Republic of Moldova

THE PARLIAMENT

LAW No. 235
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on accreditation and conformity assessment

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AMENDED
PL 168 of 26.07.2018, MO333-335/ 24.08.18 Art. 549; in force 24.02.19
PL 122 of 30.06.2017, MO253-564/21.7.17 Art.416
PL 160 of 07.07.16, OG 306-313/16.09.16 Art. 647
PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16

[Preamble excluded by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]
The Parliament adopts this organic law.

Chapter I
GENERAL PROVISIONS

Article 1. Subject matter

(1) This law establishes the legal framework for the accreditation activity of conformity assessment bodies, made on compulsory or voluntary basis, for making available products on the market and for the conformity assessment activity, regardless of whether that assessment is compulsory or not to products marketed and / or used in the Republic of Moldova.

[Art. 1 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) Where the international treaties to which the Republic of Moldova is a party establish provisions other than those in the Moldovan legislation on Accreditation and Conformity Assessment, the provisions of international treaties shall apply.

Article 2. Main definitions

Under this Law, the following main definitions shall mean:

bilateral agreement – an agreement by which both sides shall mutually recognize or accept the results of conformity assessment;

multilateral agreement – an agreement by which more than two Parties shall mutually recognize or accept the results of conformity assessment (ISO / IEC 17000);

CAA Agreement – Agreement on Conformity Assessment and Acceptance of Industrial Products, Protocol to the Association Agreement between the Republic of Moldova, of the one part, and the European Union and the European Atomic Energy Community and its Member

States, of the other part;

[Art. 2 notion introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

accreditation – an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;

economic operator – the manufacturer, the authorised representative, the importer and the distributor;;

[Art. 2 notion introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

appeal – application of a conformity assessment body for reconsideration of any adverse decision taken by the national accreditation body about the accreditation status that the first has applied for;

attestation – issuance of a statement, based on a decision taken following an analysis of the assessment, stating that fulfillment of the applicable requirements has been demonstrated;

Market surveillance authorities – central specialized bodies or their subordinate administrative authorities, empowered, within their competences, with the implementation of state policy in market surveillance;

[Art. 2 notion introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Basic requirements – requirements that are stipulated by national technical regulations, transposing Community harmonization legislation, and ensuring national security and safety of products and services for life, health and safety of people, for animal and vegetal life, for the environment and property in order to protect consumer interests, including the prevention of practices misleading consumers in terms of composition, destination, origin, quality and safety of products;

[Art. 2 notion amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

specified requirement – necessity or expectation declared in the normative documents such as regulations, standards, technical specifications;

certification – attestation performed by a third party on the products, processes, systems and persons;

accreditation certificate – an official document or a set of official documents confirming the granting of accreditation for a defined domain;

conformity certificate – a document certifying that a product properly identified has undergone conformity assessment procedures and that, when assessing, the product conforms to the applicable specified requirements;

accreditation criteria – a set of requirements, established by reference standards and documents of specialized European and international organizations, used by the national accreditation body and given for fulfillment by the conformity assessment body in order to be accredited;

declaration of conformity – written assurance, based on a decision taken following an assessment, whereby the manufacturer or his authorized representative confirms with certainty that the product complies with the specified requirements;

[Art. 2 notion amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

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

scope of accreditation – specific Conformity Assessment services for which accreditation has been applied for and / or been granted;

calibration – operation that, under specified conditions, sets: in the first stage, a relationship between measurement values and uncertainties associated, provided by the relevant standards and guidelines, with the associated measurement uncertainties; in the second stage, the use of

this information for establishing a relationship that would lead to a measurement result based on an indication;

conformity assessment – the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

peer evaluation – a process for the assessment of a national accreditation body by other national accreditation bodies, carried out in accordance with the requirements of this Law and, where applicable, additional sectoral technical specifications;

[Art. 2 notion "supplier" excluded by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

importer – any natural or legal person who places on the market a product from another country;

inspection – examination of a product design, examination of a product, a process, an installation and determination of their conformity with the specified requirements or, based on professional judgments (assessments), with the general requirements;

placing on the market – he first making available of a product on the market;

testing – determining, based on a procedure, one or more characteristics of an object subjected to conformity assessment;

Community harmonization legislation – any Community legislation harmonizing the conditions for the marketing of products;

[Art. 2 notion introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

CE marking – marking by which the manufacturer indicates that product complies with the applicable requirements established by the technical regulations providing for its affixing;

[Art. 2 notion introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

conformity assessment body – a body that performs conformity assessment activities including calibration, testing, certification and inspection;

notified conformity assessment body – conformity assessment body recognized by the regulatory authority for activities in the area covered, of which the European Commission and Member States of the European Union were officially notified;

[Art. 2 notion introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

recognized conformity assessment body – conformity assessment body accredited by the accreditation body or the national accreditation body signatory to the Multilateral Recognition Agreement with the European Cooperation for Accreditation (EA MLA) and recognized by the regulatory authority;

[Art. 2 notion introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

national accreditation body – single body having the authority to accredit, nationally recognized, vested with the right to become a member of international and regional accreditation organizations;

manufacturer – any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

making available on the market – any supply of a product for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge;

authorised representative – any natural 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 to be used by accredited conformity assessment bodies for indicating their accredited status;

Surveillance of conformity assessment bodies – a set of activities to monitor the continuous fulfillment of accreditation requirements by accredited conformity assessment bodies, except revaluation.

Article 3. The scope

The scope of this law is to ensure a high level of protection of public interests, such as health and safety in general, health and safety at work, consumer protection, environmental protection and security, facilitating cross-border trade and liquidation of technical barriers to trade.

Article 4. The body responsible for policy development in the field of accreditation and conformity assessment of products

State policy in the field of accreditation and conformity assessment are developed by the specialized central body of public administration responsible for quality infrastructure.

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

(1) The national accreditation and conformity assessment bodies shall have the following main objectives:

a) creating preconditions to recognize the results of conformity assessment activities by signing the multilateral recognition agreements by the national accreditation body with the European Cooperation for Accreditation and with the international and regional organizations for accreditation and to ensure continued membership;

b) promoting the free movement of goods and services;

c) awarding authorities and consumers' confidence in the competence, impartiality and integrity of the conformity assessment bodies;

d) contribution to increasing the competitiveness of products and services in terms of globalized markets;

e) promoting protection of life, health and safety of people and the environment.

(2) The national accreditation and conformity assessment bodies shall operate on the following basic principles:

a) the use of single assessment procedures, harmonized with the European and International rules for the accreditation of conformity assessment bodies;

b) competence and impartiality;

c) transparency, credibility and public availability;

d) representation of public interests;

e) free access without discrimination of all applicants to the accreditation process;

f) independence from the possible dominance of any specific interests;

g) ensure confidentiality and keep the professional and commercial secrecy;

h) impartial examination of appeals and complaints.

Article 6. Reference Standards

(1) Reference Standards are harmonized European standards or international standards adopted at national level, laying down criteria for competence of the national accreditation bodies and the conformity assessment bodies.

[Art. 6 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) The national accreditation and conformity assessment bodies shall always observe the applicable reference standards.

(3) The list of referenced standards shall be approved by the central public administration body responsible for quality infrastructure and published in the Official Gazette of RM.

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 shall be performed by the National Accreditation Centre, designated as the single national accreditation body, with the abbreviated name „MOLDAC".

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

(4) The National Accreditation Centre shall fulfill their duties and powers based on a regulation, approved by the Government with prior endorsement by the Parliament Committee for Economy, Budget and Finance.

(5) The National Accreditation Centre Director shall be appointed on a competitive basis, by order of the head of the specialized body of central public administration responsible for quality infrastructure. The Centre Director shall have Moldovan citizenship, higher education degrees in technical or economic areas and work experience in the field of accreditation and / or conformity assessment for at least 5 years, including at least 3 years in administrative positions.

(6) The National Accreditation Centre Director shall be removed from office, by order of the head of the specialized Central Public Administration Body responsible for quality infrastructure, in the following cases:

a) loss of citizenship;

b) incapacity to exercise the function of health reasons;

c) enrolment in another position;

d) conviction for committing deliberate crimes or conviction to imprisonment by a final court decision.

(7) The National Accreditation Centre is a non-commercial organization, operating under non-profit regime.

(8) The Government shall ensure that the National Accreditation Centre disposes:

a) free space;

b) financial resources and appropriate staffing for the proper performance of its duties, including the fulfillment of special tasks such as cooperative activities related to the European and international accreditation and activities required to support public policy in the field of accreditation and conformity assessment, where the Center is unable finance itself.

