VERŻJONI ELETTRONIKA

L.N. 241 of 2016

EXPLOSIVES ORDINANCE
(CAP. 33)

PRODUCT SAFETY ACT
(CAP. 427)

Making Available on the Market of Explosives for Civil Uses Regulations, 2016

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 Making Available on the Market of Explosives for Civil Uses Regulations, 2016.

(2) These regulations transpose Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast).

(3) These regulations lay down requirements relating to the safety and making available on the market of civil explosives and rules on their free movement in the European Union.

Conformity S.L. 33.04.

2. The making available on the market of explosives covered by the Civil Explosives Regulations which are in conformity with those regulations and which were placed on the market before 20 April 2016 shall not be impeded.

Applicability.

3. (1) These regulations shall apply to explosives for civil uses.

(2) These regulations shall not apply to:

(a) explosives, including ammunition, intended for use, in accordance with Maltese law, by the armed forces or the police;

(b) pyrotechnic articles falling within the scope of the Making Available on the Market of Pyrotechnic Articles Regulations; S.L. 427.70

VERŻJONI ELETTRONIKA

(c) ammunition, save as provided for in regulations 24 and 25.

(3) Schedule I contains a non-exhaustive list of pyrotechnic articles referred to in regulation 3(2)(b) and of ammunition as defined in these regulations.

(4) These regulations shall not prevent from designating certain substances not covered by these regulations as explosives under other laws or regulations.

Definitions.

4. For the purpose of these regulations, the following definitions shall apply:

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

"ammunition" means projectiles with or without propelling charges and blank ammunition used in portable firearms, other guns and artillery;

"approval" means the decision taken to allow envisaged transfers of explosives within the Union;

"authorised representative" means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

"CE marking" means a marking by which the manufacturer indicates that the explosive 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 an explosive have been fulfilled;

"dealer" means any natural or legal person whose occupation consists wholly or partly in the manufacture, trade, exchange, hiring out, repair or conversion of fire arms and ammunition;

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

VERŻJONI ELETTRONIKA

"economic operators" means the manufacturer, the authorised representative, the importer, the distributor and any natural or legal person who engages in the storage, use, transfer, import, export or trade of explosives;

"explosives" means the materials and articles considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations;

"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 an explosive from a third country on the Union market;

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

"manufacturer" means any natural or legal person who manufactures an explosive or has an explosive designed or manufactured, and markets that explosive under his name or trade mark or uses it for his own purposes;

"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

"national accreditation body" means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

"placing on the market" means the first making available of an explosive on the Union market;

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

"safety" means the prevention of accidents and, where prevention fails, the containment of their effects;

"security" means the prevention of use contrary to law and order;

VERŻJONI ELETTRONIKA

"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;

Cap. 510

"technical specification" means a document that prescribes technical requirements to be fulfilled by an explosive;

"transfer" means any physical movement of explosives within the Union except movements within one and the same site;

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

"withdrawal" means any measure aimed at preventing an explosive in the supply chain from being made available on the market;

Free movement.

5. The making available on the market of explosives which satisfy the requirements of these regulations shall not be prohibited, restricted or hindered.

Making available on the market.

6. Explosives may be made available on the market only if they comply with the requirements of these regulations.

Obligations of the manufacturer.

7. (1) When placing their explosives on the market or when using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Schedule II.

(2) Manufacturers shall draw up the technical documentation referred to in Schedule III and have the relevant conformity assessment procedure referred to in regulation 15 carried out.

Where compliance of an explosive 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 explosive 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 design or characteristics of the explosive and changes in the harmonised standards or in other technical specifications by reference to which conformity of an explosive is declared shall be

VERŻJONI ELETTRONIKA

adequately taken into account.

(5) Manufacturers shall ensure that explosives which they have placed on the market bear a unique identification in accordance with the system for the identification and traceability of explosives set out in regulation 13. For explosives excluded from that system, manufacturers shall:

(a) ensure that explosives which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the small size, shape or design of the explosive does not allow it, that the required information is provided on its packaging or in a document accompanying the explosive;

(b) indicate on the explosive 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 explosive. 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 the English language.

(6) Manufacturers shall ensure that explosives which they have placed on the market are accompanied by instructions and safety information in at least the Maltese or the English language. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

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

(8) Manufacturers shall, further to a reasoned request from the Commissioner of Police or from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the explosive 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 explosives which

VERŻJONI ELETTRONIKA

they have placed on the market.

Authorised representatives.

8. (1) A manufacturer may, by a written mandate, appoint an authorised representative.

(2) The obligations laid down in regulation 7(1) and the obligation to draw up technical documentation referred to in regulation 7(2) shall not form part of the authorised representative's mandate.

(3) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years after the product has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an explosive;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by explosives covered by the authorised representative's mandate.

Obligations of importers.

9. (1) Importers shall place only compliant explosives on the market.

(2) Before placing an explosive on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in regulation 15 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the explosive bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in regulation 7(5).

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

(3) Importers shall indicate, on the explosive, their name,

VERŻJONI ELETTRONIKA

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 explosive. The contact details shall be in at least the Maltese or the English language.

