

**SUBSIDIARY LEGISLATION 33.04**  
**CIVIL EXPLOSIVES REGULATIONS**

1st June, 2004

*LEGAL NOTICE 279 of 2004, as amended by Act V of 2007.*

- 1.** The title of these regulations is the Civil Explosives Regulations. Citation.
- 2.** (1) These regulations shall apply to explosives as defined in regulation 3. Scope.
- (2) The following are excluded from the scope of these regulations:
- (a) explosives, including ammunition, intended for use, in accordance with Maltese law, by the armed forces or police;
  - (b) pyrotechnical articles;
  - (c) ammunition, except as provided in regulation 10.
- 3.** For the purposes of these regulations, the following definitions shall apply. Definitions.
- "approval" shall mean the decision taken to allow envisaged transfers of explosives;
- "dealer" shall mean 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;
- "explosives" shall mean the materials and articles considered to be such in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations;
- "placing on the market" shall mean any first disposal against payment or free of charge of explosives covered by these regulations with a view to their distribution and, or, use;
- "safety" shall mean the prevention of accidents and, where prevention fails, the containment of their effects;
- "security" shall mean the prevention of use contrary to law and order;
- "the Ordinance" means the Explosives Ordinance; Cap. 33.
- "transfer" shall mean any physical movement of explosives apart from movements within one and the same site;
- "undertaking in the explosives sector" shall mean any natural or legal person possessing a licence or authorization which entitles him to engage in the manufacture, storage, use, transfer or trade in explosives;
- "United Nations recommendations" shall mean the recommendations laid down by the United Nations of Experts on

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Presumptions of conformity.	<p>the transport of Dangerous Goods, as published in the UN (Orange Book) and as amended by the date when these regulations are adopted.</p> <p><b>4.</b> (1) Explosives falling within the scope of these regulations must comply with the essential safety requirements set out in Schedule I which apply to them.</p> <p>(2) Explosives falling within the scope of these regulations which comply with the relevant national standards transposing the harmonized standards the references of which have been published in the Official Journal of the European Communities shall be considered to be in conformity with the essential safety requirements referred to in subregulation (1). The references of the national standards transposing those harmonized standards shall be published in the Gazette.</p>
General requirements.	<p><b>5.</b> (1) Updated information concerning undertakings in the explosives sector possessing licences or authorizations shall be kept by the Commissioner of Police.</p> <p>(2) The undertakings referred to in subregulation (1) must possess a system for keeping track of explosives such that those holding explosives can be identified at any time. Undertakings in the explosives sector shall keep such records of their transitions as are necessary to fulfil the obligations of this regulation.</p> <p>(3) The documents referred to in subregulation (2) must be kept for at least three years after the end of the calendar year in which the recorded transaction took place, even if the undertaking has ceased trading. They must be immediately available for inspection at the request of the Commissioner of Police or the committee referred to in article 23 of the Ordinance.</p> <p>(4) All explosives must be properly marked.</p> <p>(5) In issuing a licence or authorization for the purpose of allowing an explosives manufacturing activity to be exercised, the Commissioner of Police shall check in particular that the persons responsible are capable of complying with the technical commitments they assume.</p>
Conformity assessment procedures.	<p><b>6.</b> The procedures for the attestation of the conformity of explosives shall be either:</p> <p>(a) EC type examination (Module B) referred to in Schedule II (1), and, at the choice of the manufacturer, either:</p> <ul style="list-style-type: none"><li>(i) the type conformity (Module C) referred to in Schedule II (2), or</li><li>(ii) the production quality assurance procedure (Module D) referred to in Schedule II (3), or</li><li>(iii) the product quality assurance procedure (Module E) referred to in Schedule II (4), or</li><li>(iv) the product verification (Module F) referred to in Schedule II (5); or</li></ul> <p>(b) the unit verification (Module G) referred to in</p>

## Schedule II (6).

7. (1) Explosives falling within the scope of these regulations may be placed on the market only if they comply with all the provisions thereof, are provided with the CE marking and their conformity has been assessed in accordance with the procedures referred to in Schedule II. CE Marking.

(2) Where explosives falling within the scope of these regulations are subject to other regulations which cover other aspects and prescribe the fixing of the CE marking, this marking shall indicate that the abovementioned products are also presumed to conform to the provisions of any regulations which apply to them.

