Republic of Moldova

PARLIAMENT

Law Nr. 235
from 01.12.2011

on accreditation and conformity assessment activities

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To ensure transposition into national law of the requirements applicable to the accreditation acyivity as per Regulation (EC) no. 765/2008 of the European Parliament and Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) no. 339/93, Decision no. 768/2008/EC of the European Parliament and Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC of MS ISO / IEC 17011:2006 and the transposition of the provisions related to conformity assessment and placement of product on market,

Parliament adopts the present organic law.

Chapter I
GENERAL PROVISIONS

Article 1. Regulatory scope

(1) This Law establishes the legal framework for the accreditation activity of conformity assessment bodies, made with mandatory or voluntary title, for product placement on market and for conformity assessment activities, regardless of the fact that this evaluation is mandatory or not for products marketed and /or used in the Republic of Moldova.

(2) If the international treaties to which Moldova is party establish other provisions than those of Moldovan legislation on accreditation and conformity assessment, the provisions of international treaties prevail.

Article 2. Definitions

In this law, the following definitions apply:

bilateral agreement - agreement in which two parties mutually recognize or accept results of conformity assessment;

multilateral agreement - agreement in which more than two parties mutually recognize or accept results of conformity assessment (ISO / IEC 17000);

accreditation – attestation by the national accreditation body that a conformity assessment body meets the requirements of reference standards and, where applicable, any additional requirements, including those in specific accreditation schemes relevant for carrying out specific

conformity assessment activities;

appeal – requirement of a conformity assessment body for reconsideration of any adverse decision made by the national accreditation body in connection with accreditation status that it wants first;

attestation - issue a statement based on a decision following a review of the assessment, stating that the applicable requirements has been demonstrated;

essential requirements - requirements stipulated by national technical regulations for national security, safety products and services for life, health and human security for the animal and vegetable, for the environment and material assets in order to protect consumer interests, including the prevention practices that mislead consumers with regard to composition, destination, origin, quality and safety of products;

specified requirement - necessity or pending legal documents as are stated in regulations, standards, technical specifications;

certification – attestation done by a third party on products, processes, systems and people;

accreditation certificate - official document or set of official documents confirming the granting of accreditation for a defined scope;

certificate of conformity - the document certifying that a duly identified product was subjected to conformity assessment procedures and that at the moment of assessment the product is in accordance with applicable specified requirements;

accreditation criteria - set of requirements, established by reference standards and documents of european and international specialized organizations, used by the national accreditation body and shown to be performed by conformity assessment body to be accredited;

declaration of conformity – written assurance, based on a decision taken following an assessment, bywich the supplier confirm with certainty that the product meets the specified requirements;

distributor - any person or entity in the supply chain, other than the manufacturer or importer, who makes a product available on the market;

scope of accreditation - specific conformity assessment services for which accreditation has been requested and /or has been granted;

calibration - an operation that, under specified sets: first, a relationship between values and associated measurement uncertainties, which are provided by standards and corresponding indications with associated measurement uncertainties, the second step, use of this information to establish a relationship that will produce a measurement result starting from an indication;

conformity assessment - a process by which it is assessed the demonstration that the specified requirements for a product, process, service, system, a person or body are met;

peer evaluation - the evaluation process of the national accreditation body by foreign national accreditation bodies, held in accordance with the requirements of this law and, where appropriate, with other additional sectoral technical specifications;

provider - an organization or person who provides a product (manufacturer, distributor, retailer, seller of a product or a service, provider of information);

importer - any person or body which introduce on the market a product from another country;

inspection - a product design review, review of a product, process, facilities and determination of their compliance with specified requirements or based on judgments (appreciations) professional, with general requirements;

marketing - first release of a product available on the market;
testing - determining, based on a procedure of one or more characteristics of an object subject to conformity assessment;
conformity assessment body - the body that performs conformity assessment activities including calibration, testing, certification and inspection;
national accreditation body – the unic body having authority to make accreditation, nationally recognized, invested with the right to join international and regional accreditation organizations;
producer - any individual or legal person who manufactures a product or which are designed or manufactured such a product, and selling product under his name or trademark;
making available on the market - supply on the market a product for distribution, consumption or use in the course of a business, in return for payment or free of charge;
authorized representative - any individual or legal person who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
accreditation symbol - symbol issued by the national accreditation body for use by accredited conformity assessment bodies to indicate their accredited status;
surveillance of conformity assessment bodies - set of activities to monitor the continued fulfillment of accreditation requirements by the accredited conformity assessment bodies, except reassessment.

Article 3. Purpose of this low
The purpose of this law is to ensure a high level of protection of public interests such as health and safety in general, occupational health and safety, consumer protection, environmental protection and security, facilitation of cross frontalier trade and removal of technical barriers to trade.

Article 4. Responsible body for issuing accreditation and conformity assessment policies
The state accreditation and conformity assessment policy shall be developed by the central specialized body of public administration responsible for the quality infrastructure.

Article 5. Objectives and principles of the national accreditation body and conformity assessment bodies

(1) The national accreditation body and conformity assessment bodies have the following main objectives:
a) creating preconditions for the recognition of conformity assessment results by participation of the national accreditation body in the EA and international accreditation bodies'multilateral recognition agreements and by safeguarding its membership withing the organisations mentioned previously.
b) promotion of free movement of goods and services principle;
c) generating authorities and consumer confidence in the competence, impartiality and integrity of conformity assessment bodies;
d) contributing to increasing competitiveness of products and services in the context of markets globalization;
e) promoting the protection of life, health and safety of persons and environment.
(2) The national accreditation body and conformity assessment bodies operate on the following basic principles:
a) use of single assessment procedures, harmonized with european and international rules for the accreditation of conformity assessment bodies;

b) competence and impartiality;
c) transparency, public availability and reliability;
d) representation of public interests;
e) free access without discrimination of all applicants to the accreditation process;
f) independence of possible predominance of any specific interests;
g) confidentiality and keeping of professional and trade secrecy;
h) impartial review of appeals and complaints.