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

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

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

(7) Importers shall, for 10 years after the explosive 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 Police or the Technical Regulations Division, provide them with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an explosive 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 products which they have placed on the market.

Obligations of distributors.

10. (1) When making an explosive available on the market distributors shall act with due care in relation to the requirements of these regulations.

(2) Before making an explosive available on the market distributors shall verify that the explosive bears the CE marking, that it is accompanied by the required documents and by instructions and

VERŻJONI ELETTRONIKA

safety information in at least the English or Maltese language, and that the manufacturer and the importer have complied with the requirements set out in regulation 7(5) and regulation 9(3) respectively.

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

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

(4) Distributors who consider or have reason to believe that an explosive 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 explosive into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the explosive presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the explosive 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 Police and, or the Technical Regulations Division, provide that authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an explosive. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by explosives which they have made available on the market.

Cases in which obligations of manufacturers apply to importers and distributors.

11. 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 7, where he places an explosive on the market under his name or trademark or modifies an explosive already placed on the market in such a way that compliance with the requirements of these regulations may be affected.

Identification of economic operators.

12. (1) For explosives not covered by the system set out in regulation 13, economic operators shall, on request, identify the

VERŻJONI ELETTRONIKA

following to the Police and, or the Technical Regulations Division:

(a) any economic operator who has supplied them with an explosive;

(b) any economic operator to whom they have supplied an explosive.

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

Identification and traceability of explosives.

13. (1) Economic operators shall adhere to a uniform system for the unique identification and traceability of explosives, that takes into account their size, shape or design, except where it is not necessary to place a unique identification on the explosive due to its low level of hazard, based on its characteristics and factors such as its low detonative effects, its uses and the low security risk it presents due to the low potential effects of misuse.

The system shall not apply to explosives transported and delivered unpackaged or in pump trucks for their direct unloading into the blast-hole, or explosives manufactured at blasting sites, and that are loaded immediately after being produced (*in situ* production).

(2) That system shall provide for the collection and storage of data, including where appropriate by electronic means, enabling the unique identification and traceability of the explosive as well as for the placement of a unique identification on the explosive and, or its packaging enabling access to that data. Those data shall relate to the unique identification of the explosive, including its location while in the possession of economic operators and the identity of those economic operators.

(3) The data referred to in sub-regulation (2) shall be tested at regular intervals and protected against accidental or malicious damage or destruction. Those data shall be stored for 10 years after the transaction took place or, where the explosives have been used or disposed of, 10 years after their use or disposal, even if the economic operator has ceased trading. They shall be immediately available at the request of the Police or the Technical Regulations Division.

Presumption of Conformity of Explosives.

14. Explosives, 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 II covered by those standards or parts thereof.

VERŻJONI ELETTRONIKA

Conformity assessment procedures.

15. For the assessment of the conformity of explosives the manufacturer shall follow one of the following procedures referred to in Schedule III:

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

(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);

(iv) conformity to type based on product verification (Module F);

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

EU declaration of conformity.

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

(2) The EU declaration of conformity, which shall have the model structure set out in Schedule IV, shall contain the elements specified in the relevant modules set out in Schedule III and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the explosive is placed or made available on the market. For products placed or made available on the Maltese market, the EU Declaration of Conformity shall be translated into at least the Maltese or the English language.

(3) Where an explosive 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 explosive with the requirements laid down in these regulations.

CE marking.

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

VERŻJONI ELETTRONIKA

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

(3) The CE marking shall be affixed before the explosive 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 or his authorised representative.

(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.

(6) In cases of explosives manufactured for own use, explosives transported and delivered unpackaged or in Mobile Explosives Manufacturing Units (MEMUs) for their direct unloading into the blast-hole, and explosives manufactured at the blasting sites which are loaded immediately after being produced (in situ production), the CE marking shall be affixed to the accompanying documents.

Notification of conformity assessment bodies.

18. (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 these regulations.

(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 bodies, including compliance with the provisions of regulations 19(13) to 19(16).

(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.

VERŻJONI ELETTRONIKA

Requirements relating to notified bodies.

S.L. 427.45

19. (1) For the purposes of notification under these regulations, a conformity assessment body shall meet the requirements laid down in sub-regulations (2) to (11) and in the Method for Designating Conformity Assessment Bodies Regulations.

(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 explosive 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 explosives which they assess, nor the representative of any of those parties. This shall not preclude the use of explosives that are necessary for the operations of the conformity assessment body or the use of explosives 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 or manufacture, the marketing, installation, use or maintenance of explosives, 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.

(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 III and in relation to which it has been notified, whether

VERŻJONI ELETTRONIKA

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 explosives 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 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 II, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of the relevant national legislation;

(d) the ability to draw up certificates, records and

VERŻJONI ELETTRONIKA

reports demonstrating that assessments have been carried out.

(8) The impartiality of conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed. The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks 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 III 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 sub-regulations (1) to (11) insofar as the applicable harmonised standards cover those 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 sub-regulations (1) to (11), 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

VERŻJONI ELETTRONIKA

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 regulations Schedule III.

Notification procedures.

