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Foreword

This product certification scheme has been prepared under the direction of the Technical Committee for Surface active agents (TC -57) and published by the Ethiopian Standards Agency (ESA).


The scheme has been developed to address observed needs and to support the conformity assessment bodies, local industry and the regulatory to ensure that the conformity assessments, producer and regulatory bodies to sustainability conduct selection, determination, surveillance, review and attestation activities that makes sure the product meets the requirement in the product standards.

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1. Introduction

This product certification scheme specifies requirement for the certification of Bar soap and detergent based on compulsory standards. This product certification scheme is type 5 product certification scheme as described in ISO/IEC 17067. The purpose of initial evaluation testing is to ensure that the producer has the capability and resources to produce bar soap and detergent in accordance with the requirements specified in the product standards. A certification scheme for batch and continuous production consists of the following stages:

- initial evaluation;
- review of evidence of conformity;
- certification decision and attestation;
- surveillance activities
- inspection and supervision by an external body

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Certification scheme for bar soap used for laundry, toilet and baths

1. Scope

This document specifies rules for a certification scheme for batch and continuous production of bar soaps for toilet, laundry and bathing in order to verify conformity with requirements specified in product standards, for standards CES 42, CES 44, CES 120 and CES 123 respectively.

A product certification scheme for batch and continuous production consists of the following stages:

- Initial evaluation;
- Review of evidence of conformity;
- Certification decision and attestation;
- Surveillance activities.
- inspection and supervision by an external body

2. Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CES 42, Laundry soap - specification

CES 44, Toilet soap specification

CES 120, Laundry detergent bars for household use - specification

CES 123, Bathing bars

ES ISO /IEC 17067, Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes


ESA/PCSM/001, Product certification scheme policy manual

ES ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

ES ISO 9001, Quality management system-Requirement

ES ISO 14001, Environmental management system-Requirements

Directive for the ES Mark Licensing

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3. Terms and definitions

For the purposes of this document, the terms and definitions given in ES ISO 862 and ES ISO 6206 and the followings shall apply:

ISO – International Organization for standardization

ESA – Ethiopian Standards Agency

ES - Ethiopian Standard

CAB – Conformity assessment body

IEC - International Electrotechnical commission

ISO/IEC - International Organization for standardization and International Electrotechnical commission

CES – Compulsory Ethiopian standard

PCS - product certification scheme

TC - Technical Committee

PCM - Product Certification Manual

3.1.

certification scheme

Certification system as related to specified products, processes or services to which the same particular standards and rules, and the same procedure apply. [ISO/IEC Guide 2]

3.2.

certification body

body that conducts certification of conformity. [ISO/IEC Guide 2]

3.3.

characteristic value

value having a prescribed probability of not being attained in a hypothetical unlimited test series.

3.4.


inspection:

activities such as measuring, examining, testing, gauging one or more characteristics of a product or service and comparing these with specified requirements to determine conformity. [ES ISO 17000]

3.5.

inspection body (for certification)

body that performs inspection services on behalf of a certification body. [ISO/IEC Guide 2]

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3.6.

Sustainability

the ability to be maintained at a certain rate or level

4. GENERAL REQUIREMENTS

4.1. The manufacturer shall full fill the general requirement specified in Ethiopian Standard Agency Policy manual PCM 001.

4.2 The certification body shall comply with the requirements of ES ISO 17065.

4.3 The products considered in this certification scheme shall full fill the requirements of the respective standards.

4.4 The manufacturer shall have a defined approach to manage sustainable management system.

4.5 The manufacturer's scope shall be appropriate to the nature and scale of its activities, products and services and impacts from them.

4.6 the top management is responsible for coordination and implementation of sustainable management system and shall be responsible for ensuring that bar soaps and detergents scheme management system requirements are documented, implemented and maintained.

4.7 The manufacturer shall perform an initial review to identify the environmental, social and economic aspects of its activities, products and services within the defined scope of the management system that it can control and those that it can influence.