Article 8. The National Accreditation Centre

(1) The National Accreditation Centre shall:

a) develop accreditation and conformity assessment and provides confidence in the technical competence and integrity of the conformity assessment bodies, on the principles set out in Art. 5 para. (2);

b) constantly comply with the reference standard, European and international documents on the functioning of the accreditation body;

c) establish and maintain appropriate structures within its own activities to ensure the effective and balanced participation of all stakeholders;

d) identify the conformity assessment activities for which it is competent to perform accreditation and provide services for training and knowledge transfer in the field of accreditation;

e) accredit the conformity assessment bodies under the reference standards and issue certificates of accreditation, regardless of whether the conformity assessment is made on compulsory or voluntary basis, i.e.:

- testing laboratories;
- calibration laboratories;
- medical laboratories;
- Conformity Assessment inspection bodies;
- product certification bodies;
- management systems certification bodies;
- certification bodies for other certification schemes in the voluntary or regulated area;
- personnel certification bodies;
- organizers of interlaboratory testing schemes;
- conformity assessment bodies on new areas established by the European Cooperation for Accreditation EA or regulatory authority functions;

[Art.8 al.(1), letter f) amended by LP122 from 30.06.17, MO253-264/21.07.16 art.416]

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

h) ensure performance of its functions competently, promptly and without imposing onerous conditions on applicants for accreditation;

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

j) cooperate with the regulatory authorities and collaborate with NGOs for designing national policies on accreditation and conformity assessment;

k) assess the conformity assessment bodies applying for the right to operate in the areas covered, with subsequent recognition by the regulatory authorities;

l) establish and apply criteria for selecting, monitoring, training and selecting assessors, technical experts involved in the accreditation process;

m) participate in the elaboration of regulations on accreditation, conformity assessment;

n) participate in national, European and international standards development process in its field;

o) publish annual financial audit reports.

(2) The National Accreditation Centre shall also perform other functions provided by this law and its regulation.

(3) For exercising its powers, the National Accreditation Centre must:

a) keep records of the accreditation activity, including technical committees, evaluators and experts involved in the accreditation activity;

b) provide public information about its activity, including guides, instructions etc.;

c) ensure a balanced representation of accreditation activity stakeholders, in accordance with the reference standards;

d) establish rules under the reference standards, guidelines and recommendations associated therewith, specific to the scope of accreditation;

e) inform the regulatory authorities about activities in the field of accreditation and provide expertise on request;

f) represent the interests of the country in international and European activities in the field of accreditation;

g) develop policies, rules and procedures ensuring transparency and credibility of the accreditation process;

h) make public the results of the peer evaluations, results of accreditation by conformity assessment bodies, including cross-border accreditation;

[Art. 8 para.(3), letter h) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

i) disclose confidential information about a conformity assessment body only on its written consent, except where the law provides that this type of information may be disclosed without such consent.

[Art. 8 para.(3), letter i) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(4) In the process of its activity, the National Accreditation Centre shall ensure the use and implementation of European and international specialized organizations' documents, that establish general criteria and rules in the area of accreditation and conformity assessment.

(5) In order to exercise its duties efficiently, the National Accreditation Centre shall comply with the non-competition principle, on the following criteria:

a) independence from the conformity assessment bodies which it assesses and from commercial pressures;

b) ensuring no conflicts of interest with the conformity assessment bodies, lack of shares or other types of financial or managerial interest in a conformity assessment body;

c) no supply or provision of any activities or any service performed by conformity assessment bodies accredited by it, granting no consultancy for obtaining or maintaining the accreditation;

d) non-competition with other states' national accreditation bodies.

Article 9. The National Accreditation Centre's budget

(1) Within 30 days after approval of the state budget, the estimated expenditures of the National Accreditation Centre shall be approved by the specialized body of central public administration responsible for quality infrastructure, complying with the principles set out in this Article.

[Art. 9 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) The National Accreditation Centre's budget shall be formed on the basis of:

a) funds from state budget, necessary to fulfill obligations resulting from the signatory status within the Associate membership contract and the Multilateral Recognition Agreement with European Cooperation for Accreditation, including participation in the work of European and international accreditation organizations, arising from obligations as signatory of the respective recognition agreements and for cooperative activities related to the European and international accreditation;

b) funds from payments for accreditation, certification, training activities;

c) funds from sponsorships, grants etc. that do not contradict the requirements set for the Center.

(3) The cost of accreditation is calculated in accordance with Annex No. 1, which is an integral part of this Law. The cost set at the initiation stage of the accreditation process may be modified depending on the time actually used which shall be coordinated with the conformity assessment body.

[Art. 9 para.(3) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(4) The funds, excluding those from the state budget, unused by the National Accreditation Centre within the current financial year shall be transferred with the same destination for the next budget year.

(5) The structure and staff of the National Accreditation Center, forms and manner of employees' compensation shall be determined by the Director of the Centre within the budget limits.

Article 10. Accreditation Board

(1) To ensure impartiality, development and compliance with the operating principles and policies, as well as effective and balanced participation of all direct or indirect stakeholders in the National Accreditation Centre, an accreditation board shall be established as part of it, that is an advisory body operating on civic basis and its decisions are recommendations only.

[Art. 10 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) The Accreditation Board consists of 11 members. Its organization and functioning, as well as the manner of members' election / appointment are established within the Council Regulation, developed and approved by the National Accreditation Centre.

[Art.10 para.(2) amended by LP122 of 30.06.17, MO253-264/21.07.16 art.416]

(3) The structure of the Accreditation Board is approved by the National Accreditation Center, based of proposals made by representatives of stakeholders, namely:

[Art.10 al.(3) amended by LP122 of 30.06.17, MO253-264/21.07.16 art.416]

a) accredited conformity assessment bodies;

b) conformity assessment activities' beneficiaries;

c) consumers;

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

(4) The Accreditation Board shall have the following responsibilities:

a) examines and submits proposals on accreditation policies and rules;

[Art. 10 para. (4), letter a) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

b) examine and submit proposals on annual revenue and expenditure estimate;

[Art. 10 para.(4), letter b) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

c) examine and submit proposals on the accounting statement and revenue and loss accounts and, where appropriate, request financial audit;

[Art. 10 para.(4), letter c) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

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

[Art. 10 para.(4), letter e) repealed by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

f) examine and submit proposals on the Appeal Committee regulation;

[Art. 10 para.(4), letter f) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

g) examine and submit proposals on Technical Committees Regulation;

[Art. 10 para.(4), letter g) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

h) recommends specialized international organizations which the National Accreditation Centre must cooperate with;

i) promotes accreditation and informs society about accreditation;

j) examine and submit proposals on the list of reference standards and documents of European and international specialized organizations, that establish general criteria and rules within the field of accreditation and conformity assessment.

[Art. 10 para.(4), letter j) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(5) Stakeholders are represented equally by fair vote when taking decisions within the Accreditation Board.

Article 11. The appeal procedure

(1) In order to examine any negative decision on the granting of accreditation taken by the National Accreditation Centre, applicant can apply for accreditation appeal.

(2) The appeal shall be examined by a Board of Appeal, established ad-hoc by order of the National Accreditation Center's Director. The appeal shall be examined in accordance with the procedure of appeals' consideration, prepared on the basis of the reference standard requirements.

[Art. 11 para.(2) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2^1) The Appeal Commission Regulation shall be developed and approved by the National Accreditation Centre.

[Art. 11 para.(2^1) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) The National Accreditation Centre, in accordance with the reference standard, shall:

a) establish the procedure for consideration of appeals received from conformity assessment bodies;

b) decide on the validity of the appeal;

c) communicate the final decision to the conformity assessment body that submitted the request for appeal;

d) keep records of all appeals and final decisions.

(4) The National Accreditation Centre's decision on the restriction, suspension, withdrawal or

refusal of accreditation, and the absence of such a decision may be contested by conformity assessment bodies in the competent court in accordance with applicable legislation, if they were not settled beforehand by the National Accreditation Centre according to its procedure.

Article 12. The accreditation process

(1) Criteria for accreditation of conformity assessment bodies are established in the reference standards and documents of European and international specialized organizations, adopted at national level, applicable to the national accreditation body and Conformity Assessment Bodies.

(2) Upon fulfillment of the accreditation criteria, regardless of whether accreditation is used on a compulsory or voluntary basis, conformity assessment bodies carrying out conformity assessment activities, including certification, inspection, calibration and testing can be accredited.

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

(4) The accreditation decision is adopted if the applicant conformity assessment body meets the criteria for accreditation. The accreditation decision shall be adopted by the National Accreditation Centre. On the basis of the accreditation decision, the applicant will be issued an accreditation certificate valid for a period specified in the reference standard and enrolled in the Register of accredited conformity assessment bodies. The scope of accreditation approved by the National Accreditation Centre shall be part of the Accreditation Certificate.

[Art. 12 para.(4) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

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

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

[Art.12 para.(5) amended by PL168 din 26.07.18, MO333-335/24.08.18 art.549; in force 24.02.19]

(6) Where found that the applicant for accreditation has not removed the non-compliances identified during the on-site evaluation within the deadlines set, the National Accreditation Centre shall decide on not granting the accreditation.

(7) The National Accreditation Centre shall supervise the conformity assessment bodies for which it has issued an accreditation certificate. Surveillance is carried out to monitor the continuous fulfillment of the accreditation requirements by the accredited conformity assessment bodies.

(8) Confirmation of the accreditation validity shall be approved by decision on maintaining the accreditation, issued by the National Accreditation Centre, taking into account the positive results of the surveillance evaluations.

