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Taqsima B

L.N. 190 of 2015

PRODUCT SAFETY ACT
(CAP. 427)

Making Available on the Market of Pyrotechnic Articles Regulations, 2015

IN exercise of the powers conferred by articles 38 and 39 of the Product Safety Act, the Minister for Social Dialogue, Consumer Affairs and Civil Liberties, on the advice of the Malta Competition and Consumer Affairs Authority, has made the following regulations:-

Title and Scope.

1. (1) The title of these regulations is the Making Available on the Market of Pyrotechnic Articles Regulations, 2015.

(2) These regulations transpose Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast).

(3) These regulations establish rules designed to achieve the free movement of pyrotechnic articles in the internal market of the European Union while ensuring a high level of protection of human health and public security and the protection and safety of consumers and taking into account the relevant aspects related to environmental protection.

(4) These regulations also establish the essential safety requirements which pyrotechnic articles are to fulfil with a view to their being made available on the market.

Commence-ment.

2. (1) These regulations shall apply as from 1st July 2015.

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(2) The making available on the market of pyrotechnic articles which are in conformity with the "Placing on the Market of Pyrotechnic Articles Regulations" and which were placed on the market before 1 July 2015 shall not be impeded.

(3) Maltese national authorisations for fireworks of categories F1, F2 and F3 granted before 4 July 2010 shall continue to be valid in Malta until their expiry date or until 4 July 2017, whichever is earlier.

(4) Maltese national authorisations for other pyrotechnic

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articles, for fireworks of category F4 and for theatrical pyrotechnic articles granted before 4 July 2013 shall continue to be valid in Malta until their expiry date or until 4 July 2017, whichever is earlier.

(5) By way of derogation from sub-regulation (3), national authorisations for pyrotechnic articles for vehicles, including as spare parts, granted before 4 July 2013 shall continue to be valid until their expiry.

(6) Certificates issued under Directive 2007/23/EC shall be valid under Directive 2013/29/EU which is being transposed by these Regulations.

Applicability.

3. These regulations shall apply to pyrotechnic articles but shall not apply to:

(a) pyrotechnic articles intended for non-commercial use by the Armed Forces of Malta, the Malta Police Force or the Civil Protection Department;

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(b) equipment falling within the scope of the Conformity Assessment of Marine Equipment Regulations, transposing Directive 96/98/EC;

(c) pyrotechnic articles intended for use in the aerospace industry;

S.L. 427.40

(d) percussion caps intended specifically for toys falling within the scope of the Safety of Toys Regulations, transposing Directive 2009/48/EC;

S.L. 33.04

(e) explosives falling within the scope of the Civil Explosives Regulations, transposing Directive 93/15/EEC;

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(f) ammunition as defined under the Arms Act and its regulations;

(g) fireworks which are built by a Maltese manufacturer and let-off in Malta by the licensee of, or by a license A holder registered with, the same fireworks factory, in accordance with the provisions of the Ordinance and its regulations;

Definitions.

4. In these regulations, unless the context otherwise requires:

"accreditation" means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

"ammunition" means projectiles and propelling charges

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and blank ammunition used in portable firearms, other guns and artillery;

"CE marking" means a marking by which the manufacturer indicates that the pyrotechnic article is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

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

"conformity assessment" means the process demonstrating whether the essential safety requirements of these Regulations relating to a pyrotechnic article have been fulfilled;

"distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a pyrotechnic article available on the market;

"economic operators" means the manufacturer, the importer and the distributor;

"firework" means a pyrotechnic article intended for entertainment purposes;

"harmonised standard" means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

"importer" means any natural or legal person established within the Union who places a pyrotechnic article from a third country on the Union market;

"making available on the market" means any supply of a pyrotechnic article for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means a natural or legal person who manufactures a pyrotechnic article, or has such an article designed or manufactured, and markets that pyrotechnic article under his name or trademark;

"National Accreditation Board (Malta)" means the National Accreditation Board (Malta) established in terms of regulation 3 of the National Accreditation Board (Malta) (Establishment) Regulations; S.L. 419.07

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"notified body" means a body authorised to carry out third-party conformity assessment tasks under Directive 2013/29/EU and notified to the European Commission and to the Member States.

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"ordinance" means the Explosives Ordinance;

"person with specialist knowledge" means a person who holds a valid licence A, B, or C granted in accordance with the Ordinance and its regulations, or a person who is otherwise considered by the Commissioner of Police to have specialist knowledge;

"placing on the market" means the first making available of a pyrotechnic article on the Union market;

"pyrotechnic article" means any article containing explosive substances or an explosive mixture of substances designed to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions;

"pyrotechnic articles for vehicles" means components of safety devices in vehicles which contain pyrotechnic substances used to activate these or other devices;

"recall" means any measure aimed at achieving the return of a pyrotechnic article that has already been made available to the end-user;

the "Technical Regulations Division" means the Technical Regulations Division within the Malta Competition and Consumer Affairs Authority as established by the Malta Competition and Consumer Affairs Authority Act;

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"technical specification" means a document that prescribes technical requirements to be fulfilled by a pyrotechnic article;

"theatrical pyrotechnic articles" means pyrotechnic articles designed for indoor or outdoor stage use, including film and television productions or similar use;

"Union harmonisation legislation" means any Union legislation harmonising the conditions for the marketing of products;

"withdrawal" means any measure aimed at preventing a pyrotechnic article in the supply chain from being made

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available on the market.