Article 6. Reference Standards

(1) Reference standards are harmonized European standards or international standards adopted at national level or by an EU Member State, which stipulate criteria for the competence of the national accreditation body and of conformity assessment bodies.

(2) The national accreditation body and conformity assessment bodies will continually meet the requirements of the applicable reference standards.

(3) List of reference standards is approved by the central specialized body of government responsible for quality infrastructure and is published in the Official Gazette of the Republic of Moldova.

Chapter II
ACCREDITATION ACTIVITY

Article 7. The national accreditation body

(1) The accreditation activity is an officially recognized public authority activity.

(2) The accreditation activity is performed by the National Accreditation Center, designated as the sole national accreditation body, with short name "MOLDAC".

(3) The National Accreditation Centre is a public institution, monitored by the specialized body of central public administration responsible for the quality infrastructure, not subordinated to any public or private authority, except as provided by para (4) and (5).

(4) The National Accreditation Centre shall perform its functions and powers under a regulation approved by the Government with the prior approval of the Commission for Economy, Budget and Finance of the Parliament.

(5) The National Accreditation Center director is appointed following a contest by the order of ther head of the specialized body of central government responsible for the quality infrastructure. The Center director must have Moldovan citizenship, to have higher education in the technic or economic field and work experience in the field of accreditation and /or conformity assessment of at least 5 years, including at least 3 years in an administrative position.

(6) The director of National Accreditation Centre is dismissed by order of the head of the specialized central public administration responsible for the quality infrastructure in the following cases:

a) loss of citizenship;
b) incapacity to perform his duties for health reasons;
c) election in another position;
d) conviction for commission of intended offence or conviction to imprisonment by final court decision.

(7) The National Accreditation Centre is a non commercial not for profit organization.

(8) The Government ensures that the National Accreditation Centre benefits of:

a) free office space;
b) financial resources and appropriate personnel for the proper performance of its duties, including for special tasks like cooperation activities related to European and international accreditation activities as well as activities required to support public policy in the field of

accreditation and conformity assessment, if the center can not be self-financing.

Article 8. The National Accreditation Centre

(1) The National Center for Accreditation:

a) develops accreditation and conformity assessment and provides confidence in the technical competence and integrity of conformity assessment bodies, based on the principles laid down in Art. 5. (2);

b) complies permanently with the reference standard, european and international documents on the operation of the accreditation body;

c) establishes and maintains appropriate structures in its activities to guarantee effective and balanced participation of all stakeholders;

d) identifies the conformity assessment activities for which it has competence to perform accreditation and provides training and knowledge transfer in the field of accreditation;

e) accredits conformity assessment bodies based on the reference standards and issues accreditation certificates, regardless of whether the conformity assessment is compulsory or voluntary, namely:

- testing laboratories;
- calibration laboratories;
- medical laboratories;
- inspection bodies in the conformity assessment field;
- product certification bodies;
- management systems certification bodies;
- certification bodies for other certification schemes in the voluntary or regulated field;
- personnel certification bodies;
- organizers of interlaboratory testing schemes;
- conformity assessment bodies for new fields, established by the European Cooperation for Accreditation EA or regulatory authorities;

f) may organize proficiency testing or other comparisons for testing / calibration laboratories or inspection bodies or may involve in this process other entities which it recognizes and considers competent;

g) monitors the maintenance of competence by conformity assessment bodies for which it issued accreditation certificates;

h) ensure the exercise of its functions competently, promptly and without imposing onerous conditions to applicants for accreditation;

i) fulfills its obligations as a member of the European and international accreditation organizations;

j) cooperates with regulatory authorities and collaborates with NGOs to develop national policies on accreditation and conformity assessment;

k) assesses conformity assessment bodies requesting the right tooperate inthe regulated areas, with subsequent recognition by regulatory authorities;

l) establishes and applies selection, monitoring, training and appointment criteria of assessors and technical experts involved in the accreditation process;

m) participates in developing regulations on accreditation and conformity assessment;

n) participates at standards development process in its field, at national, european and international level;

o) publishes annual financial audit reports.

(2) The National Accreditation Center fulfills other functions as well under this law and its regulation.

(3) To exercise its responsabilities the National Accreditation Centre shall:

a) keep records relating to the accreditation activity, including to technical committees, assessors and experts involved in the accreditation activity;
b) to provide the public with information about its activity, including guides, instructions, etc..;
c) to ensure a balanced representation of stakeholders in the accreditation activity according to reference standards;
d) to establish rules according to reference standards, guidelines and related recommendations related to their specific field of accreditation;
e) to inform regulators about the accreditation activities and provide expertise on request;
f) to represent the country in international and european activities in the field of accreditation;
g) to develop policies, rules and procedures to ensure transparency and credibility of the accreditation process.
(4) In its activity, the National Accreditation Centre ensures the use and implementation of the european and international specialised organizations documents, establishing general criteria and rules in the field of accreditation and conformity assessment.
(5) In order to efficiently exercise its duties, the National Accreditation Centre respects the principle of non-competition, on the following criteria:
a) independence from conformity assessment bodies which it assesses and from commercial pressures;
b) ensuring the absence of conflicts of interest with conformity assessment bodies, not holding shares or other types of financial or administrative interests in a conformity assessment body;
c) not offering and not delivering of any activities or any service provided by conformity assessment bodies it accredited, not giving consultancy for obtaining or maintaining accreditation;
d) lack of competition with national accreditation bodies of other states.