20. (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 sub-regulation (1) shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the explosive or explosives 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 regulations 19(1) to 19(11) 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 regulations 19(1) to 19(11) 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, explosive or explosives concerned and the relevant attestation of competence.

(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.

VERŻJONI ELETTRONIKA

S.L. 427.45

(8) Where the Technical Regulations Division has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulations 19(1) to 19(11) 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.

(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.

Operational obligations for notified bodies.

21. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Schedule III.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators and private importers. 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 product technology 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 explosive with these regulations.

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

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

VERŻJONI ELETTRONIKA

(5) 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.

(6) 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.

(7) Notified bodies shall provide the other bodies notified under the Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

(8) 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 Commission.

Market surveillance.

22. (1) The Police shall take appropriate measures to ensure that explosives 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.

(2) Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to explosives.

(3) Where the Police has sufficient reasons to believe that an explosive presents a risk to the health or safety of persons, to property or to the environment, they shall carry out an evaluation in relation to the explosive concerned covering all relevant requirements laid down in these regulations. The relevant economic operators shall cooperate as necessary with the Police.

VERŻJONI ELETTRONIKA

(4) Where, in the course of the evaluation referred to in sub-regulation (3), the Police finds that the explosive 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 action to bring the explosive into compliance with those requirements, to withdraw the explosive from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe. It shall also inform the Notified Body accordingly. The Police shall also inform the Technical Regulations Division.

(5) Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in sub-regulation (4).

(6) Where the Police, in collaboration with the Technical Regulations Division, 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 the evaluation and of the actions which it has required the economic operator to take.

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

(8) Where the relevant economic operator does not take adequate corrective action within the period referred to in regulation 22(4), the Police shall take all appropriate provisional measures to prohibit or restrict the explosives being made available on the Maltese market, to withdraw the explosive from this market or to recall it. The Police shall inform the Technical Regulations Division of such measures.

(9) The Technical Regulations Division shall inform the European Commission and the other Member States, without delay, of those measures referred to in sub-regulation (8).

(10) The information referred to in sub-regulation (9) shall include all available details, in particular the data necessary for the identification of the non-compliant explosive, the origin of the explosive, 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 Police, in collaboration with Technical Regulations Division, shall indicate whether the non-compliance is due to either of the following:

VERŻJONI ELETTRONIKA

(a) failure of the explosive to meet requirements relating to the health or safety of persons, the protection of property or the environment laid down in these regulations; or

(b) shortcomings in the harmonised standards referred to in regulation 14 conferring a presumption of conformity.

(11) When the procedure under this regulation is initiated by another Member State, the Technical Regulations Division, in collaboration with the 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 explosive concerned, and, in the event of disagreement with the adopted national measure, of their objections.

(12) Where, within three months of receipt of the information referred to in sub-regulation (9), 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 Police shall ensure that appropriate restrictive measures are taken in respect of the explosive concerned, such as withdrawal of the explosive from the Maltese market, without delay.

(13) Where on completion of the procedure set out in sub-regulations (7) to (8), objections are raised against a measure taken by the Police, or where the European Commission considers a national measure to be contrary to European Union legislation, the European Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

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

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

(14) Where, having carried out an evaluation under regulation 22(3), the Police finds that although an explosive is in compliance

VERŻJONI ELETTRONIKA

with these regulations, it presents a risk to the health or safety of persons, or to property or the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the explosive concerned, when placed on the market, no longer presents that risk, to withdraw the explosive from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

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

(16) The Police, upon consultation with the Technical Regulations Division, shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the explosive concerned, the origin and the supply chain of the explosive, the nature of the risk involved and the nature and duration of the national measures taken.

(17) Without prejudice to sub-regulations (3) to (12), where the Police makes 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 regulations 17(2) to 17(6);

(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 regulations 17(2) to 17(6) 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 regulation 7(5) or regulation 9(3) is absent, false or incomplete;

VERŻJONI ELETTRONIKA

(h) any other administrative requirement provided for in regulation 7 or regulation 9 is not fulfilled.

(18) Where the non-compliance referred to in sub-regulation (17) persists, the Police shall take all appropriate measures to restrict or prohibit the explosive being made available on the Maltese market or ensure that it is recalled or withdrawn from the Maltese market.

Transfers of explosives.

23. (1) Explosives may be transferred only in accordance with sub-regulations (2) to (8).

(2) Approval to transfer explosives shall be obtained by the consignee from the Commissioner of Police. The Commissioner of Police shall verify that the consignee is legally authorised to acquire explosives and that he is in possession of a licence in terms of these Regulations. The economic operator responsible for the transfer shall notify the competent authorities of the transit Member State of any movement of explosives through the Member State concerned and shall obtain prior approval of the transit Member State concerned. Whenever explosives are transited through Malta, the Commissioner of Police shall be notified and the transit shall take place only if approval has been issued.

(3) Where the Commissioner of Police considers that there is a problem regarding the verification of the entitlement to acquire explosives referred to in sub-regulation (2), the Commissioner of Police shall forward the available information on the subject to the Commission which shall inform the other Member States thereof.