Making Available on the Market.

5. (1) Pyrotechnic articles falling within the scope of these regulations shall be placed on the Maltese market only if they satisfy the requirements of these regulations.

(2) The placing on the market of pyrotechnic articles which satisfy the requirements of these regulations shall not be prohibited, restricted or hindered.

(3) At trade fairs, exhibitions and demonstrations for the marketing of pyrotechnic articles, the showing and use of pyrotechnic articles not in conformity with the provisions of these regulations shall not be prohibited, provided that a visible sign clearly indicates the name and date of the trade fair, exhibition or demonstration in question and the non-conformity and non-availability for sale of the articles until brought into conformity. During such events, appropriate safety measures shall be taken in accordance with any requirements laid down by the Commissioner of Police.

(4) The free movement and use of pyrotechnic articles manufactured for the purpose of research, development and testing and which are not in conformity with the provisions of these regulations shall not be prohibited, provided that a visible sign clearly indicates their non-conformity and non-availability for purposes other than research, development and testing.

(5) Certificates issued under Directive 2007/23/EC shall be valid under Directive 2013/29/EU which is being transposed by these Regulations.

Categorisation of Pyrotechnic Articles.

6. (1) Pyrotechnic articles falling within the scope of these regulations shall be categorised by the manufacturer according to their type of use, or their purpose and level of hazard, including their noise level in accordance with sub-regulation (2). The notified bodies shall confirm their categorisation as part of the conformity assessment procedures.

(2) Categorisation shall be as follows:

(a) Fireworks:

(i) category F1: fireworks which present a very low hazard and negligible noise level and which are intended for use in confined areas, including fireworks which are intended for use inside domestic buildings;

(ii) category F2: fireworks which present a low

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hazard and low noise level and which are intended for outdoor use in confined areas;

(iii) category F3: fireworks which present a medium hazard, which are intended for outdoor use in large open areas and whose noise level is not harmful to human health;

(iv) category F4: fireworks which present a high hazard, which are intended for use only by persons with specialist knowledge (commonly known as fireworks for professional use) and whose noise level is not harmful to human health.

(b) Theatrical pyrotechnic articles:

(i) category T1: pyrotechnic articles for stage use which present a low hazard;

(ii) category T2: pyrotechnic articles for stage use which are intended for use only by persons with specialist knowledge.

(c) Other pyrotechnic articles:

(i) category P1: pyrotechnic articles, other than fireworks and theatrical pyrotechnic articles, which present a low hazard;

(ii) category P2: pyrotechnic articles, other than fireworks and theatrical pyrotechnic articles, which are intended for handling or use only by persons with specialist knowledge.

(3) The Commissioner of Police shall inform the Technical Regulations Division of the procedures whereby persons with specialist knowledge are identified and authorised. The Technical Regulations Division shall then inform the European Commission of such procedures.

Age Limits and Other Limitations.

7. (1) Pyrotechnic articles falling within the scope of these regulations shall not be made available on the market to persons below the following age limits:

(a) Fireworks:

(i) category F1: 12 years;

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(ii) categories F2, F3 and F4: 18 years;

(b) Theatrical pyrotechnic articles of categories T1 and T2 and other pyrotechnic articles of categories P1 and P2: 18 years.

(2) Manufacturers, importers and distributors shall not make available on the market the following pyrotechnic articles except to persons with specialist knowledge:

(a) fireworks of categories F2, F3 and F4;

(b) theatrical pyrotechnic articles of categories T1 and T2 and other pyrotechnic articles of categories P1 and P2.

(3) Other pyrotechnic articles of category P1 for vehicles, including airbag and seat belt pre-tensioner systems, shall not be made available to members of the general public unless those pyrotechnic articles for vehicles have been incorporated in a vehicle or a detachable vehicle part.

Obligations of the Manufacturer.

8. (1) When placing their pyrotechnic articles on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Schedule I.

(2) Manufacturers shall draw up the technical documentation referred to in Schedule II and have the relevant conformity assessment procedure referred to in regulation 9 carried out.

Where compliance of a pyrotechnic article with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

(3) Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the pyrotechnic article has been placed on the market.

(4) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with these regulations. Changes in pyrotechnic article design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a pyrotechnic article is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a pyrotechnic article, manufacturers shall, to protect the

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health and safety of consumers, upon a duly justified request of the competent authorities, carry out sample testing of pyrotechnic articles made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming pyrotechnic articles and pyrotechnic article recalls, and shall keep distributors informed of any such monitoring.