Article 9. National Accreditation Centre budget

(1) Prior to September 10 of each year, the income and expenditure budget of the National Accreditation Centre is approved by the specialized body of central public administration responsible for quality infrastructure with compliance to the principles set out in this article.

(2) National Accreditation Center budget is formed based on:

a) funds from the state budget, necessary to fulfill the obligations of associate member and multilateral recognition agreement signatory with the European Cooperation for Accreditation, including participation in the work of european and international accreditation organizations, arising from obligations as signatory of these agreements, and cooperation activities related to european and international accreditation;

b) funds from payments of accreditation, attestation, training activities;

c) funds from sponsorships, grants, etc., not contradicting the requirements established for the Centre;

(3) The cost of accreditation services is calculated in accordance with annex. 1, which is an integral part of this law .

(4) Funds unused by the National Accreditation Centre during the current financial year are transferred to next year budget with the same destination, except those provided by the state budget.

(5) The structure and pay roll of the National Accreditation Centre, the employees remuneration forms and ways is determined by the Director of the Centre within the limits of the approved budget.

Article 10. Accreditation Council

(1) To ensure impartiality, development and compliance with the principles and operational policies, as well as the efficient and balanced participation of all direct or indirect stakeholders in the National Accreditation Centre activity, an Accreditation Council is established, operating free of charge.

(2) The Accreditation Council consists of 15 members. Its organization and operation, as well as the way the members are elected / appointed shall be established in the Council Regulation issued by the National Accreditation Centre and approved by the central body of public administration responsible for the quality infrastructure.

(3) The Composition of the Accreditation Council is approved by the central body of government responsible for the quality infrastructure based on the proposals made by representatives of interested parties, namely:

a) accredited conformity assessment bodies;

b) beneficiaries of conformity assessment activities;

c) consumers;

d) authorities with regulatory functions concerned in the development of accreditation and conformity assessment.

(4) The Accreditation Council shall:

a) review the policies and accreditation rules and procedures;

b) examine the annual budget of revenue and expenditure;

c) review the accounting report and income and loss account and, where appropriate, may require financial audit;

d) monitor and ensure impartiality and objectivity in the accreditation process;

e) appoint a commission to examine appeals, if any;

f) approve the regulation of Appeals Commission;

g) approve the regulation of Technical Committees;

h) recommend the specialized international organizations with which National Accreditation Centre should collaborate;

i) promote the accreditation and inform society about the accreditation;

j) approve the list of reference standards and documents of european and international specialized organizations, which establish general criteria and rules in the field of accreditation and conformity assessment.

(5) In taking decisions in the Accreditation Council, stakeholders are represented equally, by fair vote.

Article 11. The appeals procedure

(1) To review any negative decision regarding granting of accreditation taken by the National Accreditation Centre, the accreditation applicant may file an apeal.

(2) The appeal shall be examined by an Appeals Commission established ad-hoc by the Accreditation Council. The Appeals Commission Regulation is approved by the head of the government body responsible for quality infrastructure. The members of the Appeals Commission are appointed by the Accreditation Council.

(3) National Center for Accreditation, in accordance with the referenced standard:

a) establishes the procedure for examining appeals raised by conformity assessment bodies;

b) decides on the validity of the appeal;

c) communicates the final decision to the conformity assessment body that has filed for appeal;

d) keeps records of all appeals and final decisions.

(4) The National Accreditation Centre decision on reducing, suspending, withdrawing or refusing accreditation as well as the absence of such a decision may be appealed by conformity assessment bodies in the competent court under the applicable law, if not previously resolved by

the National Accreditation Centre under its procedure.

Article 12. The accreditation process

(1) The Criteria for accreditation of conformity assessment bodies are established by the reference standards and by the documents of the specialized european and international organizations, adopted nationally, applicable to the National Accreditation Body and to the conformity assessment bodies.

(2) Based on meeting the accreditation criteria and regardless of the fact that accreditation is used on a compulsory or voluntary basis, conformity assessment bodies performing conformity assessment activities, including certification, inspection, calibration and testing can be accredited.

(3) Assessment of competence of a conformity assessment body involves assessing the competence of all activities performed by this body, including staff competence, validity of the conformity assessment methodology and validity of conformity assessment results, in accordance with reference standards and requirements in documents of European and international specialized organizations.

(4) Accreditation decision is adopted if the applicant conformity assessment body complies with the accreditation criteria. Accreditation decision is made by the National Accreditation Center. Based on the accreditation decision, the applicant is issued a certificate of accreditation with fixed validity and is recorded in the register of accredited conformity assessment bodies. The scope of accreditation approved by the National Accreditation Centre is integrated part of the accreditation certificate.

(5) For accreditation of testing laboratories, an intermediate stage may be attestation of technical competence according to nationally prescribed requirements.

(6) If it is found that the accreditation applicant has not removed the nonconformities identified during the on-site assessment before the deadline communicated, the National Accreditation Centre makes a decision of refusal of accreditation.

(7) The National Accreditation Center performes surveillance of the conformity assessment bodies for which an accreditation certificate was issued. Surveillance is carried out to monitor the continued fulfillment of accreditation requirements by the accredited conformity assessment bodies.

(8) Confirmation of the validity of accreditation is approved by the decision to maintain accreditation, issued by the National Accreditation Centre, taking into account the positive results of surveillance assessments.

(9) Extension of accreditation scope shall be made at the request of the conformity assessment body.

(10) The reduction of the accreditation scope shall be made upon request of the conformity assessment body or after surveillance assessment, to exclude those parts for which conformity assessment body repeatedly does not meet the criteria for accreditation.