5. Determination


5.1 General

5.1.1. The certification body or conformity assessment body shall follow the general requirement of application, review specified in ESA /PCM 001.

5.1.2. The conformity assessment or the certification body shall follow the procedure specified in ESA /PCM 001

5.1.3 Activities undertaken to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample shall include Audit, Calibration, Evaluation, Examination, Inspection and Testing.

5.1.4 The certification body shall record Results of determination of activities in a report which provides full traceability and provenance for the data and the object to which it refers.

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5.2. Registration

An manufacturer that intends to be certified on bar soaps and detergents certification scheme shall have completed the registration process with the conformity assessment body according to the general requirement stated in ESA/PCSM/001 and other relevant regulatory requirements.

5.3. Verification

The conformity assessment body reserves the right to verify the authenticity of any documents of certification submitted by an applicant according to ESA/PCSM/001 general requirement.

5.4. Conformance/Compliance

Before making application, and on an ongoing basis, the manufacturer shall ensure that it meets the requirements of this product certification scheme according to ESA/PCSM/001 general requirement.

5.5. Application

CAB shall provide the applicant with all information necessary to understand and follow the rules for this certification scheme according to ESA/PCSM/001 general requirement.

5.6. Application Review

5.6.1 Once the application is received from the applicant, the certification body shall confirm that the information provided by the applicant is clear and sufficient and, if not, shall request the applicant /client for the necessary clarification or additional information.

5.6.2 If this has been satisfactorily achieved, the applicant shall be subject to the product certification processes which involve evaluation of the product and auditing of the quality and production system of the applicant.

5.6.3 In the event that CAB rejected the client application, the Certification Services Manager shall formally write to the client stating the reasons according to ESA/PCSM/001 general requirement.


5.6.4 The CAB shall inform the manufacturer the result of application evaluation (acceptance/rejection) with a formal letter within two weeks starting from the date of application.

5.7. Management systems

5.7.1. The manufacturers shall full fill the document requirement specified in ESA/PCM 001.

5.7.2. The manufacturer shall adequately describe documented information, among others,

a) The quality aims (objectives) and the organization structure, responsibilities and authorities of the management with regard to product quality and the means to monitor the achievement of the required product quality and the effective operation of the internal quality control.

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- b) Manufacturing and quality control techniques, processes and systematic actions that will be used.
- c) The inspections and tests that will be carried out before, during and post manufacturing (storage and distribution) and the frequency of inspection and testing activities.

5.7.3 The documented information shall address the procedures operated to ensure that the manufactured bar soaps and detergents conform to the standard. The documented information may refer to associated documents which provide further details of the internal quality control system. The documented information shall be considered to include these associated documents for the purpose of product certification scheme.

5.8. Internal audits and management review

In order to ensure the continuing suitability and effectiveness of the system and the requirements of this certification scheme, the manufacturer shall perform internal audit and management review at least once a year.

- a) The Internal audit shall cover the scope of clause 4 of this certification scheme.
- b) A management review shall take into account the records of the internal audits.

5.9. Personnel Competency

The manufacturer's documented information shall describe the measures to be taken to ensure that all the personnel involved in operations that can affect internal quality control and product quality have appropriate relevant educational level and field, experience and trainings. Moreover, relevant records with respect to the competency of the experts shall be retained.

5.10. Quality records

The manufacturer shall retain quality records for at least the period required to comply with all relevant legislation.

5.11. Documents for quality control


The manufacturer shall establish documented information and appropriate test methods to ensure that the bar soaps and detergents meet the requirements of product standard and establish suitable critical control points to ensure effective and sustainable process control measure. The documented information shall describe the methods used by the manufacturer to ensure that the product conforms to the product standard, including appropriate test methods.

5.12. Internal quality control

5.12.1 General

The manufacturer's documented information shall describe:

- a) Parameters for production process;
- b) Measures to validate for test method other than test methods specified in the product standards (if any);
- c) Verification methods;

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- d) Inspection;
- e) Corrective action;
- f) The methods used by the manufacturer to ensure that the product conforms to the product standards
- g) Measures to ensure that non-conforming product is adequately managed,
- h) Measures how to ensure environmental protection
- i) Measures how to use and implement safety rules
- j) Dispatch with the associate records.