(5) Manufacturers shall ensure that pyrotechnic articles which they have placed on the market are labelled in accordance with regulation 10 or regulations 11.

(6) Manufacturers shall indicate on the pyrotechnic article their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the pyrotechnic article. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in at least the Maltese or English language.

(7) Manufacturers shall ensure that the pyrotechnic article is accompanied by instructions and safety information in at least the Maltese or English language. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

(8) Manufacturers who consider or have reason to believe that a pyrotechnic article which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that pyrotechnic article into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the pyrotechnic article presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the pyrotechnic article available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(9) Manufacturers shall, further to a reasoned request from Technical Regulations Division and/or the Commissioner of Police, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the pyrotechnic article with these Regulations, in at least the Maltese or the English language. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pyrotechnic articles which they have placed on the market.

Conformity Assessment Procedures.

9. (1) For the assessment of conformity of pyrotechnic articles the manufacturer shall follow one of the following procedures

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referred to in Schedule II:

(a) EU-type examination (Module B), and, at the choice of the manufacturer, one of the following procedures:

(i) conformity to type based on internal production control plus supervised product checks at random intervals (Module C2);

(ii) conformity to type based on quality assurance of the production process (Module D);

(iii) conformity to type based on product quality assurance (Module E);

(b) conformity based on unit verification (Module G);

(c) conformity based on full quality assurance (Module H), insofar as it concerns fireworks of category F4.

Labelling of Pyrotechnic Articles other than Pyrotechnic Articles for Vehicles.

10. (1) Manufacturers shall ensure that pyrotechnic articles other than pyrotechnic articles for vehicles are labelled visibly, legibly and indelibly in at least the Maltese or English language. Such labelling shall be clear, understandable and intelligible.

(2) The labelling of pyrotechnic articles shall include as a minimum the information about the manufacturer set out in sub-regulation 8(6) and, where the manufacturer is not established in the Union, the information about the manufacturer and the importer set out in sub-regulation 8(6) and sub-regulation 12(3) respectively, the name and type of the pyrotechnic article, its registration number and its product, batch or serial number, the minimum age limits set out in sub-regulation 7(1), the relevant category and instructions for use, the year of production for category F3 and F4 fireworks and, where appropriate, a minimum safety distance. The labelling shall include the net explosive content (NEC).

(3) Fireworks shall also display the following minimum information:

(a) category F1: where appropriate: "for outdoor use only" and a minimum safety distance;

(b) category F2: "for outdoor use only" and, where appropriate, minimum safety distance(s);

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(c) category F3: "for outdoor use only" and minimum safety distance(s);

(d) category F4: "for use only by persons with specialist knowledge" and minimum safety distance(s).

(4) Theatrical pyrotechnic articles shall also display the following minimum information:

(a) category T1: where appropriate: "for outdoor use only" and minimum safety distance(s);

(b) category T2: "for use only by persons with specialist knowledge" and minimum safety distance(s).

(5) If the pyrotechnic article does not provide sufficient space for the labelling requirements referred to in sub-regulations (2), (3) and (4), the information shall be provided on the smallest piece of packaging.

Labelling of Pyrotechnic Articles for Vehicles.

11. (1) The labelling of pyrotechnic articles for vehicles shall include the information about the manufacturer set out in sub-regulation 8(6), the name and type of the pyrotechnic article, its registration number and its product, batch or serial number and, where necessary, the safety instructions.

(2) If the pyrotechnic article for vehicles does not provide sufficient space for the labelling requirements referred to in sub-regulation (1), the information shall be provided on the packaging.

(3) A safety data sheet for the pyrotechnic article for vehicles, compiled in accordance with Annex II to Regulation (EC) No 1907/ 2006 (REACH) and which takes into account the specific needs of professional users, shall be supplied to those users in the language requested by them.

The safety data sheet may be supplied on paper or electronically, provided that the professional user has the necessary means of accessing it.

Obligations of Importers.

12. (1) Importers shall place only compliant pyrotechnic articles on the market.

(2) Before placing a pyrotechnic article on the market importers shall ensure that the appropriate conformity assessment procedure referred to in regulation 9 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the pyrotechnic article bears the CE

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marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in sub-regulations 8(5) and (6).

Where an importer considers or has reason to believe that a pyrotechnic article is not in conformity with the essential safety requirements set out in Schedule I, he shall not place the pyrotechnic article on the market until it has been brought into conformity. Furthermore, where the pyrotechnic article presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

(3) Importers shall indicate on the pyrotechnic article their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the pyrotechnic article. The contact details shall be in at least the Maltese or English language.

(4) Importers shall ensure that the pyrotechnic article is accompanied by instructions and safety information in at least the Maltese or English language.

(5) Importers shall ensure that, while a pyrotechnic article is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Schedule I.

(6) When deemed appropriate with regard to the risks presented by a pyrotechnic article, importers shall, to protect the health and safety of consumers, upon a duly justified request of the competent authorities, carry out sample testing of pyrotechnic articles made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming pyrotechnic articles and pyrotechnic articles recalls, and shall keep distributors informed of any such monitoring.