(11) Upon request of conformity assessment bodies, accreditation may be renewed by reassessment on the compliance with accreditation criteria. Reassessment of conformity assessment body is similar to an initial assessment, except that experience gained during previous evaluations is taken into account.

(12) If it is found that a conformity assessment body that has received accreditation certificate is no longer competent to carry out a specific conformity assessment activity and does not comply with the accreditation criteria established in the applicable reference standard, the National Accreditation Center takes all appropriate measures to restrict, suspend or withdraw its accreditation certificate.

(13) National Accreditation Center insures independence, objectivity and impartiality in decision making, is responsible for its decisions on granting, refusal, maintenance, extansion, reducing,

suspending and withdrawing accreditation.

Chapter III
NATIONAL ACCREDITATION MARK

Article 13. National accreditation mark and references to accreditation

(1) National accreditation mark is a symbol officially registered, legally protected, which is the exclusive property of the National Accreditation Center.

(2) The national accreditation mark is a graphical representation accompanied by the state symbols, such as the state flag and the official name of the state, as described in annex no. 2, which is an integral part of this law.

(3) The National accreditation mark, accompanied by claims about the activities covered by accreditation, represents the accreditation symbol.

(4) The National Center for Accreditation transfers to the conformity assessment bodies the right to use the accreditation symbol, according to the provisions of applicable reference standard.

(5) The procedure to use of the national mark of accreditation is determined by the National Accreditation Centre in accordance with the requirements of the European Cooperation for Accreditation.

(6) Accredited conformity assessment bodies are responsible for the use of accreditation symbol and for the references they make to accreditation.

(7) Accredited conformity assessment bodies are obliged to use the accreditation symbol on documents issued for services rendered under the accreditation.

Chapter IV
INTERNATIONAL COOPERATION

Article 14. International cooperation

(1) The National Accreditation Center represents the interests of the Republic of Moldova in the international and regional (european and interstate) accreditation organizations, shall cooperate with these and participate in their activities, to sign agreements of mutual recognition.

(2) The National Accreditation Center subjects itself to peer evaluation based on clear and transparent evaluation criteria and procedures set by European and international accreditation organisations (EA, IAF, ILAC). By peer evaluation, it is determined if the Center meets the requirements and the relevant harmonized standards.

(3) If the accreditation is requested by a foreign conformity assessment body, the National Accreditation Centre shall inform the national accreditation body in the country where the applicant conformity assessment body is established about the registered application . In such cases, the national accreditation body of the state where the applicant conformity assessment body is established may participate as an observer in the accreditation process.

(4) The National Accreditation Center may require a foreign national accreditation body to carry out some assessment activities for the purpose of accreditation of a conformity assessment body. In this case, the certificate of accreditation is issued by the National Accreditation Centre from Moldova.

(5) The conformity assessment body may request accreditation from a foreign accreditation body if the National Accreditation Centre of the Republic of Moldova does not perform accreditation of conformity assessment activities in the area requested. In this case, the Center participates as observer in the process of accreditation of the conformity assessment body in Moldova.

(6) At the request of a foreign national accreditation body, the National Accreditation Centre can perform a part of the accreditation of the applicant conformity assessment body.

Chapter V
CONFORMITY ASSESSMENT ACTIVITIES

Article 15. General provisions on conformity assessment

(1) Conformity assessment can be compulsory or voluntary.

(2) Conformity assessment, regardless of whether compulsory or voluntary, is done only by accredited conformity assessment bodies.

Article 16. Rights and obligations of accredited conformity assessment bodies

(1) the accredited conformity assessment bodies shall:

a) conform to the requirements of reference standards and european and international documents on the operation of conformity assessment bodies and the requirements established by National Accreditation Center on the fields for which accreditation is granted;

b) not act as a designer, manufacturer, supplier, installer, purchaser, owner, user or operator of products maintenance which they assess;

c) ensure the confidentiality, objectivity and impartiality of conformity assessment activities;

d) to carry out all conformity assessment tasks for seeking accreditation and to possess the necessary means to perform properly the technical and administrative tasks related to conformity assessment activities;

e) to ensure impartiality by participation of all stakeholders in policy and operating principles development of conformity assessment bodies;

f) to carry out conformity assessment activities at the highest level of professional integrity and requisite technical competence in respectiv field and to be free from all pressures and inducements, particularly financial, which might influence the activity results;

g) to keep the professional secrecy regarding all information obtained during the tasks, to protect copyright holders;

h) to inform stakeholders, including other accredited conformity assessment bodies, the measures envisaged in relation to non-compliant products (identified in the assessment process) that present risks to health and safety of persons or on other aspects of public interest protection;

i) to sign insurance contracts with insurance companies legally recognized in the Republic of Moldova to hold insurance policies to repair the damage that may be caused by third parties through their activity and to which is liable in accordance with the in force law on insurance.

(2) accredited conformity assessment body has the right to:

a) have access to publicly available information related to accreditation activity for which was requested or received accreditation;

b) negotiate, within the limits provided by National Accreditation Center procedures, exact data about the developement of various stages of evaluation process;

c) refuse the evaluation team composition only based on well-funded reasons, presented in writing to the National Accreditation Centre's management. In this case, the conformity assessment body assumes the risk to delay accreditation process from the established schedule, and Center reserves the right to use, as appropriate, and assessors from foreign accreditation bodies, with recalculation of accreditation costs, costs which will be provided additional to the conformity assessment body;

d) require to the evaluation team members to keep a privacy statements and respect his right industrial and intellectual property, and such as his costumers;

e) cancel accreditation, notifying Center at least 45 days prior;

f) refers its accreditation status only on accreditation certificate validity period and accredited activities only;
g) to appeal any unfavorable decision.