6. Specific requirement

6.1. Initial product and process evaluation

6.1.1 General

A signed certification agreement shall be concluded before commencing the certification process, covering the product range requiring certification.

6.1.2. Purpose

The purpose of product and process evaluation is to ensure that the manufacturer has the capability and resources to produce bar soaps and detergents in accordance with the requirements specified in the product standards and scheme.

6.1.3 Manufacturer

The certification body provides assessment and impartial third-party attestation that the specified requirements have been achieved. Product certification shall be conducted by certification bodies meeting the requirements of ISO/IEC 17065.

6.1.4. Procedure

6.1.4.1 General

Evaluation consists of the following stages:

- assessment of conditions for production (6.1.4.2);
- sampling and testing of specimens (6.1.4.3);
- calculation and verification of the long-term quality level (6.1.4.5).

If satisfactory results are not achieved in one stage (6.1.4.1), all the stages shall be repeated. Evaluation applies separately for each products grade (if applicable) and production methods. If a bar soap and detergent grade is produced by various production processes, evaluation shall be conducted to its full extent for each of these processes.

6.1.4.2 Assessment of the production conditions

Assessment of the production conditions shall include the following:

- the competence of the personnel
- the manufacturer production processes;
- the adequacy of the equipment for production including effective process control;
- the independence of the decision of the quality assurance body from the production department;
- the suitability of the test equipment for internal testing;
- the ability of the manufacturer's quality system to ensure the quality of the products. A quality system such as ES ISO 9001 or similar is considered satisfactory if it meets the requirements of the applicable product standard.

6.1.4.3 Sampling and testing of specimens

6.1.4.3.1 General

The test samples shall be taken from the production of the plant concerned. The test shall cover the entire range of products for which certification is applied.

6.1.4.3.2 Extent of sampling and testing

Samples representing the intended scope of approval shall be tested for each grade and manufacturing processes.

For ascertaining the conformity of the lot to the requirements of this standard, tests shall be carried out on each lot separately. The number of packages and product units from each container respectively to be selected for drawing the sample shall be in accordance with Table 1.

Table 1 — Guidance for sampling

Number of packages (cartons) in the lot N	Number of containers (cartons) to be selected n	Number of product units to be selected from each container
4 – 15	3	3
16 – 40	4	4
41 – 65	5	2

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66 – 110	7	2
111 and above	10	1

6.1.4.3.2.1 The packages (cartons) shall be selected at random, using tables of random numbers. If these are not available, the following procedure shall be applied:

Starting from any package, count all the packages in one order as 1, 2, 3 ..., N, selecting every kth package, where k is the integral part of $N \div n$.

From each package thus selected, draw at random an equal number of cakes so as to obtain a total mass of at least 2 kg.

6.1.4.3.3 Parameters to be tested

All parameters specified in the product standard shall be tested and compared with its requirements.

6.1.4.3.4 Evaluation of the test results

The results (as applicable individual values, average values, and standard deviations) of the tests shall be collated in a test report. Based on the values determined for the standard deviations, it shall be judged whether simplified values, α , for internal inspection (see 6.2.3.2) may be used. It is recommended that a long-term statistical evaluation be conducted on the results available, to aid in offering guidance to the applicant company, but this should not form part of the overall assessment for approval.

6.1.4.3.5 If any of tested samples fails to fulfil at least one requirements of the product standard, re sampling shall be done.

6.1.4.4 Certification decision and attestation


Once the inspection of the production conditions has been satisfactorily concluded, and the test results have been evaluated positively by the certification body, works identification and an approval to produce for a specific period are granted to the manufacturer. During this period the long-term quality level shall be verified. The certification body will undertake surveillance audits as detailed in Clause 7.

Note: The duration of certification is granted for maximum period of three years.