(7) Importers who consider or have reason to believe that a pyrotechnic article which they have placed on the market is not in conformity with these Regulations shall immediately take the corrective measures necessary to bring that pyrotechnic article into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the pyrotechnic article presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the pyrotechnic article available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

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(8) Importers shall, for 10 years after the pyrotechnic article has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

(9) Importers shall, further to a reasoned request from the Technical Regulations Division and/or the Commissioner of Police, provide them with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a pyrotechnic article in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pyrotechnic articles which they have placed on the market.

Obligations of Distributors.

13. (1) When making a pyrotechnic article available on the market distributors shall act with due care in relation to the requirements of these Regulations.

(2) Before making a pyrotechnic article available on the market distributors shall verify that the pyrotechnic article bears the CE marking, that it is accompanied by the required documents, and by instructions and safety information that are in at least in the Maltese or English language, and that the manufacturer and the importer have complied with the requirements set out in sub-regulations 8(5) and (6) and sub-regulation 12(3) respectively.

Where a distributor considers or has reason to believe that a pyrotechnic article is not in conformity with the essential safety requirements set out in Schedule I, he shall not make the pyrotechnic article available on the market until it has been brought into conformity. Furthermore, where the pyrotechnic article presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

(3) Distributors shall ensure that, while a pyrotechnic article is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Schedule I.

(4) Distributors who consider or have reason to believe that a pyrotechnic article which they have made available on the market is not in conformity with these Regulations shall make sure that the corrective measures necessary to bring that pyrotechnic article into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the pyrotechnic article presents a risk, distributors shall immediately inform the competent national

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authorities of the Member States in which they made the pyrotechnic article available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(5) Distributors shall, further to a reasoned request from the Technical Regulations Division and/or the Commissioner of Police, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a pyrotechnic article. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pyrotechnic articles which they have made available on the market.

Cases in which Obligations of Manufacturers apply to Importers and Distributors.

14. An importer or distributor shall be considered a manufacturer for the purposes of these Regulations and he shall be subject to the obligations of the manufacturer under regulation 8, where he places a pyrotechnic article on the market under his name or trademark or modifies a pyrotechnic article already placed on the market in such a way that compliance with the requirements of these Regulations may be affected.

Identification of Economic Operators.

15. (1) Economic operators shall, on request, identify the following to the Technical Regulations Division and/or the Commissioner of Police:

(a) any economic operator who has supplied them with a pyrotechnic article;

(b) any economic operator to whom they have supplied a pyrotechnic article.

(2) Economic operators shall be able to present the information referred to in sub-regulation (1) for a period of 10 years after they have been supplied with the pyrotechnic article and for a period of 10 years after they have supplied the pyrotechnic article.

Presumption of Conformity of Pyrotechnic Articles.

16. Pyrotechnic articles which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential safety requirements set out in Schedule I covered by those standards or parts thereof.

EU Declaration of Conformity.

17. (1) The EU declaration of conformity shall state that the fulfilment of the essential safety requirements set out in Schedule I has been demonstrated.

(2) The EU declaration of conformity shall have the model structure set out in Schedule III, shall contain the elements specified

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in the relevant modules set out in Schedule II and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the pyrotechnic article is placed or made available on the market. For pyrotechnic articles made available on the Maltese market, the EU declaration of conformity shall be in at least the Maltese or English language.

(3) Where a pyrotechnic article is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

(4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the pyrotechnic article with the requirements laid down in these Regulations.

CE Marking.

18. (1) The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

(2) The CE marking shall be affixed visibly, legibly and indelibly to the pyrotechnic articles. Where that is not possible or not warranted on account of the nature of the pyrotechnic article, it shall be affixed to the packaging and to the accompanying documents.

(3) The CE marking shall be affixed before the pyrotechnic article is placed on the market.

(4) The CE marking shall be followed by the identification number of the notified body, where that 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.

(5) The CE marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

Notification of Conformity Assessment Bodies.

19. (1) The Technical Regulations Division shall notify the European Commission and the other Member States of bodies authorised to carry out third-party conformity assessment under regulation 9.

(2) The Technical Regulations Division shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies for the purposes of these regulations, and for the monitoring of notified

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bodies, including compliance with regulation 20.

(3) The assessment and monitoring referred to in sub-regulation (2) shall be carried out by the National Accreditation Board (Malta).

(4) The Technical Regulations Division shall inform the European Commission of its procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

Requirements for Notified Bodies.

20. (1) For the purposes of notification under these regulations, a conformity assessment body shall meet the requirements laid down in sub-regulations (2) to (16) and in the Method for Designating Conformity Assessment Bodies Regulations. S.L. 427.45

(2) A conformity assessment body shall be established under Maltese law of and have legal personality.

(3) A conformity assessment body shall be a third-party body independent of the organisation or the pyrotechnic article it assesses.

