

Document name	<p style="text-align: center;">INSTRUCTION FOR ACCREDITATION OF CONFORMITY ASSESSMENT BODIES ACCORDING TO REGULATION (EU) № 305/2011 OF 9 MARCH 2011 LAYING DOWN HARMONISED CONDITIONS FOR THE MARKETING OF CONSTRUCTION PRODUCTS AND REPEALING COUNCIL DIRECTIVE 89/106/EEC</p>	Version: Revision:	1 2
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**INSTRUCTION
FOR ACCREDITATION OF CONFORMITY ASSESSMENT BODIES
ACCORDING TO REGULATION (EU) № 305/2011
OF 9 MARCH 2011 LAYING DOWN HARMONISED CONDITIONS
FOR THE MARKETING OF CONSTRUCTION PRODUCTS
AND REPEALING COUNCIL DIRECTIVE 89/106/EEC**

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1	16.04.2021	Version 1, revision 1	New revision of EA-2/17 M:2020	16.04.2021
2	20.07.201	Version 1, revision 2	Amendment and supplementation in regard to the findings of the EA Team conducted the first part of the peer-evaluation	15.09.2021

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1. PURPOSE AND SCOPE

This instruction determinates the specific rules on the accreditation of conformity assessment bodies (CABs) which wish to receive notifications in accordance with the requirements of Regulation (EU) No 305/2011 of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing council directive 89/106/EEC.

This instruction was developed on the basis of a Memorandum of Cooperation between the Ministry of Regional Development and Public Works and EA BAS ПД 02-30-11/11.04.2018 and is applied by the EA BAS and the competent authority for the notification in accordance with the Bulgarian legislation.

The purpose of this instruction is to clarify the specific requirements resulting from Regulation (EU) No 305/2011 complementing the requirements of applicable standards for the accreditation of conformity assessment bodies (CABs) of construction products wishing to obtain accreditation for notification purposes.

This instruction shall be applied in conjunction with the General Rules for Assessment and Accreditation of the CAB as defined in BAS QR 2 Accreditation procedure and BAS QI 2 Instruction for Management of Assessment programs.

The assessment of the specific procedures set out in Articles 38 and 46 of Regulation (EU) No 305/2011 is not within the competence of EA BAS and is outside the scope of this instruction.

The notification of bodies for the assessment and verification of constancy of performance of construction products as required by Regulation (EU) No 305/2011 falls within the legal framework of Decision No 768/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council on a common framework for the marketing of products.

Decision No 768/2008/EC determinates requirements for notified bodies.

Regulation (EU) No 305/2011 includes the requirements of Decision No 768/2008/EC, but adapts them to the terminology and requirements described in the Regulation.

2. DEFINITIONS, DESIGNATIONS AND ABBREVIATIONS

For the purposes of this instruction, the following definitions, indications and abbreviations shall be used

2.1. Definitions

1. **'construction product'** means any product or assembly which is manufactured and placed on the market for permanent use in construction works or parts thereof and whose performance has an impact on the performance of construction works in relation to the basic requirements for construction works;

2. **'product type'** means a set of representative levels or classes of performance of a construction product with regard to its essential characteristics, which is produced using a particular combination of raw materials or other elements by a specific production process;

3. **'harmonised technical specifications'** means harmonised standards and European assessment documents;

4. **'harmonised standard'** means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request issued by the Commission in accordance with Article 6 of that Directive;

5. **'European Assessment Document'** means a document adopted by the organisation of technical assessment bodies (TABs) for the purposes of issuing European Technical Assessments;

6. **'European Technical Assessment'** means the documented assessment of the performance of a construction product with regard to its essential characteristics in accordance with the relevant European Assessment Document;

7. **'specific technical documentation'** means documentation demonstrating that the methods within the applicable system of assessment and verification of constancy of performance have been replaced by other methods, provided that the results obtained by the other methods in question are equivalent to the results obtained by the test methods of the relevant harmonised standard;

2.2 Indications and abbreviations

Regulation (EU) No 305/2011 Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC

Regulation (EC) No 765/2008 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

Decision No 768/2008 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 Decision 93/465/EEC

NAB National accreditation body

EA BAS Executive Agency "Bulgarian accreditation service"

MRDPW Ministry of Regional Development and Public Works

NA, MRDPW	Competent for the notification authority for the Republic of Bulgaria under Regulation (EU) No 305/2011— The Minister of Regional Development and Public Works is a notifying authority pursuant to Article 40 of Regulation (EU) No 305/2011
NB	Notified body
CAB	Conformity assessment body
BAS QR 2	Accreditation procedure of EA BAS
AVCP	System for assessment and verification of constancy of performance according to Annex V to Regulation (EU) No 305/2011
LNACAB	Law on the national accreditation of conformity assessment bodies
FA-2/17	European Accreditation Organisation document 'Accreditation for notification purposes' mandatory application by the National Accreditation Bodies Party to the EA—MLA Multilateral Agreement.
M:2020	FA-2/17 M:2020 EA Document on Accreditation for Notification Purpose.