Article 17. Conformity assessment on a voluntary basis

(1) Conformity assessment on a voluntary basis is done by compliance certification by accredited conformity assessment bodies, not imposed by national technical regulations.

(2) voluntary compliance certification is done on a contract basis.

Article 18. Conformity assessment on a compulsory basis

(1) Conformity assessment on a compulsory basis is achieved for products included in the scope referred in Annex no. 3, which is an integral part of this law, and products not included in the scope of this Annex, for which there are essential requirements in technical regulations, in accordance with art. 4 par. (6) of Law no. 420-XVI of 22 December 2006 on technical regulation activity.

(2) To the products in Annex 3, the following conformity assessment procedures are applyed, which provide, for each product category, one or an appropriate combination of the following modules, described and approved by the Government:

a) module A - internal production control;
b) module A1 - internal production control and supervised product testing;
c) module A2 - internal production control and supervised product checks at random intervals;
d) module B - EC type-examination;
e) module C - conformity to type based on internal production control;
f) module C1 - conformity to type based on internal production control and supervised product testing;
g) module C2 - conformity to type based on internal production control and supervised product checks at random intervals;
h) module D - conformity to type based on quality assurance of the production process;
i) module D1 - ensuring the quality of production process;
j) module E - conformity to type based on product quality assurance;
k) module E1- quality assurance at inspection and testing the finished product;
l) module F - conformity to type based on product verification;
m) module F1 - compliance based on product verification;
n) module G - compliance based on unit verification;
o) module H - compliance based on full quality assurance;
p) module H1 - compliance based on full quality assurance plus design examination.

(3) Where procedures referred in par. (2) can not be applied to a class of products, their conformity assessment shall be carried out according to applicable technical regulations.

(4) Products not included in annex 3, regulated by applicable technical regulations, are subjected to conformity assessment in compliance with the essential requirements by applying the following procedures:

a) certification;
b) inspection;
c) test;
d) declaration of conformity at your own risk.

(5) The onformity assessment procedures referred to in para. (2) and para. (4) depend on the complexity of the product, the estimated risk at its use and is determined by the officials with regulatory functions by technical regulations.

(6) If a product is subject to several technical regulations, the authority with regulatory functions ensure consistency of the applicable conformity assessment procedures.

Article 19. Declaration of conformity

(1) The purpose of declaration is to provide confidence in compliance of identified object with the requirements specified, referred to the declaration of conformity and to specify clearly the responsible for the compliance and declaration. A declaration of conformity is a form of attestation of conformity in order to meet market demands and regulatory authority officials, to give confidence in the product placed on the market.

(2) The declaration of conformity is issued by the manufacturer or his authorized representative, or, if neither the manufacturer nor his authorized representative do not have domicile or office in Moldova, by the importer of the product.

(3) The issuer of a declaration of conformity (organization or person) is responsible for issuing, maintaining, extending, restricting, suspending or withdrawing its declaration and compliance of its object with the applicable essential requirements.

(4) Declaration of conformity is based on the results of conformity assessment.

(5) A declaration of conformity can refer both to a specific product, as well as a group of similar products, for which are imposed similar requirements to be attested. In this case, the issuer of the declaration must ensure that each individual product of the group compliance with applicable essential requirements.

(6) Declaration of conformity shall contain sufficient information to identify its issuer, the product referred to, stating compliance requirements and the person who signs for and on behalf of the issuer and shall contain at least the following:

a) the unique identification;
b) name and contact address of the issuer;
c) identify the object;
d) declaration of conformity and assuming responsibilities for product compliance;
e) complete and accurate list of standards or other requirements specified;
f) date and place of issue;
g) its validity term.

(7) Declaration of Conformity issuer shall have implemented procedures to ensure the the conformity of its object, as it was delivered or accepted, the requirements mentioned in the declaration of conformity and to reassess its validity, if occur:

a) changes affecting significant the design or specification of the declaration;
b) changes in the regulations which set out essential requirements against which conformity is declared by the declaration;
c) relevant information indicating that the declaration may not be as essential requirements.

(8) The issuer of declaration of conformity is required to make available the technical documentation for the relevant regulatory authorities and bodies with control functions.

(9) The technical documentation supporting a declaration of conformity must be developed, acquired, updated and kept constantly to allow traceability of the declaration of conformity, given by the issuer, and, as provided in the applicable technical regulations must include the folowing, but are not limited to:

a) description of the declaration object;
b) information on product design documentation;
c) product conformity assessment results;
d) identify the conformity assessment bodies involved, whose results are used and identify their accreditation status;

e) complete and accurate list of the aplicable standards or other specified requirements;

f) description of the relevant management system to the declaration object.

(10) Declaration of Conformity is registered to the accredited certification bodies for the accreditation scopes corresponding to the declaration object, with award of a number and with authentication by certification body stamp. The latter will hold the Register of registered declarations of conformity and will send monthly the information recorded to the relevant regulatory authorities and authorities with control functions regulatory authorities and authorities responsible for control functions and, upon request, to the government institutions and local public administration authorities.

(11) To record declaration of conformity, the applicant shall submit the certification body:

a) application (request) for the declaration registration;

b) two copies of the declaration on paper, that was signed and authentified by its stmp specimen;

c) copies of the documents contained in the technical documentation referred to in para. (9), and product technical regulations for which is issued the declaration.

(12) Certification Body verifies the set of documents submitted by the applicant on:

a) request the targeting accuracy of registration of the declaration of conformity;

b) completeness and accuracy of the documents referred to in para. (11).

(13) After verification, according to par. (12), of the set of documents, the certification body, within 3 days of receipt of application for registration shall register the declaration of conformity or inform the applicant as well as the authorities with control functions, on refusal of registration.