(4) (a) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of pyrotechnic articles and/or explosive substances nor the representative of any of those parties. This shall not preclude the use of pyrotechnic articles and/or explosive substances that are necessary for the operations of the conformity assessment body or the use of pyrotechnic articles for personal purposes.

(b) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of pyrotechnic articles and/or explosive substances, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

(c) Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

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(5) Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

(6) (a) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Schedule II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

(b) At all times and for each conformity assessment procedure and each kind or category of pyrotechnic articles in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(i) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(ii) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(iii) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

(c) A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

(7) The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the

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conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential safety requirements set out in Schedule I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

(8) The impartiality of conformity assessment bodies, their top level management and assessment personnel shall be ensured. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

(9) Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

(10) The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Schedule II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

(11) Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

(12) Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in these regulations insofar as the applicable harmonised standards cover those

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requirements.

(13) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in these regulations, and shall inform the Technical Regulations Division accordingly.

(14) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.

(15) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(16) Notified bodies shall keep at the disposal of the Technical Regulations Division the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under regulation 9.

Notification Procedures.

21. (1) A conformity assessment body established in Malta shall submit an application for notification under these regulations to the Technical Regulations Division.

(2) The application referred to in the preceding sub-regulation shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the pyrotechnic article or articles for which that body claims to be competent, as well as by an accreditation certificate, issued by the National Accreditation Board (Malta) attesting that the conformity assessment body fulfils the requirements laid down in regulation 20 and the Method for Designating Conformity Assessment Bodies Regulations.

S.L. 427.45

(3) The Technical Regulations Division may only notify conformity assessment bodies which have satisfied the requirements laid down in regulation 20 and the Method for Designating Conformity Assessment Bodies Regulations.

S.L. 427.45

(4) The Technical Regulations Division shall notify conformity assessment bodies to the European Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

(5) The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules, pyrotechnic article or articles concerned and the relevant attestation of competence.

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(6) The body concerned may perform the activities of a notified body only where no objections are raised by the European Commission or the other Member States within two weeks of a notification. Only such a body shall be considered a notified body for the purposes of these regulations.

(7) The Technical Regulations Division shall notify the European Commission and the other Member States of any subsequent relevant changes to the notification.

(8) Where the Technical Regulations Division has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulation 20 or the Method for Designating Conformity Assessment Bodies Regulations or that it is failing to fulfil its obligations, the Technical Regulations Division shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the European Commission and the other Member States accordingly. S.L. 427.45

(9) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the Technical Regulations Division shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the responsible notifying and market surveillance authorities, at their request.

(10) The Technical Regulations Division shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

22. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Schedule II. Operational Obligations for Notified Bodies.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process. In so doing, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the toy with these regulations.

(3) Notified bodies carrying out conformity assessments shall assign registration numbers, identifying pyrotechnic articles which

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have been subject to a conformity assessment and their manufacturers, and shall maintain a register with the registration numbers of pyrotechnic articles for which they have issued certificates.

(4) Where a notified body finds that essential safety requirements set out in Schedule I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

(5) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a pyrotechnic article no longer complies; it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

(6) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

(7) Notified bodies shall inform the Technical Regulations Division of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(8) Notified bodies shall provide the other bodies notified under Directive 2013/29/EU carrying out similar conformity assessment activities covering the same pyrotechnic articles with relevant information on issues relating to negative and, on request, positive conformity assessment results.

(9) Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the European

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Commission.

Market Surveillance.

23. (1) The Technical Regulations Division, in collaboration with the Commissioner of Police, shall take appropriate measures to ensure that pyrotechnic articles may be placed on the market only if, when properly stored and used for their intended purpose, they do not endanger the health and safety of persons.

In the case of inspections at storage and manufacturing sites of pyrotechnic articles that are covered by the scope of these Regulations, the Technical Regulations Division shall be accompanied by the Police.

(2) Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to pyrotechnic articles.

(3) The Technical Regulations Division shall inform the European Commission annually about its market surveillance activities.

(4) Where the Commissioner of Police and/or the Technical Regulations Division have sufficient reasons to believe that a pyrotechnic article presents a risk to the health or safety of persons or to other aspects of public interest protection covered by these Regulations, they shall carry out an evaluation in relation to the pyrotechnic article concerned covering all relevant requirements laid down in these Regulations. The relevant economic operators shall cooperate as necessary with the Commissioner of Police and/or the Technical Regulations Division.

(5) Where, in the course of the evaluation referred to in sub-regulation (4), the Commissioner of Police and/or the Technical Regulations Division find that the pyrotechnic article does not comply with the requirements laid down in these Regulations, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the pyrotechnic article into compliance with those requirements, to withdraw the pyrotechnic article from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe. They shall also inform the notified body accordingly.

(6) Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

(7) Where the Technical Regulations Division, in collaboration with the Commissioner of Police, considers that non-compliance is not restricted to the Maltese territory, it shall inform the European Commission and the other Member States of the results of

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the evaluation and of the actions which they have required the economic operator to take.

(8) The economic operator shall ensure that all appropriate corrective action is taken in respect of all the pyrotechnic articles concerned that it has made available on the market throughout the European Union.