6.1.4.5 Verification of the long-term quality level

6.1.4.5.1 Extent of testing

To verify the long-term quality level, the manufacturer shall perform a sufficient number of tests in order to properly evaluate the long-term quality level. If necessary, due to an insufficient number of test results or a failure to satisfy the requirements of the long-term quality level, the manufacturer shall double the extent of

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testing specified in clause 6.2.3.1 for the internal inspection. During this period surveillance shall be conducted more intensively than specified in clause 6.1.4.

Note: the number of tests to be conducted by the manufacturer shall be specified in the documented information.

6.1.4.5.2 Evaluation

After conducting sufficient number of tests, all results of internal and external inspection shall be evaluated separately and compared with each other. The long-term quality level determined by appropriate statistical methods shall correspond to the requirements of clause 6.2.4.3, if a characteristic value is specified in the product standard. If the long-term quality level of the product standard is not fulfilled, the manufacturer shall take appropriate corrective action, in association with the certification body.

6.2. Internal inspection by the manufacturer

6.2.1 Purpose

Internal inspection of production by the manufacturer is intended to ensure that the level of quality remains satisfactory with time and that, in the case of test results which do not conform to the requirements of the product standard, necessary measures can be taken to improve production process control.

6.2.2 Procedure

Internal inspection by the manufacturer consists of

- testing batches of production (see 6.2.3), and
- Determination of the long-term quality level (see 6.2.4).


6.2.3 Conformance testing

9.1 Criteria for conformity

9.1.1 For tests conducted on each primary sample the mean (\bar{x}) & the range (R) the tests result for each property shall be calculated:

Range (R) = The difference between the maximum and minimum value of test results.

$$\text{Mean}(\bar{X}) = \frac{\text{the sum of test result}}{\text{number of test result}}$$

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The lot shall be deemed to comply with the relevant requirement, if the expression.

a) $(X - 0.4R)$ is greater than or equal to a maximum value given in table 1; and,

b) $(X + 0.4R)$ is less than or equal to a maximum value given in table 1.

9.1.2 For tests conducted on the blended bulk sample test result for each property shall satisfy the relevant requirements.

9.1.3 All other remaining properties of clause 5 and 6 inspected or tested on the representative sampling units shall satisfy the relevant requirements.

6.2.4 Determination of the long-term quality level

6.2.4.1 General

The long-term quality level shall be evaluated separately for each bar soaps and detergents grade, each nominal sample and each production process route and product form.

6.2.4.2 Extent of testing

The results of tests on all test units of the batch/continuous production in accordance with 6.2.1 shall be collated and statistically evaluated and submitted to the certification body as per the quality assurance plan stated by the manufacturer, at least every six months, in order to determine the long-term quality level.

6.2.4.2.1 The laboratory of the manufacturer responsible for carrying out testing shall have at least the equipment needed to carry out tests for the properties listed in the bar soaps and detergents using the test methods specified in the respective standard.

6.2.4.2.2 The laboratories shall demonstrate the ability to provide results within a time and in a manner suitable for the manufacturer's factory production control.


Note: the laboratory can outsource some tests to be conducted by other laboratories or other manufacturer premise that comply with the requirements of ES ISO 17025.

6.2.4.2.3 Testing of the bar soaps and detergents shall be conducted by the manufacturer in a laboratory that complies with the requirements ES ISO 17025.

7. Surveillance

7.1 Certification body

The certification body shall perform surveillance activities. See ES ISO/IEC 17021

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7.2 purposes

Surveillance has three purposes:

- Surveillance of the conditions of production for compliance with the conditions established in the initial evaluation stage;
- Supervision of the proper procedures of internal inspection.
- To assure the compliance of the product with product standard.