(9) Extending the scope of accreditation shall be performed upon request by the conformity assessment body.

(10) Restricting the scope of accreditation shall be performed upon request by the conformity assessment body or following a surveillance evaluation, in order to exclude those parts where the conformity assessment body does not meet the accreditation criteria repeatedly.

(11) Upon request by the conformity assessment body, accreditation renewal can be performed by reassessing it on compliance with the accreditation criteria. Reassessment of the conformity assessment body is similar to an initial assessment, except that the experience gained during previous assessments must be taken into account.

(12) Where it is found that a conformity assessment body that received the accreditation

certificate is no longer competent to carry out a specific conformity assessment activity and does not comply with the accreditation criteria set in the applicable reference standard, the National Accreditation Centre shall take all appropriate measures for restriction, suspension or withdrawal of its accreditation certificate.

(13) The National Accreditation Centre shall ensure independence, objectivity and impartiality in decision making, shall be responsible for its decisions to grant, refuse to grant, maintain, extend, restrict, suspend and withdraw accreditation.

Chapter III
THE NATIONAL ACCREDITATION MARK

Article 13. The National Accreditation Mark and references to accreditation

(1) The National Accreditation Mark is an officially registered symbol, legally protected and represents the exclusive property of the National Accreditation Center.

(2) The National Accreditation Mark is a graphical representation accompanied by state symbols, such as the state flag and official name of the state, as described in Annex No. 2, that is an integral part of this Law.

(3) The National Accreditation Mark , accompanied by particulars on activities covered by the accreditation, represents the accreditation symbol.

(4) The National Accreditation Centre shall pass the right to use the accreditation symbol, according to the applicable reference standard, to the conformity assessment bodies.

(5) The manner of using the national accreditation mark shall be established by the National Accreditation Centre, in accordance with the requirements of the European Cooperation for Accreditation.

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

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

Chapter IV
INTERNATIONAL COOPERATION

Article 14. International cooperation

(1) The National Accreditation Centre represents the interests of the Republic of Moldova within international and regional (European and interstate) Accreditation organizations, it must cooperate with them and participate in their activities, sign mutual recognition agreements.

(2) The National Accreditation Centre is subject to peer evaluation based on clear and transparent criteria and evaluation procedures established by the European and international accreditation bodies (EA, IAF, ILAC). Peer evaluation is used to determine whether the Centre meets the relevant harmonized requirements and standards.

(2^1) The National Accreditation Centre may accredit a foreign conformity assessment body in the following instances:

a) if the state of establishment of the conformity assessment body decided not to establish a national accreditation body and did not resort to the national accreditation body of another state;

b) if the national accreditation body from the foreign state where the conformity assessment body is established does not perform accreditation in connection with conformity assessment activities for which accreditation is sought;

c) if the national accreditation body from the foreign state where the conformity assessment body is established has not successfully passed the peer evaluation in connection with conformity assessment activities for which accreditation is sought.

[Art. 14 para.(2^1) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) Where the National Accreditation Centre receives a request for accreditation from a foreign conformity assessment body, it must inform the national accreditation body from the

country where the applicant conformity assessment body is established about registering its application. In such cases, the national accreditation body of the state where the applicant conformity assessment body is established may participate in the accreditation process as an observer.

(4) The National Accreditation Centre may request a foreign national accreditation body to perform part of its assessment activities for purposes of accreditation of the conformity assessment body. In such case, the accreditation certificate shall be issued by the National Accreditation Centre from the Republic of Moldova.

(5) The Conformity Assessment Body may seek accreditation to a foreign national accreditation where the National Accreditation Centre of the Republic of Moldova does not perform accreditation of conformity assessment activities in the scope requested. In this case, the Centre shall participate as an observer at the accreditation process of the conformity assessment body from the Republic of Moldova.

(6) Upon request by a foreign national accreditation body, the National Accreditation Centre may perform part of accreditation activities of the applicant conformity assessment body.

Chapter IV[1]

RECOGNITION FOR NOTIFICATION

Article 14[1]. General provisions on recognition of Conformity Assessment Bodies for notification

(1) Recognition for notification is the procedure to attest the right of Conformity Assessment Bodies to perform conformity assessment procedures in the field covered.

(2) Conformity assessment bodies that carry out conformity assessment activities provided for in the technical regulations can be recognized.

(3) Where the Community harmonization legislation imposes conformity assessment to be carried out by conformity assessment bodies notified to the Commission and the Member States of the European Union, the regulatory authority shall be responsible for carrying out the necessary procedures for the assessment, recognition and, where appropriate, notification of the Conformity Assessment Bodies, and for the monitoring of recognized organizations and, where appropriate, notified. In this case, the regulatory authority shall acquire the status of notifying authorities at the entry into force of the CAA Agreement for the scope of accreditation covered by the recognition. Where such an agreement is not concluded, the regulatory authority shall notify the bodies recognized at the date of Moldova's accession to the European Union.

(4) The regulatory authority shall recognize and, subsequently, notify the conformity assessment bodies accredited under this law, and meet the requirements of the technical regulations.

(5) Conformity assessment bodies shall be recognized for each technical regulation transposing the Community harmonization legislation that provides for notification of Conformity Assessment Bodies.

(6) The regulatory authority shall recognize the conformity assessment bodies by orders of its manager, and subsequently notify those bodies. Orders shall be updated whenever necessary.

(7) Orders issued for the recognition for notification must contain mainly the following:

a) references to technical regulation transposing the Community harmonization legislation and whereby the conformity assessment bodies subject to recognition are to carry out conformity assessment activities;

b) information on the full name, registered address and contact details for each body undergoing recognition;

c) specific conformity assessment tasks that each recognized body has the right to perform to

enforce the Community harmonization legislation and technical regulation that transpose this legislation, including products or product groups which assessment they can carry out as a recognized and subsequently notified body.

(8) Accreditation certificates issued by national accreditation bodies signatories to the Multilateral Recognition Agreement with the European Cooperation for Accreditation, that successfully passed peer evaluations, shall be recognized and accepted by the regulatory authority .

(9) Following the entry into force of the CAA Agreement, where conformity assessment activities provided for in the technical regulations transposing the Community harmonization legislation are not included in the areas of competence for which the National Accreditation Centre has successfully passed peer evaluation, the regulatory authority shall accept accreditation certificates issued by accreditation bodies that successfully passed peer evaluation for the conformity respective assessment activities.

(10) The National Accreditation Centre shall develop accreditation schemes in the field jointly covered with the respective regulatory authority. For this purpose, the National Accreditation Centre shall identify the conformity assessment activities in respect of which it is competent to perform accreditation, by referring to technical regulations transposing the Community harmonization legislation .

(11) The National Accreditation Centre shall inform the regulatory authority about the decision granting, extending, suspending, reducing, withdrawing accreditation within 5 working days from its adoption.

(12) The recognised conformity assessment body shall submit a written report on its activity in the previous calendar year to the regulatory authority, each year, by 1 February. The annual report shall contain information on:

a) conformity assessment activities, performed within the scope of recognition;

b) any refusal, restriction, suspension or withdrawal of certificates of compliance, accompanied by motivation;

c) appeals and complaints received, including information on their settlement;

d) difficulties encountered in performing activities, actions taken and / or proposed for improvement;

e) subcontracted activities, subcontractors, measures taken and / or proposed for these activities' improvement;

f) requests from market surveillance authorities on deployment of conformity assessment activities;

g) participation in or informing the assessment staff on standardization activities within the scope of recognition.

(13) The regulatory authority, upon request by the European Commission, shall submit all the information on the process that led to the notification decision or maintenance of the relevant conformity assessment body's competence.

(14) Recognition and expanding recognition of the Conformity Assessment Bodies in the field covered shall be made free of charge.

Article 14[2]. Powers of regulatory authorities

In the recognition for notification, the regulatory authority shall have the following powers:

a) to establish criteria for recognition for conformity assessment bodies' notification in the technical regulations, within the provisions of Art. 16;

b) to recognise the accredited conformity assessment bodies for activities in the area covered within this law;

c) to ensure objectivity and impartiality in decision making on Conformity Assessment Bodies' recognition;

d) to provide decision on the conformity assessment body's recognition by another person than the one who participated in its assessment;

e) to ensure confidentiality of information obtained, except information affecting national security, protection of human life and health, and environmental protection; provides information about the Conformity Assessment Body where provided by legislation;

f) to have staff for the proper performance of their duties for the purpose of recognition;

g) participate at the accreditation process as observers and supervise, jointly with the National Accreditation Centre, the activity of accredited and recognised Conformity Assessment Bodies.

Article 14[3]. Recognition and extending recognition of Conformity Assessment Bodies

(1) For the purpose of activities recognition in the area covered, the Conformity Assessment Body shall submit an application for recognition or extending recognition to the National Accreditation Centre, along with the application for accreditation.

(2) The National Accreditation Centre, within 5 working days from granting the accreditation, shall submit the original request for recognition or extending recognition accompanied by copies of the dossier documents to the regulatory authority.