(9) Where the relevant economic operator does not take adequate corrective action within the period referred to in sub-regulation (5), the Technical Regulations Division in collaboration with the Commissioner of Police shall take all appropriate provisional measures to prohibit or restrict the pyrotechnic articles being made available on the Maltese market, to withdraw the pyrotechnic article from this market or to recall it.

(10) The Technical Regulations Division, upon consultation with the Commissioner of Police, shall inform the European Commission and the other Member States, without delay, of those measures referred to in sub-regulation (9).

(11) The information referred to in sub-regulation (10) shall include all available details, in particular the data necessary for the identification of the non-compliant pyrotechnic article, the origin of the pyrotechnic article, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the Technical Regulations Division, in collaboration with the Commissioner of Police, shall indicate whether the non-compliance is due to either of the following:

(a) failure of the pyrotechnic article to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in these Regulations; or

(b) shortcomings in the harmonised standards referred to in regulation 16 conferring a presumption of conformity.

(12) When the procedure under this regulation is initiated by another Member State, the Technical Regulations Division, upon consultation with the Commissioner of Police, shall without delay inform the European Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the pyrotechnic article concerned, and, in the event of disagreement with the adopted national measure, of their objections.

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(13) Where, within three months of receipt of the information referred to in the sub-regulation (10), no objection has been raised by either a Member State or the European Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

In such cases, the Commissioner of Police, upon consultation with the Technical Regulations Division, shall ensure that appropriate restrictive measures, such as withdrawal of the pyrotechnic article from the market, are taken in respect of the pyrotechnic article concerned without delay.

(14) Where on completion of the procedure set out in sub-regulations (8) and (9), objections are raised against the measures taken by Technical Regulations Division in collaboration with the Commissioner of Police; the European Commission shall conduct an evaluation including appropriate consultations with these entities and the relevant economic operator or operators.

If, on the basis of this evaluation, the national measure is considered justified, the Technical Regulations Division in collaboration with the Commissioner of Police, shall ensure that the non-compliant pyrotechnic article is withdrawn from the Maltese market and shall inform the European Commission accordingly.

If, on the basis of this evaluation, the national measure is considered unjustified, the national measure shall be withdrawn.

(15) Where, having carried out an evaluation under sub-regulation (4), the Technical Regulations Division, in collaboration with the Commissioner of Police, finds that although a pyrotechnic article is in compliance with these Regulations, it presents a risk to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the pyrotechnic article concerned, when placed on the market, no longer presents that risk, to withdraw the pyrotechnic article from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

(16) The economic operator shall ensure that corrective action is taken in respect of all the pyrotechnic articles concerned that he has made available on the market throughout the European Union.

(17) The Technical Regulations Division, upon consultation with the Commissioner of Police, shall immediately inform the European Commission and the other Member States. That

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information shall include all available details, in particular the data necessary for the identification of the pyrotechnic article concerned, the origin and the supply chain of the pyrotechnic article, the nature of the risk involved and the nature and duration of the national measures taken.

(18) Without prejudice to sub-regulations (4) to (13), where the Technical Regulations Division and/or the Commissioner of Police make one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of regulation 18;

(b) the CE marking has not been affixed;

(c) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of regulation 18 or has not been affixed;

(d) the EU declaration of conformity has not been drawn up;

(e) the EU declaration of conformity has not been drawn up correctly;

(f) technical documentation is either not available or not complete;

(g) the information referred to in sub-regulation 8(6) or sub-regulation 12(3) is absent, false or incomplete;

(h) any other administrative requirement provided for in regulation 8 or regulation 12 is not fulfilled.

(19) Where the non-compliance referred to in sub-regulation (18) persists, the Technical Regulations Division, in collaboration with the Commissioner of Police, shall take all appropriate measures to restrict or prohibit the pyrotechnic article being made available on the Maltese market or ensure that it is recalled or withdrawn from the Maltese market.

(20) The powers of the Commissioner of Police under this regulation may be exercised by any officer or other entity as he may direct.

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Penalties. Cap. 427.

24. (1) The penalties applicable for the infringement of any of the provisions of these regulations shall be those provided for in Part IV of the Product Safety Act:

Provided that, where it constitutes an offence punishable with a higher punishment under any other law, the higher punishment laid down in that law shall apply.

Cap..33.

(2) The necessary measures allowing the detainment of consignments of pyrotechnic articles that fail to comply with the provisions of these regulations shall be those under the Product Safety Act and the Ordinance.

Revokes S.L. 427.70.

25. The "Placing on the Market of Pyrotechnic Articles Regulations" are being revoked.

Saving.

26. (1) Any references to the revoked regulations shall be construed as references to these regulations.

(2) Any references in existing laws, regulations and administrative provisions to Directive 2007/23/EC shall be construed as references to Directive 2013/29/EU.

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Schedule I
ESSENTIAL SAFETY REQUIREMENTS

1. Each pyrotechnic article must attain the performance characteristics specified by the manufacturer to the notified body in order to ensure maximum safety and reliability.