(4) Where the Commissioner of Police approves a transfer, the Commissioner of Police shall issue to the consignee a document which includes all the information referred to in sub-regulation (5). Such a document shall accompany the explosives until they arrive at their stated destination. It shall be produced at the request of the relevant competent authorities. A copy of that document shall be retained by the consignee who shall present it, upon request, for examination by the Commissioner of Police.

(5) Prior to the transfer of explosives, the following information shall be provided by the consignee to the Commissioner of Police:

(a) the names and addresses of the economic operators concerned;

(b) the number and quantity of the explosives being transferred;

VERŻJONI ELETTRONIKA

(c) a full description of the explosives in question and of the means of identification, including the United Nations identification number;

(d) where the explosives are to be placed on the market, information on compliance with conditions for placing on the market;

(e) the means of transfer and the itinerary;

(f) the expected dates of departure and arrival;

(g) where necessary, the precise points of entry to and exit from Malta.

The Commissioner of Police shall examine the conditions under which the transfer may take place, with particular regard to security requirements. If such requirements are satisfied, approval for the transfer shall be granted.

(6) At the request of the Commissioner of Police, the consignees and the economic operators concerned shall forward the required information concerning the transfer of explosives whenever Malta is the state of departure or the state of transit.

(7) No economic operator may transfer explosives unless the consignee has obtained the necessary licences for the transfer in accordance with sub-regulations (2), (4) and (5).

Transfers of ammunition.

24. (1) Ammunition may be transferred between Malta and other Member States only in accordance with the procedure laid down in sub-regulations (2) to (5) which sub-regulations shall also apply to transfers of ammunition under mail-order sales.

(2) Where ammunition is to be transferred to another Member State the person concerned shall, before any dispatch, communicate to the Commissioner of Police the following:

(a) the names and addresses of the person selling or transferring the ammunition, of the person purchasing or acquiring the ammunition and, where appropriate, of the owner;

(b) the address to which the ammunition is to be consigned or transported;

(c) the quantity of ammunition to be consigned or transported;

VERŻJONI ELETTRONIKA

(d) data making it possible to identify the ammunition and also an indication that the ammunition has undergone a check in accordance with the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms;

(e) the means of transfer;

(f) the date of departure and the estimated date of arrival.

The information referred to in paragraphs (e) and (f) need not be supplied in the case of a transfer between dealers. The Commissioner of Police shall examine the conditions under which the transfer is to be carried out, in particular with regard to security. Where the Commissioner of Police authorises such a transfer, the Commissioner of Police shall issue an authorisation incorporating all the particulars referred to in the sub-regulation (2). That licence shall accompany the ammunition until it reaches its destination. It shall be produced whenever so required by the competent authorities.

(3) The Commissioner of Police may grant dealers the right to effect transfers of ammunition from its territory to a dealer established in another Member State without the prior authorisation referred to in sub-regulation (2). To that end, the Commissioner of Police shall issue an authorisation valid for three years which may at any time be suspended or cancelled by reasoned decision. A document referring to that authorisation shall accompany the ammunition until it reaches its destination. It shall be produced whenever so required by the competent authorities of the Member States.

Before effecting the transfer, the dealer shall communicate to the Commissioner of Police all the particulars listed in sub-regulation (2).

(4) The competent authorities shall supply the other Member States with a list of the ammunition the transfer of which to its territory may be authorised without its prior consent.

Such lists of ammunition shall be communicated to dealers who have obtained approval for transferring ammunition without prior authorisation in accordance with the procedure laid down in sub-regulation (3).

(5) The Commissioner of Police shall communicate all relevant information concerning definitive transfers of ammunition to the competent authorities of the Member State, to the territory of

VERŻJONI ELETTRONIKA

which such a transfer has been affected.

All information that the Commissioner of Police receives in accordance with this Regulation shall be communicated, not later than the time of the relevant transfers, to the Member States of destination and, where appropriate, not later than the time of transfer to the Member States of transit.

Security derogations.

25. By way of derogation from regulation 23(2), (4) and (5) and from regulation 24, the Commissioner of Police, in the event of serious threats to, or attacks on, public security as a result of illicit possession or use of explosives or ammunition, may take all necessary measures concerning transfers of explosives or ammunition in order to prevent such illicit possession or use.

The measures referred to in the first paragraph shall respect the principle of proportionality. They shall constitute neither a means of arbitrary discrimination nor a veiled restriction in trade between Member States.

If such measures are adopted, these measures shall be notified to the Commission forthwith.

Licence.

26. (1) Economic operators shall be in possession of a licence which entitles them to engage in the manufacture, storage, use, import, export, transfer or trade of explosives.

(2) Sub-regulation (1) shall not apply to employees of an economic operator possessing a licence.

Licensing of manufacturing activities.

27. Whenever the Commissioner of Police issues a licence in accordance with regulation 26, the Commissioner of Police shall seek the advice of the Explosives Committee or of the Malta Competition and Consumer Affairs Authority in relation to the compliance of operators with technical commitments.

Penalties.

28. The penalties applicable for the infringement of any of the provisions of these regulations shall be those provided for in the Explosives Ordinance.

Cap. 33.

Revocation of S.L. 33.04 and S.L.33.05.