(14) ground for refusal can serve the fact that:

a) the accreditation scope of the applicant does not include de declared product;

b) missing the necessary documents referred to in para. (11);

c) there is no provision for a declaration of conformity according to the technical regulations applicable to the product;

d) the set of documents submitted content does not meet the requirements of technical regulations.

Article 20. Conformity certification

(1) In the process of products conformity certification by accredited certification bodies, it is attested the products comply with applicable essential requirements, as described modules and certification schemes approved by the Government.

(2) certification schemes are used to certify products in fields not included in Annex nr. 3.

(3) The products with the applicable essential requirements is attested by the certificate of conformity issued by accredited certification body.

(4) The certification body will monitor the right to use the marks and certificates of conformity which was issued and will take action if incorrect references to certification status or use of certification documents, which are misleading.

(5) Certificate of conformity is issued for products that are manufactured by the same manufacturer under the same conditions that are evaluated to the same applicable requirements.

(6) Certificate of conformity form shall be developed by each certification body being the exclusive property of the issuer.

(7) No subjected to certification imported products:

a) directly by the manufacturer, which serve as raw materials or aids for use later in their technologic process, or which are components of technological equipment;

b) directly by the manufacturer as raw materials, auxiliary materials and components of the finished product, manufactured to the order of foreign recipients on a contract basis, are not intended to be placed on the market Republic of Moldova;

c) by diplomatic and consular missions located in the Republic of Moldova for personal use;
d) as exhibits, models, advertising materials for exhibitions, fairs and other advertising activities.

Article 21. Inspection

(1) The purpose of inspection is the performing of assessments required by economic and / or public administration, aiming at providing interested parties information on the inspected object compliance with regulations, standards or other specified requirements. Inspection parameters may include elements related to quantity, quality, safety and suitability of use and continued compliance with the safety at operation of an industrial object or system.

(2) The work of inspection bodies include examination materials, products, facilities, plants, processes, work procedures or services, determine their compliance with specified requirements, the subsequent reporting of the results of these activities to customers and, where appropriate, the authorities with control functions. Inspection may take into account all life cycle stages of the inspected object, including the design stage.

(3) Inspection means direct conformity determination of its object by examining its applicable essential requirements, based on professional assessments made by accredited inspection bodies. Inspection results can be used as support for certification.

(4) The products conformity in the inspections shall be attested by the inspection report and / or inspection certificate. The inspection report is a detailed description of inspection and its results. Certificate of inspection is usually a brief official certification of compliance with essential requirements.

(5) The inspection report and / or inspection certificate status information describing the object at the time of inspection. Contents of an inspection report or inspection certificate may vary depending on the type of inspection, the essential requirements. Inspection report or inspection certificate includes any defect and noncompliance discovered. In these acts must be identified representative of the inspection body that is responsible for verifying and issuing the report and /or certificate of inspection.

(6) If the inspection is carried out on behalf of state, the authorities with regulatory functions may introduce special requirements in inspection results reporting.

Article 22. Testing

(1) The purpose of the test is determination by an accredited laboratory of one or more characteristics of an object subject to conformity assessment, according to a procedure.

(2) The test report is a written communication made by a laboratory, comprising an official account of the results of performed tests.

(3) The test may be part of the inspection or certification in accordance with applicable technical regulations.

(4) Calibration services are provided only by accredited calibration laboratories.

Article 23. SM conformity mark

(1) Products subject to conformity assessment in the regulated field, until the placing on the market and / or up to use, must be marked by the manufacturer with SM conformity mark, if the technical regulation provides for such marking. Marking product with conformity mark SM indicate conformity with essential requirements laid down in applicable technical regulations.

(2) SM conformity mark applies, according to technical regulations applicable to the product directly to the product, its packaging, the documents accompanying the product and / or marking plate attached to the product so that it can not be detached. Mark applied must be visible and can not be canceled.

(3) The application under MS mark on products that were not subject to conformity assessment procedures as established, or not complying with prescribed requirements is prohibited.

(4) Registration and application of marks which may be confused with conformity mark SM is prohibited.

Article 24. Other conformity marks

(1) In the unregulated area are used other conformity marks than SM conformity mark.

(2) The applicayion of marks on products not covered by the regulations is voluntary. On these products can be applied the mark attesting that products comply with legal documents on wich base its conformity is declared.

(3) Other brands under applied should be distinguished from SM conformity mark to be visible and legible.

(4) Marking products under brand if not meet the requirements of normative documents is prohibited.

Chapter VI
PRODUCT PLACEMENT ON MARKET

Article 25. Conditions for placing the product on market

(1) The products are placed on the market and /or puted into service only if they meet the essential requirements provideing adequate protection of public interests, such as general health and safety, health and workplace safety, consumer protection, environmental protection and security, international principles of free movement of goods in domestic and international trade, and only if they are accompanied by documents which attest the compliance. The person responsible for the marketing of products is the manufacturer, manufacturer's authorized representative, importer, distributor or any other natural or legal person with entrepreneurial activities.

(2) The products conformity is evaluated based on essential requirements established for those products in the applicable technical regulations. Products that lack the technical regulations will be subject to conformity assessment under the provisions established voluntary national standards applicable to those products on the list approved by order of the regulatory authority officials and published in the Official Gazette of the Republic of Moldova and in the essential requirements and approved by order of the authority with regulatory functions, published in Official Gazette of the Republic of Moldova.

(3) The products conformity with the essential requirements may be attested by conformity certificates, the certificates and / or inspection reports, the test reports and declarations of conformity.

(4) When placing products on the market are only valid certificates of conformity, certificates and / or inspection reports and test reports issued by accredited conformity assessment bodies.