2. Each pyrotechnic article must be designed and manufactured in such a way that it can be disposed of safely by a suitable process with minimum effect on the environment.

3. Each pyrotechnic article must function correctly when used for its intended purpose.

Each pyrotechnic article must be tested under realistic conditions. If this is not possible in a laboratory, the tests must be carried out in the conditions in which the pyrotechnic article is to be used.

The following information and properties - where applicable - must be considered or tested:

(a) design, construction and characteristic properties, including detailed chemical composition (mass and percentage of substances used) and dimensions;

(b) the physical and chemical stability of the pyrotechnic article in all normal, foreseeable environmental conditions;

(c) sensitivity to normal, foreseeable handling and transportation;

(d) compatibility of all components as regards their chemical stability;

(e) resistance of the pyrotechnic article to moisture where it is intended to be used in humid or wet conditions and where its safety or reliability may be adversely affected by moisture;

(f) resistance to low and high temperatures, where the pyrotechnic article is intended to be kept or used at such temperatures and its safety or reliability may be adversely affected by cooling or heating of a component or of the pyrotechnic article as a whole;

(g) safety features intended to prevent untimely or

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inadvertent initiation or ignition;

(h) suitable instructions and, where necessary, markings in respect of safe handling, storage, use (including safety distances) and disposal;

(i) the ability of the pyrotechnic article, its wrapping or other components to withstand deterioration under normal, foreseeable storage conditions;

(j) specification of all devices and accessories needed and operating instructions for safe functioning of the pyrotechnic article.

During transportation and normal handling, unless specified by the manufacturer's instructions, the pyrotechnic articles should contain the pyrotechnic composition.

4. Pyrotechnic articles must not contain detonative explosives other than black powder and flash composition, except for pyrotechnic articles of categories P1, P2, T2 and fireworks of category F4 meeting the following conditions:

(a) the detonative explosive cannot be easily extracted from the pyrotechnic article;

(b) for category P1, the pyrotechnic article cannot function in a detonative manner, or cannot, as designed and manufactured, initiate secondary explosives;

(c) for categories F4, T2 and P2, the pyrotechnic article is designed and intended not to function in a detonative manner, or, if designed to detonate, it cannot as designed and manufactured initiate secondary explosives.

5. The various groups of pyrotechnic articles must at least also comply with the following requirements:

A. Fireworks

1. The manufacturer must assign fireworks to different categories according to Article 6 characterised by net explosive content, safety distances, noise level, or similar. The category must be clearly indicated on the label.

(a) For category F1 fireworks, the following conditions must be met:

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(i) the safety distance must be at least 1 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance,

(iii) category F1 must not comprise bangers, banger batteries, flash bangers and flash banger batteries,

(iv) throwdowns in category F1 must not contain more than 2,5mg silver fulminate.

(b) For category F2 fireworks, the following conditions must be met:

(i) the safety distance must be at least 8 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance.

(c) For category F3 fireworks, the following conditions must be met:

(i) the safety distance must be at least 15 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance.

2. Fireworks may only be constructed of materials which minimise risk to health, property and the environment from debris.

3. The method of ignition must be clearly visible or must be indicated by labelling or instructions.

4. Fireworks must not move in an erratic and unforeseeable manner.

5. Fireworks of categories F1, F2 and F3 must be protected against inadvertent ignition either by a protective cover, by the packaging, or by the construction of the pyrotechnic article.

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Fireworks of category F4 must be protected against inadvertent ignition by methods specified by the manufacturer.

B. Other pyrotechnic articles

1. Pyrotechnic articles must be designed in such a way as to minimise risk to health, property and the environment during normal use.

2. The method of ignition must be clearly visible or must be indicated by labelling or instructions.

3. The pyrotechnic article must be designed in such a way as to minimise risk to health, property and the environment from debris when initiated inadvertently.

4. Where appropriate, the pyrotechnic article must function properly until the "use by" date specified by the manufacturer.

C. Ignition devices

1. Ignition devices must be capable of being reliably initiated and be of sufficient initiation capability under all normal, foreseeable conditions of use.

2. Ignition devices must be protected against electrostatic discharge under normal, foreseeable conditions of storage and use.

3. Electric igniters must be protected against electromagnetic fields under normal, foreseeable conditions of storage and use.

4. The covering of fuses must be of adequate mechanical strength and adequately protect the explosive filling when exposed to normal, foreseeable mechanical stress.

5. The parameters for the burning times of fuses must be provided with the pyrotechnic article.

6. The electrical characteristics (e.g. no-fire current, resistance, etc.) of electric igniters must be provided with the pyrotechnic article.

7. The wires of electric igniters must be sufficiently insulated and must be of sufficient mechanical strength, including the solidity of the link to the igniter, taking account of their intended use.

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Schedule II
CONFORMITY ASSESSMENT PROCEDURES

MODULE B:EU-type examination

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a pyrotechnic article and verifies and attests that the technical design of the pyrotechnic article meets the requirements of these Regulations that apply to it.

