the suspension.
- 11.4. The suspended product can be reinstated only if the Applicant provides satisfactory evidence(s) of corrective action(s) done within the agreed period between KEBS and Applicant.
- 11.5. No charges shall be applied for suspension and reinstating suspended registered products.

### 12. Cancellation/Termination of registrations

- 12.1 Registration can be terminated due to the following reasons
  - 12.1.1. Upon Inspection, testing or compliance review, the registered products are found not to comply and the registered importer declines to take corrective actions.
  - 12.1.2. The registered importer misuses or makes any unauthorized changes in the Registration document so as to receive the benefits of Registration.
  - 12.1.3. Registered product has been subjected to recalls from the market.
- 12.2. The registered importer shall be informed about the termination of the Registration.
- 12.3. If the Registered importer satisfactorily completes the required corrective action and would like to register the product(s) again then in such cases the importer shall submit a new Registration application.

### 13. Withdrawal of Registration Certificate

- 13.1.Registration can be withdrawn by the Registered importer for various reasons but not limited to the following: 13.1.1. No shipments to the country.
  - 13.1.2. Applicant shutting down their business.
  - 13.1.3. If the ownership of the company is taken over by another entity.
  - 13.1.4. Has committed any offence relating to importation of substandard or counterfeit goods.
- 13.2. Upon receipt of such information and upon verification, KEBS shall proceed with the withdrawal of the registration.
- 13.3. If the importer intends to reinstate their withdrawn registration, then KEBS shall consider it as a new application.

### 14. Complaints and Appeals

-Complaints shall be handled as per KEBS QMP-08.

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- Any importer aggrieved by a decision on registration, may appeal to the Standards Tribunal against the decision.

### **APPENDIXES**

Appendix A: Products ineligible for registration

Appendix C: Product Recall Register.

Appendix D: Product Complaints Register

Appendix E: Certificate of Registration

Appendix F: Validation of Test Reports and Test Certificates

Appendix G: Electrical products covered by IECEE Scheme

Appendix H: Information required on the importer's declaration of conformity

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### Appendix A: Products ineligible for registration

- i. Animal and Fishery products (fresh and frozen not further processed)
- ii. Bulk Petroleum products and base oils
- iii. Bulk shipments of cereals and pulses such as rice, wheat, Barley, beans, maize etc.
- iv. Fertilizer.
- v. Fresh dairy products
- vi. Fresh horticultural produce
- vii. Liquid Petroleum Gas (LPG)
- viii. Motorcycle helmets
- ix. Steel e.g. flat bars, Angle bars, Channels, Round bars, Deformed bars, RHS and SHS
- x. Sugar
- xi. Tyres
- xii. Used or secondhand goods

### Appendix C: PRODUCT RECALL NOTIFICATION FORM

SN	Date of Recall	Products Recalled	Reasons for Recall	Quantity/ Batch Nos	Location/ Premises	Remarks
OIT						



## Appendix E: Certificate of Registration

Phon	iary Name:			
E-ma				
Item	Product Description	Country	of	Standar
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3				
4				
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7				
Rema	ırks:			

### Terms and Conditions:

- This Registration Certificate is not transferable.
- 2) This Registration certificate is valid for period shown on the certificate unless suspended or revoked.
- This Registration Certificate is solely used for the purpose of facilitation of clearance of registered product by KEBS.
- 4) Each consignment of registered goods shall be charged destination inspection fee at a rate of 0.6% of the approved customs value subject to a minimum of USD 265 and a maximum of USD 2,700
- Issuance of Local CoC for clearance of registered products shall be based on a valid registration status and compliance with destination inspection surveillance plan.
- Applications for renewal should be received at least one (1) month before expiry of registration.
- The Registration holder shall establish and maintain a system of product recall, and addressing complaints filed by its clients or concerning its registered product and shall maintain records thereof.
- 8) The Registration holder shall be responsible for ensuring that each consignment(s) of his/her product(s) continues to meet all the legal requirements, and conforms to all the standards and specification of the registered product(s).
- 9) The Registration holder shall maintain a register of complaints received related to the Registered Product. Complaints shall be investigated and where valid, addressed and resolved.
- The Registration holder shall comply with surveillance/monitoring plan as indicated in the product registration guidelines posted on the www.kebs.org

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## Appendix D: PRODUCT COMPLAINTS REGISTER

S/ No	Date receipt	of	Source of complaint (Name and address of complainant)	Nature of complaint	Source product	Date acknowle dged	Filer	Investigation officer	Date visit	Remarks/ action taken	Date resolution	Status signatur	

### Appendix F: Validation of application documents.

(a) IECEE CB test Certificates and test reports.

These shall be validated through IECEE portal https://certificates.iecee.org/ods/cb\_hm.xsp

(b) Test Reports from a laboratory with testing facilities duly accredited to ISO/IEC 17025.

Validation shall be done through the websites of the respective accreditation bodies.

(c) Test Reports from Government owned laboratories.

A formal request shall be done to the respective government laboratories.

(d) Manufacturer's Food safety management System –ISO 22000 certificate.

Validation shall be done through the websites of the respective certification bodies

(e) Manufacturer's QMS certificate –ISO 9001 certificate.

Validation shall be done through the websites of the respective certification bodies

(f) Product certification issued by National Standardization Body (NSB) of the respective country of manufacture.

Validation shall be done through the websites of the respective NSBs

g) Other documents shall be validated through provided platforms by issuing bodies/authorities

Appendix G: List electrical and electronics products covered under IECEE Scheme (List attached)

### Appendix H: Information required on the importer's declaration of conformity

- 1. The name of the importer and address.
- 2. The name of the product.
- 3. The product's trademark, brand, serial number, model or type identification.
- 4. The Name of the manufacturer, address and the country of manufacture.
- 5. A statement, stating you take full responsibility for product's compliance with the applicable Kenya standards, approved specifications and other applicable regulations.
- 6. The details of the approved body which carried out conformity assessment procedure (if applicable).

- 7. The name of manufacture and signature.
- 8. The date the declaration was issued.
- **9.** Supplementary information (if applicable).