Article 26. The manufacturer's obligations

(1) The manufacturer shall:

a) ensure that marketed products are designed and manufactured in accordance with the essential requirements;

b) establish the technical documentation and provide the application of conformity assessment procedures;

c) ensure accuracy and veracity of the declaration of conformity, holding test reports, certificates of conformity and other documents certifying compliance;

d) keep supporting documentation and declaration of conformity in the life cycle of the

declaration and the level of risk, post-market product;

e) shall, upon request of authority with control functions, information and documentation necessary to demonstrate conformity of the product;

f) ensure that the product is accompanied by instructions and safety information in a language easily understood by the consumer.

(2) The manufacturer shall ensure that procedures to ensure consistency of series production exists. Changes in design or characteristics and changes concerning related standards, against which it declares that a product is taken into account properly. Whenever this is justified by the risks of a product, the manufacturer carry out sample testing of marketed products to protect consumer health and safety, investigate and, where appropriate, keeping a register of complaints, non-conforming products and recalls products, and distributors informed of any such monitoring.

(3) If it considers or has reason to believe that a product which is marketed is not according to the applicable essential requirements, the manufacturer shall immediately take corrective measures necessary to bring the product into conformity, to withdraw or recall it as appropriate.

(4) If the product presents a risk, the manufacturer informs immediately the competent authorities with control functions, indicating the details, especially those on non-conformities and on any taken corrective action.

Article 27. Obligations of authorized representative

(1) The manufacturer may appoint, by written authorization, an authorized representative.

(2) The authorized representative shall perform the duties specified in the mandate received from the manufacturer, which allows it to meet the following:

a) put the declaration of conformity and technical documentation available to the authority with control functions;

b) to provide authority with control functions, based on a reasoned request from it information and documentation necessary to demonstrate compliance of a product.

(3) The obligations laid down in Art. 26 para. (1) lett. a) and b) are not part of the authorized representative mandate.

Article 28. Importer obligations

(1) Where neither the manufacturer nor his authorized representative do not have domicile or office in Moldova, the responsibility for maintaining technical documentation certifying compliance and its submission, at the request of bodies with control functions, it is the importer.

(2) The importer places on the market products complying essential requirements under a declaration of conformity, issued on its own responsibility under the manufacturer's technical documentation, translated and legalized in the state language, referred to in art. 19 para. (9).

(3) Imports of goods is made based on contract delivery, indicating the mandatory essential requirements.

(4) The importer shall, upon request authority control functions, information and documentation necessary to demonstrate product compliance with essential requirements placed on the market.

(5) Before placing a product on the market, the importer ensures that the manufacturer has met the appropriate conformity assessment procedure. If it do not have all the technical documentation required for issuing the declaration of conformity, the importer shall ensure the conducting of conformity assessment procedures and issue the declaration of conformity based on the results of evaluations conducted in Moldova by an accredited conformity assessment body.

(6) The importer shall ensure that, while a product is their responsibility, storage or transport conditions do not jeopardize its compliance with the essential requirements set.

(7) To protect consumer health and safety, if this is justified by the risks of a product, the importer will require accredited testing laboratory sample testing of marketed products, investigate and, where appropriate, keeping a register of complaints, non-conforming products and product recalls, and inform distributors about the monitoring.

(8) The importer shall keep a copy of the declaration as long as the product life cycle and according to risk level.

(9) If it considers or has reason to believe that a product complies with essential requirements, the importer can not place the product on the market before being brought into conformity.

(10) If it considers or has reason to believe that a product which is marketed under the applicable essential requirements, the importer shall immediately take corrective measures necessary to bring the product into conformity, to withdraw it or recall, if necessary. Whether there is a risk, importers shall immediately notify the authority with control functions, indicating the details, especially on non-compliance and any corrective measures taken.

(11) The importer or retailer is considered a manufacturer under this law and subject to the obligations of manufacturers under this article when markets a product under the name or trademark or modifies a product already in place, in a manner that creates the possibility of affecting compliance with the essential requirements.

Article 29. Obligations of distributors

(1) The distributor provides a product on the market after it was marketed by the manufacturer or importer and take the necessary steps to ensure that its operations handling products do not have a negative impact on its compliance.

(2) Before making a product available on the market, the dealer checks if accompanied by the documents provided, by the instructions and safety information.

(3) The distributor shall ensure that during a product is in their responsibility, storage or transport conditions do not jeopardize its compliance with the essential requirements.

(4) At the reasoned request of the authority with control functions, the distributor shall provide the information and documentation necessary to demonstrate compliance of the product.

(5) If it considers or has reason to believe that a product do notcomplies with essential requirements, the distributor do not provide the product on the market as long as it is not made in accordance. Whether there is a risk, the distributor shall inform the manufacturer or importer, and authorities with control functions.

(6) If it considers or has reason to believe that a product which provided the market does not meet the essential requirements, the distributor shall ensure that necessary corrective measures are taken to bring the product into conformity, to withdraw or recall, if necessary. Whether there is a risk, the distributor shall immediately notify the authorities with control functions, indicating the details, especially on non-compliance and any corrective measures taken.

Article 30. Powers of authorities with regulatory functions

In the conformity assessment field, authorities with regulatory functions are responsible for the following functions:

a) establish, into the technical regulations for the planning phase and / or production phase, possibilities of use of conformity assessment procedures that will ensure the necessary safety and achieving the technical regulation objective; technical criteria based on which manufacturer may choose for the products the most suitable conformity assessment procedures prescribed by law, test methods and sampling used in the conformity assessment;

b) establish, for products or product groups, one or more conformity assessment procedures, the same as proof level, which would allow the applicant to choose the most appropriate procedure;
c) establish criteria under which the manufacturer can choose the product most appropriate conformity assessment procedures provided by law;
d) establish, for product groups, the applicability of modules or certification schemes;
e) establish test methods and sampling methods used in the process of conformity assessment;
f) establish the content of technical documentation for issuing the declaration of conformity;
g) identify the national standards and prestandards used to assess compliance.
h) cooperate with the National Accreditation Centre, including the notification of conformity assessment bodies in regulated area.