(3) The dossier shall include:

a) evaluation report on the recognition or extending recognition, prepared by the National Accreditation Centre after granting the accreditation or extension of accreditation;

b) decision of accreditation or accreditation extension, adopted by the National Accreditation Centre;

c) accreditation certificate attesting that the Conformity Assessment Body meets the requirements of technical regulations transposing the Community harmonization legislation, including the annex / annexes thereto, issued by the National Accreditation Centre;

d) the list of conformity assessment body's staff;

e) the list of conformity assessment body's equipment, where applicable;

f) the list of subcontracted activities, where applicable.

(4) Copies of the documents shall be numbered and shall be signed by the head of the National Accreditation Centre.

(5) If the dossier submitted to the regulatory authority is drawn with deviations from provisions of para. (3), the latter shall communicate the National Accreditation Centre, in writing, about receiving incomplete information, indicating the date when receiving the dossier.

(6) Documents submitted for recognition or recognition extension shall be subject to examination by the regulatory authority, that creates the recognition recommendations committee. Committee rules and composition shall be approved by the regulatory authority.

(7) Examination of documents submitted for recognition or extending recognition and decision making shall be made within up to 15 working days from receipt of the dossier on recognition or extending recognition.

(8) After examining the documents submitted, the regulatory authority shall issue an order granting or, where appropriate, extending recognition.

(9) Where, under terms set in para. (7) of this Article, no order granting or, where appropriate, extending recognition was issued and no refusal of granting or extending recognition was expressed, the principle of tacit approval under Law No. 235-XVI of 20 July 2006 on basic principles regulating the entrepreneurial activity shall apply.

(10) Recognition or extending recognition is granted on the validity of the accreditation certificate.

(11) The regulatory authority shall inform the National Accreditation Centre about the decision for granting or extending recognition or refusal of granting or extending recognition of the conformity assessment body, providing grounds for refusal, within 5 working days of the decision adoption.

(12) Information on recognised conformity assessment bodies shall be registered by the National Accreditation Centre in the Register of recognised conformity assessment bodies, that is managed by the National Accreditation Centre and can be accessed on its official website.

(13) The list of recognised conformity assessment bodies and the specific tasks for which they have been recognized shall be managed by the National Accreditation Centre and published on web-page of National Accreditation Center.

[Art.14[3] al.(3) modified by LP122 of30.06.17, MO253-264/21.07.16 art.416]

Article 14[4]. Suspension, restriction or withdrawal of recognition of conformity assessment bodies

(1) In respect of suspension, restriction or withdrawal of recognition, the National Accreditation Centre shall submit copies of the following documents to the regulatory authority:

a) evaluation report on suspension, restriction or withdrawal of recognition, prepared by the National Accreditation Centre as a result of surveillance or unplanned evaluation of the recognised conformity assessment body;

b) decision of suspension, restriction or withdrawal of accreditation, adopted by the National Accreditation Centre.

(2) Copies of the documents shall be numbered and shall be signed by the head of the National Accreditation Centre.

(3) The National Accreditation Centre shall submit the documents in accordance with para. (1) within 5 working days of the decision to suspend, restrict or withdraw accreditation.

(4) The regulatory authority shall suspend recognition in the following cases:

a) upon request by the recognised conformity assessment body;

b) if the recognised conformity assessment body was suspended accreditation according to the decision of accreditation suspension, adopted and submitted by the National Accreditation Centre;

c) if, by decision of the regulatory authority, misuse of the status of recognized conformity assessment body has been found (including in the case of wrong references to the certification system, certificates or marks, in advertisements, catalogues, etc.);

d) where an insolvency court issued a decision on bankruptcy under the Insolvency Law No. 149 of 29.06.2012 to the conformity assessment body, or where liquidation proceedings were initiated under the Civil Code, in both cases based on the extract from the State Register of Legal Entities.

(5) The regulatory authority shall restrict recognition in the following cases:

a) upon request by the recognised conformity assessment body ;

b) if the recognised conformity assessment body has not demonstrated competence for part of the accredited area, according to the decision to restrict accreditation, adopted and submitted by the National Accreditation Centre.

(6) The regulatory authority shall withdraw recognition in the following cases:

a) upon request by the recognised conformity assessment body ;

b) whether accreditation of the conformity assessment body has been withdrawn under the decision on withdrawal of accreditation adopted and submitted by the National Accreditation Centre;

c) where the activity of the conformity assessment body has ceased following it removal from the State Register of Legal Entities.

(7) The regulatory authority shall suspend, restrict or withdraw recognition of conformity assessment body by issuing a relevant order.

(8) In the case referred to in paragraph (4) letter c) of this Article, the regulatory authority suspends recognition in accordance with the Law No. 235-XVI of 20 July 2006 on basic principles regulating entrepreneurial activity.

(9) Where non-conformities detected, that caused the suspension of recognition, were

removed, suspension may be raised by order to the regulatory authority, issued after the presentation of evidence on the removal of non-compliance, or, in the case under para. (4) c) after the adoption of an appropriate decisions by Court.

(10) Suspension or withdrawal of recognition results in termination of conformity assessment activities in the respective field. Documents issued after the suspension or withdrawal of recognition shall be considered void. The Conformity Assessment Body shall be liable, under the Contravention Code for documents issued after suspension or withdrawal of recognition.

(11) Suspension, restriction or withdrawal of recognition of conformity assessment body shall not affect the test reports and certificates of conformity issued prior to adopting the decision on suspension, restriction or withdrawal of recognition.

(12) In the event where the recognized conformity assessment body has ceased its activity, it shall ensure submission of documents and records on evaluations conducted or in progress, from the period when it was recognized, to another recognized organization in the field, and shall inform the regulatory authority thereof or shall submit them to the regulatory authority and the responsible market surveillance authority, at their request.

(13) The regulatory authority shall inform the National Accreditation Centre on the decision of suspension, cancellation of suspension, restriction or withdraw of recognition of the conformity assessment body within 5 working days from its adoption.

[Chapter IV[1] introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Chapter V
CONFORMITY ASSESSMENT ACTIVITY

Article 15. General provisions on conformity assessment

(1) Conformity assessment can be compulsory or voluntary.

(2) Conformity assessment in the regulated area shall be made only by the accredited conformity assessment bodies.

[Art. 15 para.(2) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) The conformity assessment of products with essential requirements shall be performed by applying, at the discretion of manufacturer, of one of the conformity assessment procedures set out in the applicable technical regulation.

[Art. 15 para.(3) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 16. Requirements for accredited conformity assessment bodies

[Art. 16 title in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(1) The accredited conformity assessment bodies shall have the following obligations:

a) comply with the requirements of the reference standards and the European and international documents on the operation of conformity assessment bodies and the requirements set out by the National Accreditation Centre on areas for which accreditation is granted. In the case of recognised conformity assessment bodies and, where appropriate, notified on the areas covered, provided for in Annex No. 3, which is an integral part of this Law, meet the requirements of notified bodies, set by Community harmonization legislation and technical rules implementing that legislation;

[Art. 16 para.(1), letter a) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

b) act neither as designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they evaluate, nor as authorized representative of any of these parties;

[Art. 16 para.(1), letter b) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

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

d) perform all conformity assessment tasks for which accreditation is requested, and possess the means required to perform properly the technical and administrative tasks related to conformity assessment, including secure access to all necessary equipment or facilities;

[Art. 16 para.(1), letter d) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

e) ensure impartiality by means of participation of all interested parties in development of policies and principles of operation of conformity assessment bodies;

f) carry out conformity assessment at the highest level of professional integrity and technical competence required in the relevant field, and shall be free of any pressure and incentive, particularly financial ones, which might influence the results of the work;

f^1) for certification and inspection bodies, to use the test results, issued by accredited testing laboratories, when subcontracting laboratories;

[Art. 16 para.(1), letter f^1) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

g) maintain professional secret about all information obtained in the course of performance of their duties, and protect the copyright;

h) inform the interested parties, including other accredited conformity assessment bodies, about the measures envisaged in relation to the non-conforming products (identified in the course of evaluation) that have risks to the health and safety of persons or about other aspects of protection of public interest;

i) conclude insurance contracts with insurance companies legally recognized in the Republic of Moldova and have insurance policies to repair the damage that can be caused to third parties by their activity and to whom they bear responsibility in accordance with current legislation on insurance.

(2) The Conformity Assessment Body shall have the right to:

a) access publicly available information, related to the accreditation activity for the area he has sought or received accreditation;

b) negotiate, within the limits set out by the procedures of the National Accreditation Centre, accurate data about the performance of various phases of the evaluation process;

c) refuse the membership of the evaluation team only on good grounds, submitted in written form to the National Accreditation Center. In this case, the conformity assessment body shall assume the risk of delay of accreditation as compared to the established schedule, and the Centre shall reserves the right to use, where appropriate, evaluators from foreign accreditation bodies as well, to recalculate the costs of accreditation that shall be communicated additionally to the conformity assessment body;

d) request the members of the evaluation team to provide declarations of confidentiality and respect for its industrial and intellectual property right, as well as such right of its customers;

e) waive accreditation, notifying the Centre at least 45 days in advance;

e^1) apply for accreditation to the national accreditation body signatory of multilateral recognition agreement with the European Cooperation for Accreditation where the National Accreditation Centre is not competent to provide the accreditation services requested in the area covered under Annex No. 3;

[Art. 16 para.(2), letter e^1) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

f) make reference to its accreditation status only within the validity period of the accreditation certificate and only for accredited activities;

g) appeal any unfavorable decision;

h) require access to the workplace and the quality system documentation from the manufacturer within the conformity assessment, in order to perform both announced and

unannounced evaluation visits, if necessary.