3. DESCRIPTION OF THE ACTIVITY

3.1. General

Under the Law on National Accreditation of Conformity Assessment Bodies, EA BAS performs accreditation of CAB in a regulated and non-regulated area of activity. The scope of the activities of EA BAS includes legal persons who have declared a wish to obtain accreditation for notification under Regulation (EU) No 305/2011.

The scope of accreditation granted to the CAB includes the elements specified in Annex A by EA-2/17 M:2020. The order for accreditation of the CAB is according to the LNACAB, BAS QR 2 and BAS QI 2, which shall be supplemented and applied together with this instruction.

This instruction applies to accreditation of CAB applying and/or notified under the requirements of Regulation (EU) No 305/2011 as follows:

- Accreditation according to the requirements of EN ISO/IEC 17065:2012 for bodies involved in the assessment and verification of constancy of performance (product certification and factory production control) under AVCP 1+, 1, 2+;
- Accreditation according to the requirements of EN ISO/IEC 17025:2018 for SACCPA testing laboratories 3.

3.2 This instruction has been developed on the basis of:

- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 for setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;

- Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 for determination of harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC;
- Law on Technical Requirements for Products (LTRP)
- In order to harmonise the fulfilment of requirements in the European Union, the mandatory management of the European Accreditation Organisation should also be respected, EA-2/17 M:2020 EA Document on Accreditation for Notification Purpose;
- Ordinance № ПД-02-20-1 of 5 February 2015 on the terms and conditions for use of construction products in the construction of the Republic of Bulgaria and the procedure for issuing authorisations to persons for evaluation of construction products and for exercising control over their activities (Annex No 2 to Art.17, Para.2 of Ordinance № ПД-02-20-1);
- The accreditation rules are set out in point 3 of BAS QR2 and are supplemented by this instruction.

4. COMPETENCE OF PERSONS INVOLVED IN THE ACCREDITATION PROCESS FOR NOTIFICATION PURPOSES

4.1. General competence criteria for leading assessors, technical assessors and experts

The common competence criteria for leading assessors, technical assessors and experts included in assessments of applicants for accreditation for the purposes of notification under Regulation (EU) No 305/2011 are regulated in Annex 1, Table 1 of BAS QR 7.

4.2 Specific qualification criteria for leading assessors, technical assessors and experts

The following qualification criteria are additions and amendments to the general criteria determined in Annex 2, Table 3 of BAS QR 7.

4.2.1 Lead assessors – no change.

4.2.2 Technical assessors and Experts:

The assessor teams includes technical assessors/technical experts from the Register of EA BAS and authorised by the Minister of Regional Development and Public Works experts from the Construction Products Department of the Technical Rules and Norms Directorate.

The order of assessment of lead assessors/technical assessors and experts is described in BAS QR 7, using the Assessment Card of lead assessor/technical assessor/technical expert, BAS QF 7.3

5. SUBMISSION OF APPLICATION AND INITIATION OF ACCREDITATION PROCEDURE FOR NOTIFICATION PURPOSES

5.1. Conformity assessment bodies wishing to be accredited for the purposes of notification under Regulation (EU) No 305/2011 shall submit an application for accreditation to EA BAS under the procedure determined in item 4.1.1 of BAS QR 2 using the CAB application form in accordance with the applicable AVCP under Regulation (EU) No 305/2011.

The application shall be accompanied by a signed CAB declaration on exemption from confidentiality allowing EA BAS to share the related information with the competent authority, the MRDPW.

The declaration form, Annex 1 to BAS QI 2.4. is published on the EA BAS website together with the application forms.

5.2. When an accredited conformity assessment body wishes to be accredited also for notification under Regulation (EU) No 305/2011, shall submit an application for extension pursuant to point 7 of BAS QR 2. In this case, the extension of the scope is in a new area of activity and is carried out with a separate assessment for extension. In establishing that the CAB complies with the requirements for accreditation, EA BAS shall reissue the current certificate for the period of its validity.

5.3. The appointment of a lead assessor and the opening of the accreditation procedure is in accordance with item 4.1.3 of BAS QR 2.

5.4. The set of documents under the open procedure is sent in official order to the MRDPW.

6. ASSESSMENT

6.1 PRELIMINARY INVESTIGATION

Following the rules of item 4.2 of BAS QR 2.

6.2 ASSESSMENT

6.2.1 Planning an on-site assessments

When preparing, planning and organising the assessment, the general rules of BAS QI 2 shall be followed with the following amendments and additions:

6.2.1.1 After receipt in the official order of the documentation package, the CN proposes technical assessors/experts meeting the requirements of item 4.2.2.