Article 31. Recognition of the conformity assessment activities
(1) Are recognize the certificates of conformity or test reports issued by foreign accredited conformity assessment bodies by the accreditation bodies which are signatory of Multilateral Agreement of European Cooperation for Acreditation, issued for products imported from member states of EU, translated into state language and confirmed by the importer stamp specimen.
(2) Are recognized the certificates of conformity and test reports issued by foreign conformity assessment bodies, based on bilateral agreements on mutual recognition of conformity assessment activities. Recognition of certificates of compliance shall be made by issuing a new certificate of compliance by certification bodies accredited by National Accreditation Center.
(3) For recognition of the certificate of conformity referred to in para. (2) the applicant presents the certification body accredited in Moldova for the same field a request, the original or copy, certified by the organization issuing the certificate of conformity in the country of origin, and the original or copy, certified by the issuing organization, test report on the tests for certification.
(4) The certification body referred to in para. (3) carry out the identification (origins, organoleptic properties, as appropriate, legality, quantity and marking) of products and notify the applicant of its decision to issue national certificate of conformity. If a negative decision, written reports are clear grounds to refuse to recognize certificates issued by a foreign conformity assessment body.
(5) In the process of recognition under paragraph. (3) and (4), the certification body may establish additional for testing whether the essential requirements in force in Republic of Moldova does not meet the requirements specified in the certificate of conformity issued by a foreign conformity assessment body.
(6) In the absence of compliance certificates or declarations of conformity of imported products subject to conformity assessment procedures applicable to products, national technical regulations applicable.

Chapter VII
FINAL AND TRANSITIONAL PROVISIONS

Article 32

On the date of accession of Moldova to the European Union, conformity assessment bodies carrying out conformity assessment in the areas specified in Annex no. 3 will be designated and notified the European Commission in accordance withnational legislation harmonized with concerned EU legislation.

Article 33

(1) This Law shall come into force at the expiration of nine months of its publication, except art. 31 which shall enter into force on expiry of three months from the date of publication of this law.

(2) The Government within nine months from the date of publication of this law:

a) ensure the reorganization of the State Enterprise "Centre of Accreditation in the field of Products Conformity Assessment " into the public institution "National Accreditation Centre of Republic of Moldova", the abbreviated name "MOLDAC", designated as a national accreditation body;

b) amend its regulations under this Act;

c) approve conformity assessment procedures that describe modules and certification schemes for products subject to compulsory conformity assessment;

d) will fulfill this law by the competent central government authorities.

Article 34

At the date of entry into force of this law, is approved the Law no. 186-XV of 24 April 2003 on products conformity assessment (Official Gazette of the Republic of Moldova, 2003, no. 141-145, art. 566).

PARLIAMENT SPEAKER **Marian LUPU**

No. 235. Chisinau, December 1, 2011

anexa nr.1

Anexa nr. 2

National Accreditation Mark

National Accreditation Mark "MOLDAC" consists of an ellipse, inclined at an angle of 78 °, which includes the words "MOLDAC" and "Moldova" and the image Flag of Republic of Moldova. Graphical representation is a horizontal axis and a vertical axis with an inclination of 78 °. Dimension horizontal and vertical axis is 31 mm respectively 36 mm.

The horizontal axis is the axis of symmetry for the words "Republic of Moldova" and lines that outline the ellipse. The inscription "Republic of Moldova" at a height of 0.85 mm inner horizontal axis has the following dimensions: Trebuchet MS font, size 8, italic, bold.

Vertical lines flanking the official name of the state are parallel to the thickness of 2.2 mm, and ellipse arc senestra interrupted horizontal line on a length of 2 mm thickness is increased from the dextra senestra from 1 mm to 3 , 3 mm at the point of intersection with the horizontal line.

The vertical axis is an axis of symmetry for:

- The letters "MOLDAC", placed at the top, at a height of 2.3 mm from the horizontal axis, with dimensions: Trebuchet MS font, size 17, italic, bold;
- The State flag, placed in the back, a distance of 1.8 mm from the horizontal axis, with dimensions: height - 6.9 mm and length - of 12.7 mm.

Mark is colored as follows:

All words and lines except the state flag are blue (red = 40 components, Green = 22, blue = 111);

State Flag - the official colors.

If the mark shall be increased or decreased, it is necessary to respect the proportions given in the description.

Anexa nr. 3

List of regulated areas

1. Low Voltage equipment
2. Pressure recipients
3. Toys
4. Construction products
5. Electromagnetic compatibility
6. Industrial machinery
7. Individual protective equipment
8. Weight devices with non-automatic operation
9. Active implantable medical devices
10. Burning gaseous fuels
11. Hot water boilers
12. Explosives for civil use
13. Medical devices
14. Potentially explosive environments
15. Recreational craft
16. Elevators
17. Refrigeration equipment
18. Pressure equipment
19. In vitro diagnostic medical devices
20. Radio and telecommunications terminal equipment
21. Packaging and packaging waste
22. Cableway installations for persons
23. System interoperability of the trans-European high-speed rail
24. Marine equipment
25. Transportable pressure equipment
26. Environmental noise emission by equipment for outdoors use
27. Interoperability of the trans-European conventional rail system
28. Measuring equipment