7.3 Inspection at the production conditions

7.3.1. Inspection of the production conditions shall include the following:

7.3.1.1. The competence of the personnel

7.3.1.2. Satisfactory work of the manufacturer;

7.3.1.2. The adequacy of the equipment for production;

7.3.1.3. The independence of the department responsible for quality assurance from the production department;

7.3.1.4. The suitability of the test equipment for internal testing;

7.3.1.5. The ability of the producer's quality system to ensure the quality of the products.


7.3.1.6. Inspection of measures taken to protect environment from depletion.

7.3.1.7. Inspection of implementation of safety rules as per the procedure developed by the manufacturer.

- the competence of the personnel
- the manufacturer production processes;
- the adequacy of the equipment for production including effective process control;
- the independence of the decision of the quality assurance body from the production department;
- the suitability of the test equipment for internal testing;
- The ability of the producer's quality system to ensure the quality of the products.
 - Inspection of measures taken to protect environment from depletion.
 - Inspection of implementation of safety rules as per the procedure developed by the manufacturer.

7.4 surveillance period

7.4.1 Surveillance and supervision of the manufacturer shall be conducted at maximum intervals of three months by the certification body.

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b) The name of the Firm and location(s) of the works/premises to which it applies.

c) The certification number applicable to the Firm.

d) Designation according to the product standard.

7.6.2 Permission of the use of national quality mark shall be provided according to Directive for the ES Mark Licensing.

7.6.3 The CAB shall announce certified manufacturers with the type of product they are certified to the public through accessible media.

7.6.4 The certificate of approval shall be withheld, suspend, or withdraw if the manufacturer fails to meet the requirements stated in this document.

7.6.5 Withheld, suspend, or Withdrawal of the Certificate of Approval


The decision to withheld, suspend, or withdraw a Certificate of Approval is made by the CAB. After the decision the Firm in question has the right to appeal to the Appeals Panel. A Firm who has been removed from the approved list can re-apply for approval. Examples of the reasons for withheld, suspend, or withdrawals of the Certificate of Approval are:

- a) Frequent non-compliance with any of the specified requirements or other criteria specified in the relevant Standard or Scheme.
- b) Uncorrected major deficiencies noted during a surveillance visit.
- c) Misuse of the Certification Mark or failure to use them.
- d) Refusal or hindrance to allow the CAB to carry out inspection.
- e) Refusal to produce documentary evidence of monitoring results.
- f) Circumstances which may affect the confidence of the public or CAB on the reliability the manufacturer in accordance to the Scheme.

7.6.3. Handling and storage

The documented information shall describe the precautions taken for the protection of the quality of the bar soaps and detergents and other while under the responsibility of the manufacturer. It shall include:

- a description of the procedures used at the storage area
- Delivery documentation that shall allow traceability to the products.
- Handling and storage of the bar soaps and detergents shall be done in accordance the documented information of the manufacturer.

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7.7. Criteria for the assessment of laboratories

7.7.1 The laboratory responsible for carrying out testing shall have at least the equipment needed to carry out tests for the parameters listed in the bar soaps and detergents using the test methods specified in the respective standard. The laboratories shall demonstrate the ability to provide results within a time and in a manner suitable for the manufacturer's factory production control.

8. Tasks for CAB

8.1 The CAB has responsibility for three separate functions;

- a. certification,
- b. inspection and
- c. Testing.

8.1.1 These three functions may be carried out by one body or by more than one body.

8.1.2 The inspection function may be carried out by an inspection body and the testing function by a testing body. The CAB shall comply with ES ISO/IEC 17065, ES ISO 17020 and ES ISO 17025 which are relevant with this scheme for the evaluation of conformity.

8.2. Initial inspection of the factory

8.2.1. Inspection of a new factory

In the case of a new factory; an initial inspection of the factory and the factory production control shall be made, based on information on the factory production control and the equipment to be used to produce bar soaps and detergents. The inspection shall, among other things:

- a) Verify that the documented information complies with the requirements of this scheme.
- b) Verify that the equipment used to produce and test in the product standards meets the criteria in this document.

8.2.2. Inspection an existing factory

In case of existing factory,

- Information on any significant changes concerning the factory production control and the equipment shall be considered.
- Any major change in the documented information shall be inspected to verify that it meets the relevant criteria of this scheme.
- Any newly introduced product

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8.2. Criteria for the assessment of the production equipment

The inspection shall assess the suitability of the production equipment in relation to the documented information and in relation to providing the ability to meet the requirements of the bar soaps and detergents.