[Art. 16 para.(2), letter h) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) The conformity assessment body shall perform the conformity assessment procedure proportionately, avoiding unnecessary burdens for economic agents, taking into consideration the field of activity and the structure of a company, the complexity of the technology used for products and the serial or mass nature of production process. Meanwhile, the conformity assessment body shall comply with the level of required protection for the product conformity to the technical regulations applicable to the product.

[Art. 16 para.(3) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(4) If a conformity assessment body finds that the requirements of the technical regulations applicable to the product or harmonized European standards adopted as Moldovan standards or relevant technical specifications have not been met by the manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

[Art. 16 para.(4) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(5) If, during the monitoring of conformity, following the issue of certificate, a conformity assessment body finds that a product is no longer conformant, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate, as appropriate.

[Art. 16 para.(5) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(6) If corrective measures are not taken or do not have the required effect, the Conformity Assessment Body shall restrict, suspend or withdraw the certificate issued.

[Art. 16 para.(6) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(7) The recognised conformity assessment body shall inform the regulatory authority about:

a) any refusal, restriction or revocation of certificates;

b) circumstances affecting the scope and conditions of recognition by regulatory authorities;

c) any request of the market surveillance authorities for information on performed conformity assessment;

d) the conformity assessment performed within the scope of the notification/recognition and in relation to any other activity performed, including cross-border activities and subcontracting.

[Art. 16 para.(7) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(8) The conformity assessment body shall cooperate with other conformity assessment bodies, which perform similar conformity assessment and cover the same products by providing relevant information on issues of negative results of conformity assessments and, upon request, positive results of conformity assessments.

[Art. 16 para.(8) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(9) Conformity assessment bodies shall participate in the information or ensure that their assessment personnel is informed of the relevant standardization activities within its scope of activities.

[Art. 16 para.(9) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 17. Conformity assessment on a voluntary basis

(1) Conformity assessment on a voluntary basis shall be carried out through conformity

certification performed by accredited conformity assessment bodies, not being imposed by the national technical regulations.

[Art. 17 para.(1) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) Voluntary conformity certification shall be performed on contract basis.

Article 18. Conformity assessment on a mandatory basis

(1) Conformity assessment on a mandatory basis is made for the products from the fields laid down in for in Annex No. 3, as well as the products that are not included in the fields listed in this annex, for which there are requirements laid down in the respective technical regulations, in accordance with Art. 4 para. (6) of Law No. 420-XVI of 22 December 2006 on technical regulation activity.

(1) Conformity assessment on a mandatory basis is made for the products from the fields laid down in for in Annex No. 3, as well as the products that are not included in the fields listed in this annex, for which there are requirements laid down in the respective technical regulations.

[Art. 18 para.(1) amended by PL168 din 26.07.18, MO333-335/24.08.18 art.549; in force 24.02.19]

[Art. 18 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) The following procedures of conformity assessment are applied to the products from the annex No. 3, they provide for each category of products, one module or an adequate combination of the following modules, described and approved by a Government decision:

a) module A – internal production control;

b) module A1 – internal production control plus supervised product testing;

c) module A2 – internal production control plus 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 plus supervised product testing;

g) module C2 – conformity to type based on internal production control plus supervised product checks at random intervals;

h) module D – conformity to type based on quality assurance of the production process;

i) module D1 – quality assurance of the production process;

j) module E – conformity to type based on product quality assurance;

k) module E1 – quality assurance of final product inspection and testing;

l) module F – conformity to type based on product verification;

m) module F1 – conformity based on product verification;

n) module G – conformity based on unit verification;

o) module H – conformity based on full quality assurance;

p) module H1 – conformity based on full quality assurance plus design examination.

(3) Where the procedures laid down in the para. (2) cannot be applied to a product category, the conformity assessment is made according to the provisions of the applicable technical regulation.

(4) The products covered by the applicable technical regulations that are not included in the fields from the annex No.3 shall be made subject to a conformity assessment by applying the following procedures:

[Art. 18 para.(4) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

a) certificates;

b) inspection;
c) testing.
[Art. 18 para.(4), letter d) repealed by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]
(5) Procedures regarding the conformity assessment mentioned in para. (2) and para. (4) depend on the degree of complexity of the product, the assessment of the risk upon its use and shall be established by the regulatory authority by means of the respective technical regulations.
(6) Where a product is subject to several technical regulations, the consistency among the applicable conformity assessment procedures shall be ensured by the regulatory authority.
(7) Where a technical regulation requires conformity assessment to be performed in respect of a particular product with a mandatory involvement of a third party, the manufacturer may choose between quality assurance and product certification modules.
[Art. 18 para.(7) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]
Article 19. Declaration of conformity
(1) The aim of the declaration is to give confidence in what regards the conformity of a product with the specified requirements, to which the declaration of conformity refers and to specify explicitly the responsible person for this conformity and declaration. A declaration of conformity is a form of conformity attestation necessary to comply with the requirements of the market and of the authorities empowered with regulatory functions, to give confidence in the product that is being placed on the market.
[Art. 19 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]
(2) The declaration of conformity shall be issued by the manufacturer or his authorised representative, if the respective task is laid down in the mandate received from the manufacturer. By drawing up the declaration of conformity, the manufacturer shall assume the responsibility for the conformity of the product.
[Art. 19 para.(2) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]
(2^1) Where Community harmonization legislation requires the manufacturer to declare that the fulfillment of requirements relating to a product has been demonstrated, applicable requirements shall be those provided by Technical Regulations that transpose the respective Community legislation.
[Art. 19 para.(2^1) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]
(3) The issuer of a declaration of conformity (an organisation or an individual) shall be responsible for the conformity of its object with the essential applicable requirements in accordance with technical regulations that transpose the Community harmonization legislation.
[Art. 19 para.(3) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]
(4) The declaration of conformity shall be based on the outcome of the conformity assessment.
(5A declaration of conformity may refer both to a particular product and a group of similar products, for which there are established similar requirements that shall be attested. In this case, the issuer of the declaration shall ensure that each particular product of the group complies with the essential applicable requirements.
(6) A declaration of conformity shall cover sufficient information as to identify its issuer, the product that it refers to, the requirements by which the conformity is declared and the person who signs it for and on behalf of the issuer and shall contain at least the following:
a) its unique identification;
b) the name and the contact address of the issuer;

c) the identification of the product;
d) the declaration of conformity and a statement of assuming the responsibility for the conformity of the product;
e) a full and explicit list of the standards or other specified requirements;
f) date and place of issuance;
g) the name and the number of the notified/acknowledged conformity assessment body, the number of the certificate issued by it and the description of its intervention;

[Art. 19 para.(6), letter g) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

h) identification of the elements specified in the relevant modules.

[Art. 19 para.(6), letter h) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(7) The issuer of the declaration of conformity must have the implemented procedures to ensure the ongoing conformity of its object, as it was delivered or accepted, with the requirements mentioned in the declaration of conformity, and to reassess its validity, in case there shall arise:
a) modifications that significantly affect the project or the specification of the declaration's object;
b) modifications in the regulatory acts that establish the essential requirements in relation to which the conformity of the declaration's object is declared;
c) relevant information that notice the possibility that the object of the declaration does not comply anymore with the essential applicable requirements.
(8) The issuer of the declaration of conformity must make accessible to the relevant regulatory authorities and to the market surveillance authorities the technical documentation.

[Art. 19 para.(8) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(9) The technical documentation that requires the elaboration, accumulation, the ongoing updating and keeping of a declaration of conformity to allow the traceability from the declaration of conformity, given by issuer and, as provided for in the applicable technical regulation, it must include, but not be limited to the following:
a) description of the object of declaration;
b) information regarding the design documentation of the product;
c) product's conformity assessment outcomes;
d) identification of the conformity assessment bodies involved, whose outcomes shall be used, as well as the identification of their accreditation status;
e) a full and explicit list of the applicable standards or other specified requirements;
f) the description of the relevant management system for the object of declaration.
(10) The technical documentation must be drafted by the manufacturer and must allow the conformity assessment of the product with the relevant requirements, as well as it must include risk analysis and assessment.

[Art. 19 para.(10) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(11) For registering the declaration of conformity the applicant shall submit to the certification body:

a) request (application) for the registration of statement;

b) two copies of the declaration in hard copy, signed by the applicant;

[Art. 19 para.(11), letter b) amended by LP160 din 07.07.16, MO306-313/16.09.16 Art. 647]

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

[Art. 19 para.(11) repealed by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 01.04.17 date of entry into force of Law No. 7 of 26 February 2016]

(12) The certification body shall check the package of documents submitted by the applicant on:

a) accuracy of directing the application for registration of the declaration of conformity;

b) completeness and correctness of the documents submitted, provided for in para. (11).