6.2.1.2 The assessment team shall be agreed in the order of item 4.3.2 by BAS QR 2.

6.2.2 Assessment. General requirements

The designated assessment team of EA BAS shall carry out CAB assessment in accordance with the requirements of the applicable Accreditation Standard EN ISO/IEC 17065:2012

and/or EN ISO/IEC 17025:2018 and EA-2/17 M:2020 EA Document on Accreditation for Notification Purpose, all specific requirements included in Regulation (EU) No 305/2011.

6.2.3 Assessment. Specific requirements applicable to notified bodies within the meaning of Regulation (EU) No 305/2011

During the on-site assessment, the EA BAS assessment team shall assess and report the fulfilment of the specific requirements specified in this instruction.

This clause includes only those requirements of Regulation (EU) No 305/2011 that are not or are partly covered by the accreditation standard (EN ISO/IEC 17065:2012 and EN ISO/IEC 17025:2018)

It is the duty of the technical assessors/technical experts from the MRDPW, included in the team of EA BAS, to assess compliance with the additional requirements set to the applicants for notification in Art. 43 of Regulation (EU) No 305/2011 as follows:

6.2.3.1 Independence and impartiality

Article 43 (3) of Regulation (EU) No 305/2011:

The notified body shall be a third party independent of the organisation or construction product it assesses. A body belonging to an economic association or a professional federation representing undertakings involved in the design, manufacture, supply, assembly, use or maintenance of the construction products it assesses may be considered to be such a body in condition that its independence and lack of conflict of interest are proven.

Article 43 (4) of Regulation (EU) No 305/2011:

The notified body, its top management and the personnel responsible for carrying out the tasks as a third party in the process of assessment and verification of constancy of performance shall not be a designer, manufacturer, supplier, installer, buyer, owner, user, or carrying out the maintenance of the construction products that it assesses, nor an authorised representative of any of those persons. This does not preclude the use of evaluated products that are necessary for the performance of the notified body or the use of the products for private purposes.

The notified body, its senior management and the personnel responsible for carrying out the tasks as a third party in the process of assessment and verification of constancy of performance shall not be directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of such construction products, nor shall they represent the persons involved in those activities. They shall not participate in any activity which may conflict with the independence of their judgment and integrity in respect of the activities of which they have been notified. This applies in particular to advisory services;

The notified body shall ensure that the activities of its units or subcontractors do not affect the confidentiality, objectivity and impartiality of its assessment and/or verification activities.

Article 43 (5) of Regulation (EU) No 305/2011:

The notified body and its staff shall carry out tasks as a third party in the process of assessing and verifying constancy of performance with the highest degree of professional integrity and necessary technical competence in the specific field and shall be completely free from any pressures and incentives, especially financial ones, which may affect their judgment or the results of their evaluation and/or verification activities, especially by persons or groups of persons interested in the results of those activities.

Article 43 (8) of Regulation (EU) No 305/2011:

The impartiality of the notified body, its top management and its assessment staff shall be guaranteed.

The remuneration of the top management of the notified body and its assessment staff shall not depend on the number of assessments carried out or on the results thereof.

6.2.3.2 Competence

Art. 43 (6) of Regulation (EU) No 305/2011:

The notified body shall be able to carry out all the tasks as a third party in the process of assessment and verification of constancy of performance assigned to it in accordance with Annex V in respect of which it has been notified, regardless those tasks are carried out by or on behalf of the notified body itself and under its responsibility.

At any time and for each system for assessment and verification of constancy of performance, and for each type or category of construction products, essential characteristics and tasks in relation to which it has been notified, the notified body shall have the following:

a) the necessary personnel with technical knowledge and sufficient and appropriate experience to carry out tasks as a third party in the process of assessment and verification of constancy of performance;

b) the necessary description of the procedures under which the performance assessment is carried out to ensure transparency and the possibility of repeating those procedures. It shall implement appropriate policies and procedures to distinguish between the tasks it performs as a notified body and other activities;

c) the procedures necessary to carry out its activities, taking due account of the size of an factory, the sector in which it operates, its structure, the degree of complexity of the product technology concerned and the mass or serial nature of production.

The notified body shall have the means necessary for the appropriate performance of the technical and administrative tasks relating to the activities for which it has been notified and shall have access to the necessary equipment or facilities.

6.2.3.3 Staff

Article 43 (7) of Regulation (EU) No 305/2011:

The staff responsible for carrying out the activities in respect of which the body has been notified shall have the following:

- a) in-depth technical and vocational training covering all third party tasks in the process of assessment and verification of constancy of performance within the relevant scope for which the body has been notified;
- b) satisfactory knowledge of the requirements for the assessments and checks they carry out and appropriate powers to carry out such actions;
- c) adequate knowledge and understanding of the applicable harmonised standards and the relevant provisions of the Regulation;
- d) The ability required for the production of certificates, records and reports proving that the assessments and verifications have been carried out.