2. EU-type examination shall be carried out as an assessment of the adequacy of the technical design of the pyrotechnic article through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete product (combination of production type and design type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation. The technical documentation shall make it possible to assess the pyrotechnic article"s conformity with the applicable requirements of these Regulations and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pyrotechnic article. The technical documentation shall contain, wherever applicable, at least the following elements:

(i) a general description of the pyrotechnic article;

(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;

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(iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations including a list of other relevant technical specifications applied. In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out, etc.;

(vi) test reports;

(d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the pyrotechnic article:

4.1. Examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the pyrotechnic article.

For the specimen(s):

4.2. Verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. Carry out appropriate examinations and tests, or have them

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carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;

4.4. Carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer, including those in other relevant technical specifications applied, meet the corresponding essential safety requirements of these Regulations;

4.5. Agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of these Regulations that apply to the pyrotechnic article concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pyrotechnic articles with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of these Regulations, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the

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technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the pyrotechnic article with the essential safety requirements of these Regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the European Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market.

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

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of these Regulations that apply to them.

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2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pyrotechnic articles with the type described in the EU-type examination certificate and with the requirements of these Regulations that apply to them.

3. Product checks

A notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the pyrotechnic article, taking into account, *inter alia*, the technological complexity of the pyrotechnic articles and the quantity of production. An adequate sample of the final products, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised 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 these Regulations. Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pyrotechnic article performs within acceptable limits, with a view to ensuring conformity of the pyrotechnic article.

The manufacturer shall, under the responsibility of the notified body, affix the notified body"s identification number during the manufacturing process.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual pyrotechnic article that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

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A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

MODULE D: Conformity to type based on quality assurance of the production process

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of these Regulations that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pyrotechnic articles concerned.

The application shall include:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the pyrotechnic article category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2. The quality system shall ensure that the pyrotechnic articles are in conformity with the type described in the EU-type examination certificate and comply with the requirements of these Regulations that apply to them.

All the elements, requirements and provisions adopted by the

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manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; and

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer’s premises. The auditing team shall review the technical documentation referred to in point 3.1(e) to verify the manufacturer’s ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

The decision shall be notified to the manufacturer. The

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notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body.

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

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5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter''s identification number to each individual pyrotechnic article that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

MODULE E: Conformity to type based on product quality assurance

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the

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EU-type examination certificate and satisfy the requirements of these Regulations that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pyrotechnic articles concerned.

The application shall include the following information:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the pyrotechnic article category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2. The quality system shall ensure compliance of the pyrotechnic articles with the type described in the EU-type examination certificate and with the applicable requirements of these Regulations.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

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(b) the examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

(d) the means of monitoring the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e), in order to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification

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shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter’s identification number to each individual pyrotechnic article that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

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6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

MODULE G: Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the pyrotechnic article concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of these Regulations that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the pyrotechnic article’s conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pyrotechnic article. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the pyrotechnic article;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

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(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;

(d) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pyrotechnic article has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pyrotechnic article with the applicable requirements of these Regulations.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the pyrotechnic article with the applicable requirements of these Regulations, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved pyrotechnic article, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market.

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5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each pyrotechnic article that satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

MODULE H: Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned satisfy the requirements of these Regulations that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1.The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pyrotechnic articles concerned.

The application shall include:

(a) the name and address of the manufacturer;

(b) the technical documentation for one model of each pyrotechnic article category intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the pyrotechnic article;

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- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;

- a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

- results of design calculations made, examinations carried out, etc.;

- test reports;

(c) the documentation concerning the quality system;

(d) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the pyrotechnic articles with the applicable requirements of these Regulations.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards will not be applied in full, the means that

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will be used to ensure that the essential safety requirements of these Regulations will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the pyrotechnic articles pertaining to the pyrotechnic article category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer’s premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer’s ability to identify the applicable requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

The manufacturer shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records as provided for by the design part of the quality system such as the results of analyses, calculations, tests, etc.;

(c) the quality records as provided for by the manufacturing part of the quality system such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out,

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with a test report.

4.5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

(a) the technical documentation referred to in point 3.1;

(b) the documentation concerning the quality system referred to in point 3.1;

(c) the information relating to the change referred to in point 3.5, as approved;

(d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

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Schedule III
EU DECLARATION OF CONFORMITY (No XXXX)*

1. Registration number issued in accordance with the "Traceability of Pyrotechnic Articles Regulations"**.

2. Product, batch or serial number:

3. Name and address of the manufacturer:

4. This declaration of conformity is issued under the sole responsibility of the manufacturer.

5. Object of the declaration (identification of product allowing traceability):

6. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

7. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

8. The notified body … (name, number) performed … (description of intervention) and issued the certificate:

9. Additional information:

- Signed for and on behalf of:

- (place and date of issue):

- (name, function) (signature):

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* It is optional for the manufacturer to assign a number to the declaration of conformity.
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