[Art. 19 para.(12) repealed by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 01.04.17 date of entry into force of Law No. 7 of 26 February 2016]

(13) Following the verification of the set of documents, in accordance with (12), the certification body shall register the declaration of conformity or inform the applicant and the controlling authorities about the refusal of registration within 3 business days after receiving the application for registration.

[Art. 19 para.(13) repealed by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 01.04.17 date of entry into force of Law No. 7 of 26 February 2016]

(14) Grounds for refusal may serve the following:

a) the field of the applicant's accreditation does not include the declared product;

b) lack of the set of documents provided for in para. (11);

c) lack of provision on Conformity Assessment through declaration of conformity in the technical regulation applicable to the product;

d) the content of the set of documents submitted does not comply with the provisions of the applicable technical regulation.

[*Art. 19 para. (14) repealed from 01.04.17 date of entry into force of Law No.7 of 26 February 2016 by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 08.04.16]*

Article 20. Certification

[Art. 20 title amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(1) During the process of conformity certification of the products by the accredited certification bodies, the conformity of the products with the applicable essential requirements is attested, in accordance with the modules and certification schemes approved by the Government.

(2) Certification schemes shall be used in certification of products in the areas not included in Annex No. 3.

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

(4) The accredited certification body will monitor the right to use trademarks and certificates of conformity that it issued and will take measures in case of incorrect references to the certification status or use of misleading certification documents.

[Art. 20 para.(4) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(5) The certificate of conformity is issued for products that are manufactured by the same manufacturer in the same conditions and are assessed by the same applicable requirements.

(6) The form of the certificate of conformity shall be drafted by each certification body, and the issuer has full ownership upon it.

(7) products intended for exhibitions, fairs and the other publicity actions as exhibits, models, advertising materials shall not be subject to certification.

[Art. 20 para.(7) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 21. Inspection

(1) The aim of inspection consists in performing the assessments upon the request of economic agents and/or of public administration authorities, having the objective to deliver the information regarding the conformity with regulations, standards or other specific requirements of the inspected object to the party concerned. The benchmarks of the inspection may include

elements related to quantity, quality, security and usability, and to ongoing compliance of security in the functioning of the objects or industrial systems.

(2) The activity of inspection bodies cover the examination of materials, products, facilities, plants, processes, working procedures or services, determining of their conformity with the specified requirements, the subsequent reporting of the results of those activities to the clients and, if appropriate, to the regulatory authorities. Inspection may take into account all the phases of the life cycle of the inspected object, including the design phase.

[Art. 21 para.(2) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) Inspection means direct determining of the conformity of its object by examination of the applicable essential requirements, based on a professional assessment performed by the accredited inspection bodies. The results of the inspection may be used as a support for certification.

(4) The conformity of the products in the framework of inspection is attested by an inspection report and/or by a certificate of inspection. The inspection report represents a detailed description of an inspection and of its results. The certificate of inspection usually represents a short official attestation of the conformity with the applicable essential requirements.

(5) The inspection report and/or certificate of inspection describes information regarding the condition of the object at the moment of inspection. The content of an inspection report or a certificate of inspection may vary depending on the type of inspection, the essential requirements. The inspection report or the certificate of inspection includes any defect and non-conformity found. In these acts there must be identified the representative of the inspection body, who is in charge of verification and issuing a report and/or a certificate of inspection.

(6) If the inspection is performed on behalf of the state, the authorities empowered with regulatory functions may introduce special requirements for the reporting of the results of the inspection.

[Art. 21 para.(6) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 22. Testing

(1) The aim of testing consists in determining by an accredited laboratory of one or several characteristics of an object that is being subjected to conformity assessment based on a procedure.

(2) The test report represents a written statement, made by a laboratory, comprising an official description of the results of the made tests.

(3) Testing may be a part of inspection or certification in conformity with the applicable technical regulations.

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

Article 23. Conformity mark SM

[Art. 23 title amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(1) Products subject to conformity assessment in the regulated field, before making available and/or using, must be marked by the manufacturer with the conformity mark SM, if the technical regulation provides for such a marking. Marking a product with the conformity marking SM indicated its conformity to the essential requirements established in the applicable technical regulation that transposes the Community harmonization legislation. Conformity mark SM shall be affixed only by the manufacturer or his authorized representative.

[Art. 23 para.(1) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) Conformity mark SM shall be affixed according to principles and rules established in Art. 23^{1}. The graphical presentation and dimensions of the conformity marking SM are laid down in Annex No. 4, which is an integral part of this Law.

[Art. 23 para.(2) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) The application of the conformity mark SM on the products that were not subjected to procedures of conformity assessment in the established mode or that do not correspond to the prescribed requirements is prohibited.

(3) The application of the conformity mark SM on the products that were not subjected to procedures of conformity assessment in the established mode or that do not correspond to the requirements prescribed in legislation is prohibited.

[Art. 23 para.(3) amended by PL168 din 26.07.18, MO333-335/24.08.18 art.549; in force 24.02.19]

[Art. 23 para.(3) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(4) Registration and application of marks that may be confused with the conformity mark SM are prohibited.

[Art. 23 para.(4) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 23[1]. General principles and norms of application of the CE marking

(1) The CE marking shall be affixed only on the areas covered under Annex No. 3. Prior to entry into force of the CAA Agreement or prior to the accession of the Republic of Moldova to the European Union, where such an agreement is not concluded, Conformity mark SM provided for in Art. 23 shall be affixed. During this transition period, the CE marking shall be recognized under the conditions of Art. 31 para. (1^1).

(2) The CE marking shall be affixed only by the manufacturer or his authorized representative. The graphical presentation and dimensions of the CE marking are laid down in Annex No. 5, which is an integral part of this Law.

(3) The CE marking shall be affixed only on products that the technical regulation provides affixing for and shall not be affixed on any other product.

(4)) By the fact of application or requesting the application of CE marking, the manufacturer indicates the fact that he undertakes the responsibility for the conformity of the product to all the applicable requirements.

(5) CE marking is the only marking that attests the conformity of the product with the applicable requirements.

(6) It is prohibited to apply on products some markings, records or inscriptions that may be misleading the third parties in what regards the CE marking. Any other marking may be affixed on a product only under the condition that its application will not affect the visibility, readability and the meaning of the CE marking.

(7) CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where this is not possible or not warranted on account of the nature of the product, the marking shall be affixed on the packaging and on the accompanying documents, where the legislation provides for such documents.

(8) The CE marking shall be affixed before the product is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

(9) The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control phase. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

[Art. 23^1 introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 24. Other conformity marks

[Art. 24 title amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(1) In the unregulated field shall be used other conformity marks than the conformity mark

SM.

[Art. 24 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) Affixing of conformity marks on the products are not related to the regulated field shall be made on voluntary basis. The conformity mark may be affixed on these products, attesting that the product corresponds with the normative documents on which basis their conformity is declared.

[Art. 24 para.(2) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) Other conformity marks affixed must distinguishable from the conformity mark SM and must be visible and readable.

[Art. 24 para.(3) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(4) Marking of products with the conformity mark where they do not correspond with the requirements of the normative documents in force shall be prohibited.

[Art. 24 para.(4) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Chapter VI
PLACING AND MAKING PRODUCTS AVAILABLE ON THE MARKET

[Chapter VI title in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 25. The terms of placing and making products available on the market

(1) Placing and/or making available on the market of products within the regulated field provided for in Annex No. 3 shall be carried out in accordance with provisions of this Law and the requirements of the applicable technical regulations. Products are placed and / or made available on the market if only they satisfy essential requirements that provide an adequate level of protection of public interests, such as health and safety in general, health and safety at work, consumer protection, environmental protection and security, in compliance with the international principles of free movement of goods within domestic and international trade and only if they are accompanied by documents attesting their compliance. The person responsible for placing and/or making products available on the market shall be the trader who carries out entrepreneurial activities.

(2) Economic agents shall be responsible in relation to their roles and duties provided for in the technical regulations that transpose the Community harmonization legislation, that they have in placing and making available products on the market, for the compliance of their products with all applicable technical regulations.

(3) Economic agents shall also be responsible for ensuring that all information they provide with regard to their products are accurate and complete in accordance with technical regulations transposing the Community harmonization legislation.

(4) Conformity of products from the fields not covered by Annex No. 3 shall be assessed on the basis of essential requirements established for those products in the applicable technical regulations .

(5) Conformity of products from the fields not covered by Annex No. 3 with the essential requirements set out for those products in the applicable technical regulations may be attested by certificates of conformity, certificates and / or inspection reports, by test reports, issued by the accredited conformity assessment bodies, as well as by affidavit, issued by the manufacturer or his authorized representative.