(3) The CE marking of conformity shall be affixed in such a way as to be visible, easily legible and indelible on the explosives themselves or, if this is not possible, on an identification plate attached thereto or, in the last resort, if the first two methods cannot be used, on the packaging. The identification plate must be so designed as to make its re-use impossible. The model to be used for the CE marking shall be that reproduced in Schedule IV.

(4) It shall be prohibited to affix on explosives any mark or inscription which may confuse third persons as to the meaning and style of writing of the CE marking. Any other mark may be affixed on explosives provided the visibility and legibility of the CE marking is not impaired.

(5) Without prejudice to the provisions of subregulation (2), where it is established that the CE marking has been unduly affixed, the manufacturer, his agent or, failing these, the person responsible for placing the product in question on the market shall be obliged to restore the product to conformity with regard to the provisions on marking and end the infringement, without prejudice to any other measures which may be taken by the Commissioner of Police in accordance with the Ordinance.

(6) Where non-compliance to the provisions persists, the Commissioner of Police shall take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in regulation 8.

8. (1) Where it is established that an explosive bearing CE conformity marking and being used for its intended purpose may compromise safety, the Commissioner of Police shall take all interim measures that are necessary to withdraw the explosive from the market or prohibit its being placed on the market or its freedom of movement.

Withdrawal and prohibition from market.

(2) Any measures taken pursuant to subregulation (1) shall be communicated to both the Consumer and Industrial Goods Directorate and the Foodstuffs, Chemicals and Cosmetics Directorate of the Malta Standards Authority.

Provisions governing the supervision of transfers of explosives.

9. (1) Explosives covered by these regulations may be transferred between Malta and Member States of the European Community only in accordance with the following provisions:

- (a) In the case of transfers of explosives from a Member State of the European Community to Malta, approval to transfer such explosives shall be obtained by the consignee from the Commissioner of Police. The Commissioner of Police shall verify that the consignee is legally authorized to acquire explosives and that he is in possession of the necessary licences or authorizations.
- (b) Where the Commissioner of Police approves a transfer from a Member State of the European Community to Malta, he shall issue to the consignee a document which includes all the information referred to in paragraph (d). Such a document must accompany the explosives until they arrive at their stated destination. It must be produced at the request of any relevant competent authorities. A copy of this document shall be retained by the consignee who shall present it for examination by the Commissioner of Police, at the latter's request.
- (c) Without prejudice to the provisions of paragraph (d), paragraphs (a) and (b) shall also apply to transfers of explosives within Malta.
- (d) Where the Commissioner of Police considers that special security requirements such as those referred to in paragraph (b) are unnecessary, explosives can be transferred within Malta on their territory or part thereof without prior provision of information within the meaning of paragraph (e). The Commissioner of Police shall then grant an approval for a fixed period and liable to suspension or withdrawal at any time on the basis of a reasoned justification. The document referred to in paragraph (b) which must accompany the explosives until they arrive at their destination, shall refer solely to the abovementioned approval.
- (e) Where transfers of explosives must be specially supervised in order to comply with special security requirements, prior to the transfer the following information shall be provided by the consignee to the Commissioner of Police:
  - (i) the names and addresses of the operators concerned; this information must be detailed enough to enable the operators to be contacted and confirmation to be obtained that the persons in question are legally entitled to receive the consignment;
  - (ii) the number and quantity of the explosives being transferred;
  - (iii) a full description of the explosive in question and of the means of identification, including the

- United Nations identification number;
- (iv) where the explosives are to be placed on the market, information on compliance with conditions for placing on the market;
  - (v) the means of transfer and the itinerary;
  - (vi) the expected dates of departure and arrival, where necessary;
  - (vii) the precise points of entry to and exit from Malta and/or any Member States of the European Community.

The Commissioner of Police shall examine the conditions under which the transfer may take place, with particular regard to the special security requirements. If the special security requirements are satisfied, approval for the transfer shall be granted. In the event of transit through the territory of other States forming part of the European Community, the consignee must obtain the necessary authorizations for the transfer through those States in accordance with the provisions of paragraphs (a) to (d).