The following criteria shall be considered:

- a) The product shall be protected from any degrading agents.
- b) All Equipment shall be suitable for batch and continuous production.
- c) Measures shall be taken to prevent the improper mixing of additives.
- d) Stores /dispatch points shall be clearly marked with an indication of the bar soaps and detergents batch number and any additional identification required.
- e) Points where the product is released from the factory and/or depot shall allow samples to be taken in accordance with the methods in ES ISO 8212.

8.3. Inspection, measuring and testing

The equipment used for measuring and testing shall be regularly checked and calibrated in accordance with the procedures and frequencies laid down in the operational manual. These procedures may include comparison of test results with other laboratories (external quality assurance). The test shall be conducted according to the test method specified in respective bar soaps and detergents standard.

9. Control of non conforming products

The documented information shall contain non conforming product handling procedures or any means that shows how to manage non conforming product(s).

9.1 Classification of non-conformities and recommendations (During Surveillance)


9.1.1 Major non-conformities

A Major non-conformity exists when the auditor observes a regulatory violation of mandatory requirements of the standard which requires that the manufacturer to:

- a. Immediately interrupts production.
- b. Hold products in quarantine.
- c. Discontinue distribution to customers.
- d. Recall the product.

9.1.2 Minor non-conformities

A minor non-conformity exists when requirements of these evaluation criteria document requirements have been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented.

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9.1.3 Opportunity for improvements (recommendations)

In addition to non-conformities, opportunities for improvements may be made by an auditor according to his observations, with a view to help the continual improvement of the manufacturer's Management System. The basic requirement to identify and to record improvement opportunities is that the requirements of product standards and this conformity evaluation document have been fulfilled but there are still areas for potential improvement of system effectiveness and efficiency. Opportunity for Improvement shall be checked during the following regular audit. If an opportunity for improvement is not resolved and closed by then, the Opportunity for Improvement can be changed in to non conformity -

9.2 Corrective action

9.2.1. The documented information shall include procedures for the review and adjustment of the factory production control in case of non-conformity.

9.2.2. The actions which are taken in the case of non-conformity shall be recorded (report subject to inspection during the management review).

9.2.3. In the case of test results which show non conforming to the single result limit value conformity criteria specified in respective bar soaps and detergents standard product specification, the manufacturer or supplier shall immediately determine the affected quantity, take appropriate action to prevent the dispatch of this quantity and inform the affected customer if such product has been released.

9.2.4. The CAB shall inform the non conformity to the manufacturer and regulator without undue delay for further decision.

10. Re-certification audit

CAB shall conduct re-certification audit every 3 years. A re-certification audit takes place prior to end of a certification period. The audit shall be planned in due time, in order to avoid expiration of the certificate.

Note: A failure to perform the re-certification audit before the expiration of the certificate results in the interruption of the certification cycle. In this case, the wording "certified since" cannot be included on the certificate. If a re-certification is conducted after the expiry of a certificate, Initial Audit shall be carried out.


11. Reports

Following each evaluation a confidential report shall be prepared and sent a copy to the manufacturer

12. Declaration of conformity

The declaration of conformity of bar soaps and detergents is made by the manufacturer following the certification of the factory production control by the certification body. The declaration of conformity shall include:

a) The grade and brand of the bar soaps and detergents

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- b) The name and address of the manufacturer and of the factory;
- c) The name and address of the certification body which certifies the factory production control.
- d) The standard designation of the bar soaps and detergents according to respective standard (Labeling and marking shall be as specified in the product specification).
- e) Statements of bar soaps and detergents conforms to requirement of respective standard
- f) The evaluation of conformities described in this and other relevant certification scheme.
- g) The date of issue of the declaration and the certificate of factory production control.

13. Standard mark

The declaration of conformity entitles the manufacturer to use the Standard mark on labeling and documentation used for the declared product (where it is required).