[Art. 25 in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 26. Obligations of manufacturers

(1) When placing their products on the market, manufacturer shall have the following

obligations:

[Art. 26 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

a) to ensure that his products placed on the market were designed and manufactured in accordance with the essential requirements;

b) to draw up the technical documentation and ensures the application of conformity assessment procedures;

c) to ensure the correctness and veracity of the declaration of conformity, the possession of test reports, certificates of conformity and other documents that attest conformity;

d) keep the technical documentation and declaration of conformity for the a period determined by the technical regulation applicable to the product, depending on the life cycle of the declaration object and level of risk, after introducing a product on the market;

[Art. 26 para.(1), letter d) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

e) provide, upon the request of the market surveillance authority, information and documentation necessary to demonstrate the conformity of the product;

[Art. 26 para.(1), letter e) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

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

g) to ensure the fact that their products bear the type, batch or serial number or any other element allowing their identification. Where the size or nature of the product does not allow it, the manufacturer shall ensure that the required information is provided on the packaging or in a document accompanying the product;

[Art. 26 para.(1), letter g) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

h) indicate on the product its name, registered trade name or registered trade mark and the address at which he can be contacted or, where this is not possible, on the packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

[Art. 26 para.(1), letter h) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(1^1) Where conformity of product with the applicable requirements was proved through the applicable conformity assessment procedure, manufacturers draw up a declaration of conformity and affix the marking of conformity.

[Art. 26 para.(1^1) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) The manufacturer shall ensure that there are procedures to ensure the continued conformity of series production. Changes in product design or characteristics and changes in the related standards by reference to which conformity of a product is declared shall be adequately taken into account. When deemed appropriate with regard to the risks presented by a product, the manufacturer shall carry out sample testing of marketed products to protect the health and safety of consumers, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

[Art. 26 para.(2) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) Where the manufacturer considers or has reason to believe that a product that he has placed on the market is not in conformity with the applicable essential requirements, the manufacturer shall take without delay the necessary corrective measures to bring the product into conformity, to withdraw it or to recall it, if appropriate.

(4) Where the product presents a risk, the manufacturer shall immediately inform the competent national authorities giving details, in particular, of the non-conformity and of any corrective measures taken.

[Art. 26 para.(4) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(5) The manufacturer shall ensure compliance with the provisions specified in the technical regulations applicable to the product.

[Art. 26 para.(5) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 27. Obligations of the authorised representative

(1) The manufacturer may designate, by written mandate, an authorised representative.

(2) The authorised representative shall perform the tasks specified in the mandate received from the manufacturer, which shall allow him to carry out at least the following:

a) to provide the declaration of conformity and the technical documentation to the regulatory authority;

[Art. 27 para.(2), letter a) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

b) to provide to the regulatory authority, further to a reasoned request, the information and documentation necessary to demonstrate the conformity of a product.

[Art. 27 para.(2), letter b) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(3) Obligations laid down in the Art. 26 para. (1) letter a) and b) shall not form part of the authorised representative's mandate.

Article 28. Obligations of the importer

(1) Where neither the manufacturer nor his authorised representative does not reside or is not established in the Republic of Moldova, the responsibility to keep the technical documentation that attests the conformity and make it available upon request of control bodies is placed on the importer.

[Art. 28 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) Importer shall place on the market only the products that comply with the essential requirements pursuing to technical documentation of the manufacturer, translated into the state language and certified, upon the request of the market surveillance authorities, mentioned in the Art. 19 para. (9).

(2) The importer places on the market only products which comply with the essential requirements pursuant to the manufacturer's technical documentation, provided for in Art. 19 para. (9). The technical documentation shall be translated into the official language by a translator authorized by the Ministry of Justice at the request of market surveillance authorities.

[Art. 28 para.(2) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 01.04.17 date of entry into force of Law No. 7 of 26 February 2016]

(3) Import of products shall be carried out pursuing to a delivery contract, where the applicable essential requirements shall be indicated on a mandatory basis.

(3) Import of products shall be carried out pursuing to a delivery contract, where the applicable essential requirements shall be indicated on a mandatory basis. The importer shall indicate on the product or, if this is not possible, on the packaging or in a document accompanying the product: its name, its registered commercial name or registered trademark and the address to be contacted.

[Art. 28 para.(3) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 01.04.17 date of entry into force of Law No. 7 of 26 February 2016]

(4) Importer shall provide, upon the request of the market surveillance authorities, information and necessary documentation to demonstrate the conformity with essential requirements of the product placed on the market.

(4) The importer shall provide, at the request of the market surveillance authority, the information and documentation necessary to demonstrate conformity of the product placed on the market with the essential requirements and cooperates with the respective authority, upon request thereof, on any action taken to eliminate the risks posed by products he has placed on the market.

[Art. 28 para.(4) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 01.04.17 date of entry into force of Law No. 7 of 26 February 2016]

(5) Before placing a product on the market, the importer shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. If the importer doesn't have all the technical documentation necessary to issue the declaration of conformity, he shall ensure carrying out the respective procedures of conformity assessment and shall issue the declaration of conformity based on the results of assessment carried out in Republic of Moldova by an accredited conformity assessment body.

(5) Prior to placing a product on the market, the importer shall ensure that the manufacturer has met the requirements provided for in Art. 26 para. (1) letter g) and h), as well as the relevant procedure for conformity assessment. The importer shall ensure that the product is accompanied by instructions and safety information in the state language.

[Art. 28 para.(5) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 01.04.17 date of entry into force of Law No. 7 of 26 February 2016]

(6) The importer shall ensure that during the period in which a product is under his responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out.

(7) To ensure health protection and consumer safety, where this is justified by the risks presented by a product, importer will request the accredited test laboratory to carry out sample testing of marketed products, investigating, and, if necessary, keeping a register of complaints, of non-conforming products and product recalls and will keep distributors informed of such monitoring.

(8) Importer shall keep a copy of the declaration of conformity through the whole life cycle of the product and depending on the level of risk.

(8) The importer shall keep a copy of the declaration of conformity depending on the life cycle of the product and the level of risk, as well as ensure that the technical documentation can be made available to the market surveillance authorities upon request, in accordance with the applicable technical regulations.

[Art. 28 para.(10) in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force since 01.04.17 date of entry into force of Law No. 7 of 26 February 2016]

(9) Where he considers or has reason to believe that a product is not in conformity with the applicable essential requirements, the importer cannot place product on the market before bringing it into conformity.

(10) Where he considers or has reason to believe that a product that he has placed on the market is not in conformity with the applicable essential requirements, the importer shall take without delay the necessary corrective measures to bring the product into conformity, to withdraw it or to recall it, if appropriate. Where the product presents a risk, the importer shall immediately inform the national regulatory authority giving details, in particular, of the non-conformity and of any corrective measures taken.

[Art. 28 para.(10) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(11) The importer or distributor shall be considered a manufacturer for the purposes of this

law and he shall be subject to the obligations of the manufacturer under this article, where he places a product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the essential requirements may be affected.

[Art. 28 para.(11) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 29. Obligations of distributors

(1) The distributor shall make a product available on the market after it has been placed on the market by the manufacturer or importer and shall take all the necessary measures to ensure that his operations in handling the product do not have a negative impact on its compliance.

(2) Before making a product available on the market, the distributor shall verify whether the product is accompanied by the required documents, instructions and safety information, if the product bears the marking or marks of conformity provided for by the applicable technical regulation, and that the manufacturer and the importer have complied with the requirements provided for in Art. 26 para. (1) letter g) and h), and Art. 28 para. (3), respectively.

[Art. 29 para.(2) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

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

(4) Following a reasoned request from the market surveillance authority, the distributor shall provide information and documentation necessary to demonstrate the product compliance.

[Art. 29 para.(4) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(5) Where he considers or has reason to believe that a product is not in conformity with the essential requirements, the distributor shall not make the product available on the market before bringing it into conformity Where the product presents a risk, the distributor shall inform the manufacturer or the importer, as well as the regulatory authority.

[Art. 29 para.(5) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(6) Where he considers or has reason to believe that a product that he has make available on the market is not in conformity with the essential requirements, the distributor shall ensure that the necessary corrective measures are taken to bring the product into conformity, to withdraw it or to recall it, if appropriate. Where the product presents a risk, the distributor shall immediately inform the regulatory authorities giving details, in particular, of the non-conformity and of any corrective measures taken.

[Art. 29 para.(6) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(7) The distributor, upon reasoned request by the market surveillance authority, shall provide it with all the information and documentation necessary to demonstrate the conformity of the product. The distributor shall cooperate with the respective authority, upon request thereof, on any action to eliminate the risks posed by products made available on the market.

[*Art. 29 para. (7) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]*

Article 30. Powers of regulatory authorities

Regulatory authorities shall have the following duties in the area of conformity assessment,:

a) establish opportunities for use of conformity assessment procedures in the technical regulations, for project and / or production phase, that will ensure the level of security required and achievement of the technical regulation objective; basic criteria for the manufacturer to be able to choose for his products the most appropriate conformity assessment procedures, provided for by law; test and sampling methods, usable during the conformity assessment process;

b) determine, for products or product groups, one or more conformity assessment procedures,

identical at level of proof, that would allow the applicant to choose the most appropriate procedure;

c) establish criteria under which the manufacturer may choose for his products the most appropriate conformity assessment procedures, provided for by law;

d) establish, for product groups, applicability of modules or certification schemes;

e) establish testing and sampling methods, usable in the conformity assessment process;

f) determine the content of technical documentation for the issuance of the declaration of conformity;

g) identifies national standards and pre-standards used for the purpose of conformity assessment.

h) communicates and cooperates with the National Accreditation Centre, including for the notification of the Conformity Assessment Bodies in the field covered.