29. The Civil Explosives Regulations and the Civil Explosives (Identification) Regulations are hereby revoked.

Saving.

30. (1) Any references to the Regulations mentioned in regulation 29 shall be construed as references to these regulations.

(2) Any references in existing laws, regulations and administrative provisions to Directive 93/15/EEC as amended and to Directive 2004/57/EC shall be construed as references to Directive 2014/28/EU.

VERŻJONI ELETTRONIKA

Schedule I

ARTICLES CONSIDERED IN THE RELEVANT UNITED NATIONS RECOMMENDATIONS TO BE PYROTECHNIC OR AMMUNITION

UN No	NAME and DESCRIPTION	CLASS/ DIVISION	GLOSSARY (to be used as a guide for information only)
Group G			
0009	Ammunition, Incendiary with or without burster, expelling charge or propelling charge	1.2 G	Ammunition Generic term related mainly to articles of military application consisting of all kind of bombs, grenades, rockets, mines, projectiles and other similar devices. Ammunition, Incendiary Ammunition containing incendiary substance. Except when the composition is an explosive per se, it also contains one or more of the following: a propelling charge with primer and igniter charge; a fuze with burster or expelling charge.
0010	Ammunition, Incendiary with or without burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0009
0015	Ammunition, Smoke with or without burster, expelling charge or propelling charge	1.2 G	Ammunition, Smoke Ammunition containing smoke-producing substance. Except when the substance is an explosive per se, the ammunition also contains one or more of the following: a propelling charge with primer and igniter charge; a fuze with burster or expelling charge.
0016	Ammunition, Smoke with or without burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0015

VERŻJONI ELETTRONIKA

UN No	NAME and DESCRIPTION	CLASS/ DIVISION	GLOSSARY (to be used as a guide for information only)
0018	Ammunition, Tear-producing with burster, expelling charge or propelling charge	1.2 G	Ammunition, Tear-producing with burster, expelling charge or propelling charge Ammunition containing tear-producing substance. It also contains one or more of the following: a pyrotechnic substance; a propelling charge with primer and igniter charge; a fuze with burster or expelling charge.
0019	Ammunition, Tear-producing with burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0018
0039	Bombs, photo-flash	1.2 G	Bombs Explosive articles which are dropped from aircraft. They may contain a flammable liquid with bursting charge, a photo-flash composition or a bursting charge. The term includes: bombs, photo-flash.
0049	Cartridges, Flash	1.1 G	Cartridges, Flash Articles consisting of a casing, a primer and flash powder, all assembled in one piece ready for firing.
0050	Cartridges, Flash	1.3 G	See Entry for UN No 0049
0054	Cartridges, Signal	1.3 G	Cartridges, Signal Articles designed to fire coloured flares or other signals from signal pistols, etc.
0066	Cord, Igniter	1.4 G	Cord, Igniter Article consisting of textile yarns covered with black powder or another fast burning pyrotechnic composition and of a flexible protective covering; or it consists of a core of black powder surrounded by a flexible woven fabric: It burns progressively along its length with an external flame and is used to transmit ignition from a device to a charge.
0092	Flares, Surface	1.3 G	Flares Articles containing pyrotechnic substances which are designed for use to illuminate, identify, signal or warn.
0093	Flares, Aerial	1.3 G	See Entry for UN No 0092

VERŻJONI ELETTRONIKA

UN No	NAME and DESCRIPTION	CLASS/ DIVISION	GLOSSARY (to be used as a guide for information only)
0101	Fuse, non-detonating	1.3 G	Fuse/Fuze Although these two words have a common origin (French fusée, fusil) and are sometimes considered to be different spellings, it is useful to maintain the convention that fuse refers to a cord-like igniting device whereas fuze refers to a device used in ammunition which incorporates mechanical, electrical, chemical or hydrostatic components to initiate a train by deflagration or detonation. Fuse, instantaneous, non-detonating (quick-match) Article consisting of cotton yarns impregnated with fine black powder (quickmatch). It burns with an external flame and is used in ignition trains for fireworks, etc.
0103	Fuse, Igniter, tubular, metal clad	1.4 G	Fuse, igniter, tubular, metal clad Article consisting of a metal tube with a core of deflagrating explosive.
0171	Ammunition, illuminating with or without burster, expelling charge or propelling charge	1.2 G	Ammunition, illuminating with or without burster, expelling charge or propelling charge Ammunition designed to produce a single source of intense light for lighting up an area. The term includes illuminating cartridges, grenades and projectiles; and illuminating and target identification bombs.
0191	Signal devices, hand	1.4 G	Articles designed to produce signals.
0192	Signals, railway track, explosive	1.1 G	See Entry for UN No 0191
0194	Signals, distress, ship	1.1 G	See Entry for UN No 0191
0195	Signals, distress, ship	1.3 G	See Entry for UN No 0191
0196	Signals, smoke	1.1 G	See Entry for UN No 0191
0197	Signals, smoke	1.4 G	See Entry for UN No 0191
0212	Tracers for ammunition	1.3 G	Tracers for ammunition Sealed articles containing pyrotechnic substances, designed to reveal the trajectory of a projectile.