6.2.3.4 Insurance to cover liability

Article 43 (9) of Regulation (EU) No 305/2011:

The notified body shall take out insurance to cover its liability unless liability is assumed by the State under national law or the Member State is directly responsible for the assessment and/or verification carried out.

6.2.3.4 Confidentiality

Article 43 (10) of Regulation (EU) No 305/2011:

The staff of the notified body shall be obliged to keep professional secrecy with regard to the information obtained in carrying out the tasks set out in Annex V, except with regard to the competent administrative authorities of the Member State in which it operates. Property rights are protected.

6.2.3.5 Participation in committees

Article 43(11) of Regulation (EU) No 305/2011:

The notified body shall participate in or ensure that the personnel responsible for evaluations are informed of the relevant standardisation activities and the activities of the coordination group of notified bodies established under this Regulation and shall apply, as general guidance, administrative decisions and documents issued as a result of the work of that group.

6.2.4 Range

The scope of accreditation for notification purposes *shall not* be provided flexible.

The harmonised technical specifications, the standards with test methods and AVCP to which a horizontal notification is made have been determined by the relevant decisions of the European Commission.

The test methods for notification purposes are defined in the harmonised technical specifications.

6.2.5 Witnesses

The witness activities shall be carried out in accordance with Annex C and Table 6 of EA-2/17 M:2020 and *Annex 9 to BAS QI 2*.

6.2.6 Post-assessment reporting

Follow the requirements of 4.3.4 to 4.3.6.2 of BAS QR 2.

7. DECISION FOR ACCREDITATION AND SUBMISSION OF AN APPLICATION FOR NOTIFICATION TO THE MRDPW

Upon receipt of an accreditation certificate by EA BAS, the accredited conformity assessment body must formally apply for notification under Regulation (EU) No 305/2011 to the Minister of Regional Development and Public Works under the procedure specified by the Ministry of Regional Development and Public Works.

8. MAINTENANCE OF ACCREDITATION OF THE ACCREDITED NOTIFIED BODY

Following the requirements of item 5.1 of BAS QR 2 with the following amendments and additions:

- The teams for planning surveillance include technical assessors/technical experts from the Register of EA BAS and authorised by the Minister of Regional Development and Public Works experts from the Construction Products Department of the Technical Rules and Norms Directorate meeting the criteria set out in item 4.2.2 of this instruction.
- Upon completion of the surveillance assessments, EA BAS shall submit reports of the assessment results of the assessment of the bodies accredited for notification purposes to the notifying body.

9. ADMINISTRATIVE MEASURES

Following the requirements of item 5.4 of BAS QR 2

10. PUBLIC REGISTER

EA BAS publishes and maintains up-to-date data on the CABs accredited for the purposes of notification on its website.

- EA BAS publishes on its website information about the notified bodies accredited by it
- EA BAS shall publish on its website information on the notified bodies accredited by it.

11. EXCHANGE OF INFORMATION

EA BAS sends the reports from the assessments of the accredited NB to CN Minister of Regional Development and Public Works.

EA BAS informs the Minister of Regional Development and Public Works in due time when the accredited notified body no longer complies with the requirements for accreditation.

COMPETENT NOTIFYING AUTHORITY

Ministry of Regional Development and Public Works

Directorate "Technical rules and norms"

Building Products Department

Address: gr. Sofia 1202, St. St. St. John's Day. Cyril and Methodius 17-19

Wire: 02 94 05 900, 02 94 05 238

Fax: 02 987 25 17

Website: [Http://mrrb.government.bg](http://mrrb.government.bg);

[Http://cpcp.mrrb.government.bg](http://cpcp.mrrb.government.bg)

12. RELATED DOCUMENTS:

BASE QR 2 Accreditation procedure for EA BSA

BAS QI 2 Instruction for Management of Assessment programs

BAS QI 2.3 Instruction for accreditation for purposes of notification

BAS QA 2.1.1 Application for accreditation of test laboratories

BAS QA 2.3.1 Application for accreditation of product certification bodies

Annex 1 Declaration of exemption from confidentiality

Law on Technical Requirements for Products

Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC

Ordinance N^o RD-02-20-1 of 5 February 2015 on the terms and conditions for use of construction products in the construction works of the Republic of Bulgaria and the procedure for issuing authorisations to persons for evaluation of construction products and for

exercising control over their activities (Annex No. 2 to Art.17, para.2 of Ordinance N° RD-02-20-1);

Guidance of the group of notified bodies