- (f) No supplier may transfer explosives to a consignee within Malta or the European Community unless the consignee has obtained the necessary authorizations for the transfer in accordance with the provisions of paragraphs (a) to (d).

(2) The provisions of subregulation (1) shall also apply to the transfer of explosives from third countries to Malta. In such cases, the consignee must also be in possession of a valid importation licence issued by the Department of Trade.

**10.** (1) Ammunition may be transferred within Malta and between Malta and Member States of the European Community only in accordance with the procedure laid down in the following regulations. These provisions shall also apply to transfers under mail-order sales:

Transfer of  
ammunition.

- (a) Where ammunition is to be transferred from Malta to a consignee in Malta or a Member State of the European Community, the person concerned shall, before any dispatch, communicate to the Commissioner of Police:
  - (i) 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;
  - (ii) the address to which the ammunition is to be consigned or transported;
  - (iii) the quantity of ammunition to be consigned or transported;
  - (iv) 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 1st July 1969

on the Reciprocal Recognition of Proofmarks on Small Arms;

- (v) the means of transfer;
- (vi) the date of departure and the estimated date of arrival.

The information referred to in subparagraphs (v) and (vi) need not be supplied in the event 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. When such a transfer is authorized the Commissioner of Police shall issue a licence incorporating all the particulars referred to in subparagraph (i). That licence shall accompany the ammunition until it reaches its destination; it shall be produced whenever so required by the competent authorities of that country.

- (b) Dealers may be granted the right to effect transfers of ammunition from Malta to a dealer established in a Member State of the European Community without the prior authorization referred to in paragraph (a). To that end the Commissioner of Police may issue an authorization valid for three years which may at any time be suspended or cancelled by reasoned decision. A document referring to that authorization must accompany the ammunition until it reaches its destination. It must be produced whenever so required by the relevant competent authorities. Before effecting the transfer, the dealer shall communicate to the Commissioner of Police all the particulars listed in subparagraph (a)(i).

(2) The provisions of subregulation (1) shall also apply to the transfer of ammunition from third countries to Malta. In such cases, the consignee must also be in possession of a valid importation licence issued by the Department of Trade.

(3) By derogation from subregulations (1) and (2) and regulation 9(1)(b) to (e) and (2), the Commissioner of Police may, in case of grave threats to, or attacks upon, public security through the illicit possession or use of explosives covered by these regulations, take all necessary measures concerning transfers of explosives or ammunition in order to prevent such illicit possession or use. These measures shall respect the principle of proportionality. They must constitute neither a means of arbitrary discrimination nor a veiled restriction in trade between countries.

Reference to  
Product Safety  
Act.  
Cap. 427.

**11.** Explosives, as defined by these regulations, and with the exception of the exclusions mentioned in regulation 2(2), shall fall within the scope of the duties of the Director of Market Surveillance, as defined in article 27 of the Product Safety Act.

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## SCHEDULE I

## 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 including until such time as 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 when appropriate techniques are employed it can be disposed of in a manner which minimizes effects on the environment.

## II. Special requirements.

1. As a minimum, the following information and properties - where appropriate - must be considered. Each explosive should be tested under realistic conditions. If this is not possible in a laboratory, the tests should be carried out in the conditions in which the explosive is to be used.

- (a) Construction and characteristic properties, including chemical composition, degree of blending 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. environment endangered by firedamp, hot masses, etc.) 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 in Maltese and/or English.
- (l) The ability of the explosive, its covering or other components to withstand deterioration during storage until the use by date specified by the manufacturer.

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- (m) Specification of all devices and accessories needed for reliable and safe functioning of the explosive.
2. The various groups of explosives must at least also comply with the following requirements:
- A. Blasting explosives
- (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 gases 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.
- B. Detonating cords, safety fuses, igniter cords and shock tubes
- (a) The covering of detonating cords, safety fuses and igniter cords 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.
- C. Detonators (including delay detonators) and relays
- (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) Relays must be capable of being reliably initiated.
  - (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, etc.).
  - (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.
- D. Propellants and rocket propellants
- (a) These materials must not detonate when used for their intended purpose.
  - (b) Propellants where necessary (e.g. those based on nitrocellulose) must be stabilized 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 II

*Amended by:  
V. 2007.25.*

## 1. MODULE B: EC type-examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that an example, representative of the production envisaged, meets the relevant provisions of the regulations.