VERŻJONI ELETTRONIKA

UN No	NAME and DESCRIPTION	CLASS/ DIVISION	GLOSSARY (to be used as a guide for information only)
0254	Ammunition, illuminating with or without burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0171
0297	Ammunition, illuminating with or without burster, expelling charge or propelling charge	1.4 G	See Entry for UN No 0254
0299	Bombs, photo-flash	1.3 G	See Entry for UN No 0039
0300	Ammunition, incendiary with or without burster, expelling charge or propelling charge	1.4 G	See Entry for UN No 0009
0301	Ammunition, tear-producing with burster, expelling charge	1.4 G	See Entry for UN No 0018
0303	Ammunition, smoke with or without burster, expelling charge	1.4 G	See Entry for UN No 0015
0306	Tracers for ammunition	1.4 G	See Entry for UN No 0212
0312	Cartridges, signal	1.4 G	Cartridges, signal Articles designed to fire coloured flares or other signals from signal pistols.
0313	Signals, smoke	1.2 G	See Entry for UN No 0195
0318	Grenades, practice, hand or rifle	1.3 G	Grenades hand or rifle Articles which are designed to be thrown by hand or to be projected by a rifle. The term includes: Grenades practice, hand or rifle.
0319	Primers, tubular	1.3 G	Primers, tubular Articles consisting of a primer for ignition and an auxiliary charge of deflagrating explosive such as black powder used to ignite the propelling charge in a cartridge case, e.g. cannon.
0320	Primers, tubular	1.4 G	See Entry for UN No 0319
0333	Fireworks	1.1 G	Fireworks Pyrotechnic articles designed for entertainment.
0334	Fireworks	1.2 G	See Entry for UN No 0333
0335	Fireworks	1.3 G	See Entry for UN No 0333

VERŻJONI ELETTRONIKA

UN No	NAME and DESCRIPTION	CLASS/ DIVISION	GLOSSARY (to be used as a guide for information only)
0336	Fireworks	1.4 G	See Entry for UN No 0333
0362	Ammunition, practice	1.4 G	Ammunition, practice Ammunition without a main bursting charge, containing a burster or expelling charge. Normally it also contains a fuze and a propelling charge.
0363	Ammunition, proof	1.4 G	Ammunition, proof Ammunition containing pyrotechnic substances, used to test the performance or strength of new ammunition, weapon component or assemblies.
0372	Grenades, practice, hand or rifle	1.2 G	See Entry for UN No 0318
0373	Signal devices, hand	1.4 S	See Entry for UN No 0191
0403	Flares, aerial	1.4 G	See Entry for UN No 0092
0418	Flares, surface	1.2 G	See Entry for UN No 0092
0419	Flares, surface	1.1 G	See Entry for UN No 0092
0420	Flares, aerial	1.1 G	See Entry for UN No 0092
0421	Flares, aerial	1.2 G	See Entry for UN No 0092
0424	Projectiles, inert with tracer	1.3 G	Projectiles Articles such as a shell or bullet which are projected from a cannon or other artillery gun, rifle or other small arm. They may be inert, with or without tracer, or may contain a burster or expelling charge or a bursting charge. The term includes: Projectiles, inert, with tracer; projectiles with burster or expelling charge; projectiles with bursting charge.
0425	Projectiles, inert with tracer	1.4 G	See Entry for UN No 0424

VERŻJONI ELETTRONIKA

UN No	NAME and DESCRIPTION	CLASS/ DIVISION	GLOSSARY (to be used as a guide for information only)
0428	Articles, pyrotechnic for technical purposes	1.1 G	Articles, pyrotechnic for technical purposes Articles which contain pyrotechnic substances and are used for technical purposes such as heat generation, gas generation, theatrical effects, etc. The term excludes the following articles which are listed separately: all ammunition; cartridges, signal; cutters, cable, explosive; fireworks; flares, aerial; flares, surface; release devices, explosive; rivets, explosive; signal devices, hand; signals, distress; signals, railway track, explosive; signals, smoke.
0429	Articles, pyrotechnic for technical purposes	1.2 G	See Entry for UN No 0428
0430	Articles, pyrotechnic for technical purposes	1.3 G	See Entry for UN No 0428
0431	Articles, pyrotechnic for technical purposes	1.4 G	See Entry for UN No 0428
0434	Projectiles with burster or expelling charge	1.2 G	Projectiles Articles such as a shell or bullet which are projected from a cannon or other artillery gun, rifle or other small arm. They may be inert, with or without tracer, or may contain a burster or expelling charge or a bursting charge. The term includes: projectiles, inert, with tracer; projectiles with burster or expelling charge; projectiles with bursting charge.
0435	Projectiles with burster or expelling charge	1.4 G	See Entry for UN No 0434
0452	Grenades, practice, hand or rifle	1.4 G	See Entry for UN No 0372
0487	Signal, smoke	1.3 G	See Entry for UN No 0194
0488	Ammunition, practice	1.3 G	Ammunition, practice Ammunition without a main bursting charge, containing a burster or expelling charge. Normally it also contains a fuze and a propelling charge. The term excludes the following articles which are listed separately: Grenades, practice.
0492	Signals, railway track, explosive	1.3 G	See Entry for UN No 0194