Article 31. Recognition of conformity assessment activities

(1) Certificates of conformity or test reports issued by notified conformity assessment bodies, accredited by national accreditation bodies signatory to the Multilateral Recognition Agreement with European Cooperation for Accreditation, issued for products imported from Member States of the European Union, translated into the official language and confirmed by importer's signature shall be recognized.

[Art. 31 para.(1) amended by LP160 din 07.07.16, MO306-313/16.09.16 Art. 647]

[Art. 31 para.(1) amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(1^1) Recognition under para. (1) assumes that the presence of the CE marking and markings laid down by technical regulations applicable to the product shows that it has been subject to conformity assessment procedures and therefore, it is no longer necessary to repeat the conformity assessment procedures already performed when the product is placed or made available on the market.

[Art. 31 para.(1^1) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(1^2) Provisions of para. (1) and (1^1) shall apply without prejudice to Community harmonization legislation, in accordance with the obligations arising from agreements concluded between the Republic of Moldova, of the one part, and the European Union and its Member States, of the other part.

[Art. 31 para.(1^2) introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

(2) Certificates of conformity or test reports issued by foreign conformity assessment bodies, under bilateral agreements for mutual recognition of conformity assessment activities shall be recognized. Recognition of conformity certificates shall be made by issuing a new conformity certificate by the certification bodies accredited by the National Accreditation Centre.

(3) For the recognition of the conformity certificate referred to in para. (2), the applicant shall provide to the certification body accredited in the Republic of Moldova for the same domain a request, original or copy, authenticated by the issuing entity, of the conformity certificate from the product's country of origin, and the original or copy, authenticated by the issuing entity, of the test report on tests performed for certification.

(4) The certification body referred to in para. (3) shall perform the identification (origin; organoleptic properties, as appropriate, lawfulness, amount and marking) of products and shall notify the applicant on the decision for issuing the national conformity certificate. In the event of a negative decision, clear reasoning of the refusal to recognize the conformity certificate issued by a foreign conformity assessment body shall be given in writing.

(5) In the process of recognition provided for in para. (3) and (4), the certification body may establish conducting additional tests where essential requirements in force in the Republic of

Moldova do not meet the requirements set in the conformity certificate issued by a foreign conformity assessment body.

(6) In case of lack of conformity certificates or conformity statements, the imported products shall be subject to conformity assessment in accordance with products applicable procedures, under the applicable national technical regulations.

Chapter VII
FINAL AND TRANSITIONAL PROVISIONS

Article 32

(1) This law is compatible with Chapter I „GENERAL PROVISIONS", Chapter II „ACCREDITATION" and Chapter IV „The CE marking " of Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 laying down the requirements for accreditation and market surveillance concerning the marketing of products and repealing Regulation (EEC) No. 339/93 (text with EEA relevance), published in the Official Journal of the European Union L 218 of 13 August 2008, with Articles 1–6 and Annex No. I – Chapter R1 „Definitions", Chapter R2 „Obligations of economic operators", Chapter R3 „Conformity of the product" and Chapter R4 „Notification of conformity assessment bodies" – of Decision No. 768/2008/EC of the European parliament and of the council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (text with EEA relevance), published in the Official Journal of the European Union L 218 of 13 August 2008, and sets the legal framework for the implementation of the European standard EN ISO / IEC 17011.

(2) Upon the date of Moldova's accession to the European Union, conformity assessment bodies, performing conformity assessment in the areas specified in Annex No. 3, shall be designated and notified to the European Commission, under the national legislation harmonized with the relevant European legislation.

[Art. 32 in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Article 33

(1) This Law shall enter into force upon the expiration of nine months from the date of its publication, except Art. 31, that shall enter into force upon the expiration of 3 months from the date of publication of this Law.

(2) The Government, within 9 months from the publication of this law, shall:

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

b) bring its legislation in conformity with this law;

c) approve the conformity assessment procedures describing modules and certification schemes applicable to products subject to compulsory conformity assessment;

d) ensure enforcement of this law by competent central public administration authorities.

Article 34

Upon the date of entry into force of this Act, Law No. 186-XV of 24 April 2003 on product conformity assessment shall be repealed (The Official Gazette of RM, 2003, No. 141–145, Art. 566).

PARLIAMENT SPEAKER **Marian LUPU**

No. 235. Chisinau, 1 December 2011

Annex No.1

[Annex No.1 in the wording of PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Annex No. 2

The National Accreditation Mark

The National Accreditation Mark „MOLDAC" consists of an ellipse, inclined at an angle of 78°, including the words „MOLDAC" and „Republic of Moldova", as well as the image of the State Flag of the Republic of Moldova. Graphical representation consists of a horizontal axis and a vertical axis with an inclination of 78°. The size of the horizontal and vertical axis is 31 mm and 36 mm respectively.

The horizontal axis represents the symmetry axis for the words „Republic of Moldova" and for the lines outlining the ellipse. The inscription „Republic of Moldova" at a height of 0.85 mm from the inner horizontal axis has the following dimensions: font Trebuchet MS, corp 8, italic, bold.

The vertical lines flanking the official state name are parallel to the thickness of 2,2 mm, and the dashed ellipse arc sinister from the horizontal line over a length of 2 mm has an increasing thickness from sinister to dexter from 1 mm to 3.3 mm the point of intersection with the horizontal line.

The vertical axis is a symmetry axis for:

- letter s „MOLDAC", placed at the top, at a height of 2.3 mm from the horizontal axis, with the dimensions: font Trebuchet MS, corp 17, italic, bold;
- The State Flag, placed at the rear, at a distance of 1.8 mm from the horizontal axis, with the dimensions: height - 6.9 mm and length - 12.7 mm.

The Mark is colored as follows:

all the words and lines, except the National Flag, are colored blue (comprising components: red = 40; green = 22; blue = 111);

The State Flag – in the official colors.

Where the mark has to be enlarged or reduced, proportions shall comply with the description given.

Annex No. 3

THE LIST
of areas covered

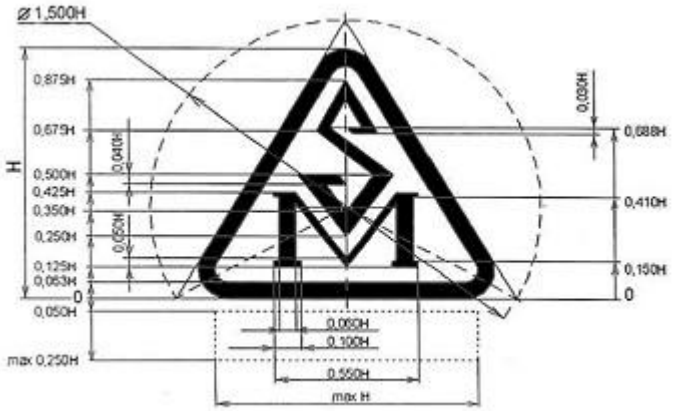
1. Low-voltage equipment
2. Pressure receptacles
3. Toys
4. Construction products
5. Electromagnetic compatibility
6. Industrial machinery
7. Personal protective equipment
8. Non-automatic weighing device
9. Active implantable medical devices
10. Gaseous fuels burners
11. Hot water boilers
12. Explosives for civil uses
13. Medical devices
14. Potentially explosive atmospheres
15. Pleasure boats
16. Lifts
17. Refrigeration Equipment
18. Pressure Equipment

19. In vitro diagnostic medical devices
20. Radio and telecommunications terminal equipment
21. Packaging and packaging waste
22. Cable transport facilities for disabled
23. Interoperability of the trans-European high-speed rail system
24. Marine equipment
25. Transportable Pressure Equipment
26. Noise emissions in the environment of equipment for use outdoors
27. Interoperability of the trans-European conventional rail system
28. Measuring instruments
29. Pyrotechnic articles
30. Energy labeling

[Annex No.3 amended by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Annex No. 4

Conformity mark SM

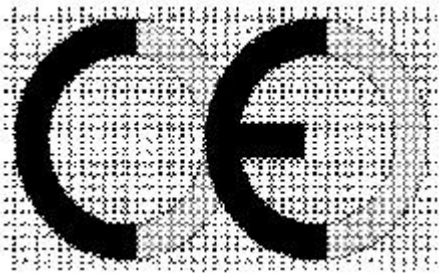


[Annex No.4 introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]

Annex No. 5

The CE marking

1. The CE marking consists of the initials "CE", having the following form:



2. Where the CE marking is reduced or enlarged, the proportions given in the graduated

drawing in paragraph 1 shall be respected.

3. Where legislation does not impose specific dimensions, the CE marking shall have a height of at least 5 mm.

[Annex No.5 introduced by PL 9 of 26.02.16, OG 90-99/08.04.16 Art. 166; in force 08.04.16]