2. The application for EC type-examination is lodged by the manufacturer or his authorized representative with a notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, the name and address in addition,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documents, as described in Section 3.

The applicant must place at the disposal of the notified body an example representative of the production envisaged, hereinafter called "type". The notified body may request further examples if needed for carrying out the test programme.

3. The technical documents must enable the conformity of the appliance with the requirements of the regulations to be assessed. They must, as far as is relevant for such assessment, cover the design, manufacture and operation of the appliance and contain as far as is relevant for assessment:

- a general type-description,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of the drawings and diagrams and the operation of the product,
- a list of the standards referred to in regulation 4(2) of these regulations, applied in full or in part, and descriptions of the of the solutions adopted to meet the essential requirements of these regulations,
- results of design calculations made, examinations carried out, etc.,
- test reports.

## 4. The notified body must -

- 4.1. examine the technical documents, verify that the type has been manufactured in conformity with those documents and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in regulation 4(2) of these regulations as well as the components which have been designed without applying the relevant provisions of those standards;
- 4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in regulation 4(2) of these regulations have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the regulations;
- 4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the

relevant standards, these have actually been applied;

4.4. agree with the applicant the location where the examinations and necessary tests are to be carried out.

5. Where the type meets the relevant provisions of these regulations, the notified body issues an EC type-examination certificate to the applicant. The certificate contains the name and address of the manufacturer, the conclusion of the examination and necessary data for identification of the approved type.

A list of the relevant parts of the technical documents is annexed to the certificate and a copy kept by the notified body.

If the manufacturer or his authorized representative is refused a type certificate, the notified body must provide detailed reasons for such refusal.

An appeal shall lie from the decision of the notified body to the Administrative Review Tribunal established in terms of article 5 of the Administrative Justice Act, and the provision of this Act shall apply to such an appeal.

6. The applicant informs the notified body that holds the technical documents concerning the EC type-examination certificate of all modifications to the approved appliance which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type-examination certificate.

7. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.

8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorized representative must keep with the technical documents copies of EC type-examination certificates and their additions for a period of at least 10 years after the last date of manufacture of the product concerned.

## 2. MODULE C: Conformity to type

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative ensures and declares that the explosives concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of these Regulations that apply to them. The manufacturer must affix the CE mark to each explosive and draw up a written declaration of conformity.

2. The manufacturer must take all measures necessary to ensure that the manufacturing process assures the conformity of the manufactured product with the type as described in the EC type-examination certificate with the essential safety requirements of the regulations.

3. The manufacturer or his authorized representative must keep a copy of the declaration of conformity for a period of at least 10 years after the last date of manufacture of the product concerned.

4. A notified body chosen by the manufacturer must perform or have

performed examinations of the product at random intervals. A suitable sample of the finished products, taken on the spot by the notified body, is examined and appropriate test, defined in the applicable standard or standards referred to in regulation 4(2) of these regulations or equivalent tests are carried out to check the conformity of the product with the requirements of the corresponding regulations. In the event of one or more samples of the products examined not conforming, the notified body must take the appropriate measures.

Under the responsibility of the notified body the manufacturer shall affix the identification symbol of that body during the manufacturing process.

### 3. MODULE D: Production quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of Section 2 ensures and declares that the explosives concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of these regulations. The manufacturer affixes the CE mark to each explosive and draws up a written declaration of conformity. The CE mark is accompanied by the identification symbol of the notified body responsible for the checks referred to in Section 4.

2. The manufacturer must operate an approved quality system for production, final product inspection and testing as specified in Section 3. He is subject to the checks referred to in Section 4.

#### 3. Quality system

3.1. The manufacturer lodges an application for assessment of his quality system with a notified body of his choice, for the explosives concerned.

The application must include:

- all relevant information for the explosive category envisaged,
- the documents concerning the quality system,
- the technical documents pertaining to the approved type and a copy of the EC type examination certificate.

3.2. The quality system must ensure conformity of explosives with the type as described in the EC type-examination certificate and with the requirements of these regulations that apply to them.