VERŻJONI ELETTRONIKA

UN No	NAME and DESCRIPTION	CLASS/ DIVISION	GLOSSARY (to be used as a guide for information only)
0493	Signals, railway track, explosive	1.4 G	See Entry for UN No 0194
0503	Air bag inflators, or Airbag modules, or seat belt pre-tensioners,	1.4 G	
Group S			
0110	Grenades, practice, hand or rifle	1.4 S	See Entry for UN No 0318
0193	Signals, railway track, explosive	1.4 S	See Entry for UN No 0194
0337	Fireworks	1.4 S	See Entry for UN No 0334
0345	Projectiles, inert with tracer	1.4 S	Projectiles Articles such as a shell or bullet which are projected from a cannon or other artillery gun, rifle or other small arm. They may be inert, with or without tracer, or may contain a burster or expelling charge or a bursting charge.
0376	Primers, tubular	1.4 S	See Entry for UN No 0319
0404	Flares, aerial	1.4 S	See Entry for UN No 0092
0405	Cartridges, signal	1.4 S	Cartridges, Signal Articles designed to fire coloured flares or other signals from signal pistols, etc.
0432	Articles, pyrotechnic or technical purpose	1.4 S	

Schedule II

ESSENTIAL SAFETY REQUIREMENTS

I. General requirements

1. Each explosive must be designed, manufactured and supplied in such a way as to present a minimal risk to the safety of human life and health, and to prevent damage to property and the environment under normal, foreseeable conditions, in particular as regards the safety rules and standard practices until it is used.

2. Each explosive must attain the performance characteristics specified by the manufacturer in order to ensure maximum safety and reliability.

3. Each explosive must be designed and manufactured in such a way that

VERŻJONI ELETTRONIKA

when appropriate techniques are employed it can be disposed of in a manner which minimises effects on the environment.

II. Special requirements

1. As a minimum, the following information and properties, where appropriate, must be considered or tested:

   (a) design and characteristic properties, including chemical composition, degree of homogeneity and, where appropriate, dimensions and grain size distribution;

   (b) the physical and chemical stability of the explosive in all environmental conditions to which it may be exposed;

   (c) sensitiveness to impact and friction;

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

   (e) the chemical purity of the explosive;

   (f) resistance of the explosive against influence of water where it is intended to be used in humid or wet conditions and where its safety or reliability may be adversely affected by water;

   (g) resistance to low and high temperatures, where the explosive 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 explosive as a whole;

   (h) the suitability of the explosive for use in hazardous environments (e.g. firedamp atmospheres, hot masses) if it is intended to be used under such conditions;

   (i) safety features intended to prevent untimely or inadvertent initiation or ignition;

   (j) the correct loading and functioning of the explosive when used for its intended purpose;

   (k) suitable instructions and, where necessary, markings in respect of safe handling, storage, use and disposal;

   (l) the ability of the explosive, its wrapping or other components to withstand deterioration during storage until the ‘use by’ date specified by the manufacturer;

VERŻJONI ELETTRONIKA

(m) specification of all devices and accessories needed for reliable and safe functioning of the explosive.

2. Each explosive shall be tested under realistic conditions. If this is not possible in a laboratory, the tests shall be carried out in the conditions in which the explosive is to be used.

3. Requirements for the groups of explosives

3.1. Blasting explosives shall also comply with the following requirements:

(a) the proposed method of initiation must ensure safe, reliable and complete detonation or deflagration as appropriate, of the blasting explosive. In the particular case of black powder, it is the capacity as regards deflagration which shall be checked;

(b) blasting explosives in cartridge form must transmit the detonation safely and reliably from one end of the train of cartridges to the other;

(c) the fumes produced by blasting explosives intended for underground use may contain carbon monoxide, nitrous gases, other gases, vapours or airborne solid residues only in quantities which do not impair health under normal operating conditions.

3.2. Detonating cords, safety fuses, other fuses and shock tubes shall also comply with the following requirements:

(a) the covering of detonating cords, safety fuses, other fuses and shock tubes must be of adequate mechanical strength and adequately protect the explosive filling when exposed to normal mechanical stress;

(b) the parameters for the burning times of safety fuses must be indicated and must be reliably met;

(c) detonating cords must be capable of being reliably initiated, be of sufficient initiation capability and comply with requirements as regards storage even in particular climatic conditions.

3.3. Detonators (including delay detonators) and relays shall also comply with the following requirements:

(a) detonators must reliably initiate the detonation of the blasting explosives which are intended to be used with them under all foreseeable conditions of use;

(b) delay connectors for detonating cords must be reliably initiated;

VERŻJONI ELETTRONIKA

(c) the initiation capability must not be adversely affected by humidity;

(d) the delay times of delay detonators must be sufficiently uniform to ensure that the probability of overlapping of the delay times of adjacent time steps is insignificant;

(e) the electrical characteristics of electric detonators must be indicated on the packaging (e.g. no-fire current, resistance);

(f) the wires of electric detonators must be of sufficient insulation and mechanical strength including the solidity of the link to the detonator, taking account of their intended use.

