Guideline for the practical application of the conformity assessment procedures (modules B, C2, D, E, and H) according to Annex II of the Directive 2013/29/EU

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This Document gives guidance on the practical application of the following conformity assessment procedures as set out in the Annex II of the Directive 2013/29/EU:

Module	Application on categories
B (EU-type examination)	F1-F4, T1-T2, P1-P2
C2 (conformity to type)	F1-F4, T1-T2, P1-P2
D (production quality assurance)	F1-F4, T1-T2, P1-P2
E (product quality assurance)	F1-F4, T1-T2, P1-P2
H (full quality assurance)	F4 only

Notified Bodies (NBs) under the Directive 2013/29/EU apply as a general guidance the harmonized principles as stated below.

Module granting order regarding modules B, C2, D, and E

As described in the relevant chapters of the Directive 2013/29/EU and the Guide to the implementation of directives based on the New Approach and the Global Approach ("blue guide"; chapter 5.1), type examination according to module B is a precondition of the modules C2, D, and E.

For module H a separate procedure is defined (see below).

Module B: **EU-type examination**

NBs shall carry out type tests according to the relevant product standards, if possible.

If the manufacturer of the articles is located outside the EU, only the information regarding the importer, if owner of the certificate, has to be included into the final EU-type examination certificate.

Module C2: Conformity to type based on internal production control plus supervised product checks at random intervals

A notified body, chosen by the manufacturer, shall carry out batch tests for every production batch according the relevant parts of the harmonized standards and/or equivalent tests set out in other relevant technical specifications in order to verify the quality of the internal production control measures and conformity to type of the pyrotechnic article at random intervals. The technological complexity of the pyrotechnic articles and the quantity of production shall be taken into account. An adequate sample according to the relevant parts of the harmonized standards and/or equivalent procedures shall be taken directly from the production line(s) by the notified body before the placing on the market. These samples shall be examined and appropriate tests as identified by the relevant parts of the harmonized standards and/or equivalent tests set out in other relevant technical specifications shall be carried out to check the conformity of the pyrotechnic article with the type described in the EU-type examination certificate and with the relevant requirements of this Directive. These tests include the verification of the internal production control measures on site at the production line(s).

In case of positive assessment, a certificate shall be given to the manufacturer. This certificate includes (or give respective reference to) the full identification of the examined samples. This is done by specific and unique lot/batch numbers, which have to be displayed on the labels of the articles.

Module D: Production quality assurance - procedure

An audit according to module D cannot comprise all generic types of the respective categories, if the company does not have type tested articles of all possible generic types, due to significantly differing production lines of the generic types and articles. NBs apply the following procedure:

- Definition of scope of audit (categories, generic types and articles) between company and NB
- Review of quality management handbook (QMH) on a document level; before and during audit
- QMH *should* be based on ISO 9001 in general (or other applicable system standards)
- QMH *shall* comprise all relevant production steps (such as incoming goods inspections, traceability of initial substances, raw materials, chemicals, intermediate products, in-process inspections etc.) and the necessary test requirements with regard to final article inspection and testing
- Number of auditors typically 2 (due to reasons of impartiality and complexity with regard to technical and organisational/legal questions)
- Check of incoming goods inspections
- Check of traceability of initial substances and intermediate products
- Check of in-process inspections
- Check of sampling abilities (e.g. deviation from ISO 2859-1 possible after adjustment with NB)
- Check of final end product testing abilities on test site

- Check of nonconformity assessments carried out by the company and procedure on how to handle nonconforming articles/lots
- NB provides an abridged audit report (requirements; oral or written) at the last day of audit
- NB draws up an audit report (incl. actions during audit, observations, and requirements) after the audit according *to 2013/29/EU,* Annex II, Module D, 4.3
- NB audits company periodically (typically 2 years, e.g. based on the performance of previous audits, market surveillance etc.)
- NB gives out certificate (with a defined time of validity aligned to the expected periodicity of audit and information on the respective categories and generic types and articles included) after the fulfilment of all requirements, if applicable

Module E: Product quality assurance - procedure

An audit according to module E can comprise all generic types of the respective categories, even if the company does not have type tested articles of all possible generic types, since the batch testing abilities of the respective generic types are checked. NBs apply the following procedure:

- Definition of scope of audit (categories, generic types) between company and NB
- Review of quality management handbook (QMH) on a document level; before and during audit
- QMH *should* be based on ISO 9001 in general (or other applicable system standards) and *shall* comprise all batch test requirements with regard to final article inspection and testing according to the relevant pyrotechnic article standards (e.g. chapter 10 of EN 15947-5)
- Number of auditors typically 2 (due to reasons of impartiality and complexity with regard to technical and organisational/legal questions)
- Check of final end product testing abilities according to batch test criteria (e.g. chapter 10 of EN 15947-5) on test site
- Check of sampling abilities (e.g. according to ISO 2859-1)
- Check of nonconformity assessments carried out by the company and procedure on how to handle nonconforming articles/lots
- NB provides an abridged audit report (requirements; oral or written) at the last day of audit
- NB draws up an audit report (incl. actions during audit, observations, and requirements) after the audit according to 2013/29/EU, Annex II, Module E, 4.3
- NB audits company periodically, 1 or 2 years, e.g. based on the performance of previous audits, market surveillance etc.
- NB gives out certificate (with a defined time of validity aligned to the expected periodicity of audit and information on the respective categories and generic types included) after the fulfilment of all requirements, if applicable

Module H: Full quality assurance - procedure

An audit according to module H cannot comprise all generic types of the respective categories, if the company does not have type tested articles of all possible generic types, due to significantly differing production lines of the generic types and articles.

NBs apply the following procedure:

- Definition of scope of audit (generic types, subtypes and articles) between company and NB
- Review of quality management handbook (QMH) on a document level; before and during audit
- QMH *should* be based on ISO 9001 and ISO 17025 in general
- QMH *shall* comprise the design phase, all relevant production steps (such as incoming goods inspections, traceability of initial substances, raw materials, chemicals, intermediate products, in-process inspections etc.) and the necessary test requirements with regard to final article inspection and testing
- Number of auditors typically 2 (due to reasons of impartiality and complexity with regard to technical and organisational/legal questions)
- Check of design phase
- Check of the ability to perform type tests (e.g. thermal and mechanical conditionings etc.), usually according to the standard prEN 16261
- Check of incoming goods inspections
- Check of traceability of initial substances and intermediate products
- Check of in-process inspections
- Check of sampling abilities (e.g. deviation from ISO 2859-1 possible after adjustment with NB)
- Check of final end product testing abilities on test site
- Check of nonconformity assessments carried out by the company and procedure on how to handle nonconforming articles/lots
- NB provides an abridged audit report (requirements; oral or written) at the last day of audit
- NB draws up an audit report (incl. actions during audit, observations, and requirements) after the audit according to 2013/29/EU, Annex II, Module H, 4.3
- NB audits company periodically (typically 2 years, e.g. based on the performance of previous audits, market surveillance etc.)
- NB gives out certificate (with a defined time of validity aligned to the expected periodicity of audit and information on the respective categories and generic types and articles included) after the fulfilment of all requirements, if applicable
- Possible procedure for issuing the registration number: e.g. the company hands over the type test report, NB carries out ESR assessment and issues the assessment report incl. the registration number and all relevant certificate related documents