3.4. Propellants and rocket propellants shall also comply with the following requirements:

(a) these materials must not detonate when used for their intended purpose;

(b) propellants where necessary (e.g. those based on nitrocellulose) must be stabilised against decomposition;

(c) solid rocket propellants, when in compressed or cast form, must not contain any unintentional fissures or gas bubbles which dangerously affect their functioning.

Schedule III

CONFORMTIY 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 an explosive and verifies and attests that the technical design of the explosive 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 explosive 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).

VERŻJONI ELETTRONIKA

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 and, if the application is lodged by the authorised representative, his name and address as well;

(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 explosive'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 explosive. The technical documentation shall contain wherever applicable, at least the following elements:

(i) a general description of the explosive;

(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 explosive;

(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 event 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;

VERŻJONI ELETTRONIKA

(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 explosive:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the explosive.

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 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 applying other relevant technical specifications 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 explosive 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

VERŻJONI ELETTRONIKA

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 explosives 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 technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the explosive 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 authority 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 authority 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 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

VERŻJONI ELETTRONIKA

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 explosive has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Module C 2

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 explosives 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 take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured explosives 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 that body, in order to verify the quality of the internal checks on the explosive, taking into account, inter alia, the technological complexity of the explosives 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 explosive with the type described in the EU-type examination certificate and with the relevant requirements of these

VERŻJONI ELETTRONIKA

regulations. Where a sample does not conform to the acceptable quality level, the notified body shall take appropriate measures.

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

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 explosive 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 explosive type and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive type 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.

5. *Authorised representative*

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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 explosives 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*

VERŻJONI ELETTRONIKA

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the explosives 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 explosives concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

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

(c) all relevant information for the explosive 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 explosives 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 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

VERŻJONI ELETTRONIKA

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.;

(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 (e) of point 3.1 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 explosive 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 shall contain the conclusions of the examination and the reasoned assessment decision.

VERŻJONI ELETTRONIKA

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 explosive 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 explosive type and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive type 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 explosive has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

VERŻJONI ELETTRONIKA

(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 authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority 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.

8. *Authorised representative*

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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 explosives 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 final product inspection and testing of the explosives 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 explosives concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is

VERŻJONI ELETTRONIKA

lodged by the authorised representative, his name and address as well;

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

(c) all relevant information for the explosive 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 explosives 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. This 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 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 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

VERŻJONI ELETTRONIKA

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 (e) of point 3.1, 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 explosive 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 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.

VERŻJONI ELETTRONIKA

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 explosive 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 explosive type and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive type 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 explosive 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 authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority 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.

8. *Authorised representative*

VERŻJONI ELETTRONIKA

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module F

Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the explosives concerned, which have been subject to the provisions of point 3, 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 take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured explosives with the approved type described in the EU-type examination certificate and with the requirements of these regulations that apply to them.

3. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the explosives with the approved type described in the EU-type examination certificate and with the appropriate requirements of these regulations.

The examinations and tests to check the conformity of the explosives with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 4 or by examination and testing of the explosives on a statistical basis as specified in point 5.

4. *Verification of conformity by examination and testing of every product*

4.1. All explosives shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and, or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of these regulations. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.2. The notified body shall issue a certificate of conformity in respect of the

VERŻJONI ELETTRONIKA

examinations and tests carried out, and shall affix its identification number to each approved explosive or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the explosive has been placed on the market.

5. *Statistical verification of conformity*

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his explosives for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot. All explosives in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and, or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of these regulations and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. If a lot is accepted, all explosives of the lot shall be considered approved, except for those explosives from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved explosive 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 explosive has been placed on the market.

5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent the placing on the market of that lot. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

6. *CE marking and EU declaration of conformity*

6.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3, the latter’s identification number to each individual explosive that is in conformity

VERŻJONI ELETTRONIKA

with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of these regulations.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each explosive type and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive type 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.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the explosives.

If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the explosives during the manufacturing process.

7. *Authorised representative*

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

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 explosive 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*

2.1. 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 explosive'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 explosive. The technical documentation shall, wherever applicable, contain at least the following

VERŻJONI ELETTRONIKA

elements:

(a) a general description of the explosive;

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

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

(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., and

(f) t est reports.

2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the explosive 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 explosive 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 explosive 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 explosive, or have it affixed under its

VERŻJONI ELETTRONIKA

responsibility.

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

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 explosive 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 explosive has been placed on the market. The EU declaration of conformity shall identify the explosive 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. *Authorised representative*

The manufacturer's obligations set out in points 2.2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Schedule IV

EU DECLARATION OF CONFORMITY No xxxxx*

1. No … (product, type, batch or serial number):

2. Name and address of the manufacturer and, where applicable, his authorised representative:

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

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

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

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

VERŻJONI ELETTRONIKA

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

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

8. Additional information:

Signed for and on behalf of:

(*place and date of issue*):

(*name, function*) (*signature*):

VERŻJONI ELETTRONIKA

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — ***Printed at the Government Printing Press on recycled paper***

Prezz/*Price*
€4.86