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

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the explosives,
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried

out,

- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means of monitoring the achievement of the required quality of explosive and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It must presume conformity with those requirements in respect of quality systems that implement the relevant harmonized standard. The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure includes an inspection visit to the manufacturer's premises.

The decision is notified to the manufacturer. The notification must contain the conclusions of the examination and the duly substantiated assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer or his authorized representative must keep the notified body that has approved the quality system informed of any proposed change in the quality system.

The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in paragraph 3.2 or whether reassessment is required.

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

#### 4. Monitoring under the responsibility of the notified body

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

4.2. The manufacturer must allow the notified body access for inspection purposes to the manufacturing, inspection, testing and storage premises and provide it with all necessary information, in particular:

- the quality system documents,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and provides an audit report to the manufacturer.

4.4. Additionally the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or have them carried out to verify that the quality system is functioning correctly; if necessary, the notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of at least 10 years after the last date of manufacture of the product, keep at the disposal of the national authorities:

- the document referred to in the second indent of paragraph 3.1,
- the updating referred to in second paragraph of paragraph 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of paragraph 3.4, and in paragraphs 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

#### 4. MODULE E: Product quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of Section 2 ensures and declares that the explosives are in conformity with the type as described in the EC type-examination certificate. The manufacturer must affix the CE mark to each explosive and draw up a written declaration of conformity. The CE mark must be accompanied by the identification symbol of the notified body responsible for the checks referred to in Section 4.

2. The manufacturer must operate an approved quality system for final explosive inspection and testing as specified in Section 3. He must be subject to the checks referred to in Section 4.

#### 3. Quality system

3.1. The manufacturer lodges an application with a notified body of his choice for the assessment of the quality system for his explosives.

The application must include:

- all relevant information for the explosive category envisaged,
- the quality system's documentation,
- the technical documents pertaining to the approved type and a copy of the EC type-examination certificate.

3.2. Under the quality system, each explosive is examined and appropriate tests as defined in the relevant standard(s) referred to in regulation 4(2) of these regulations or equivalent tests are carried out in order to verify its conformity with the relevant requirements of the regulations. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must enable the quality programmes, plans, manuals and records to be interpreted in a uniform manner.

It must in particular contain an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the examination and tests that will be carried out after manufacture,
- the means of monitoring the effective operation of the quality system,
- quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It must presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure must include an inspection visit to the manufacturer's premises.

The manufacturer must be notified of the decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer or his authorized representative must keep the notified body which has approved the quality system informed of any proposed change in the quality system.

The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

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

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

- the quality system documentation,
- the technical documents,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or have them carried out to verify that the quality system is functioning correctly; if necessary, the notified body must provide the manufacturer with a visit report and, if a test has been carried out, with a test reports.

5. The manufacturer must for a period of at least 10 years after the last date of manufacture of the product keep at the disposal of the national authorities:

- the documents referred to in the second indent of paragraph 3.1,
- the changes referred to in the second paragraph of paragraph 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of paragraph 3.4, and in paragraphs 4.3 and 4.4.

6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

## 5. MODULE F: Product verification

1. This module describes the procedure whereby a manufacturer or his authorized representative checks and attests that the explosives subject to the provisions of paragraph 3 are in conformity with the type as described in the EC type-examination certificate and satisfy the relevant requirements of the regulations.

2. The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the explosives with the type as described in the EC type-examination certificate and with the requirements of the regulations that apply to them. He shall affix the CE mark to each explosive and shall draw up a declaration of conformity.

3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the explosive with the relevant requirements of the regulations by examination and testing of every explosive as specified in paragraph 4.

The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last explosive has been manufactured.

4. Verification by examination and testing of every explosive

4.1. All explosives shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in regulation 4(2) of these regulations or equivalent tests shall be carried out in order to verify their conformity with the relevant type and requirements of the regulations.

4.2. The notified body shall affix or cause to be affixed, its identification symbol to each approved explosive and draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

6. MODULE G: Unit verification

1. This module describes the procedure whereby the manufacturer ensures and declares that the explosive which has been issued with the certificate referred to in Section 2 conforms to the relevant requirements of the regulations. The manufacturer must affix the CE mark to the explosive and draw up a declaration of conformity.

2. The notified body must examine the explosive and carry out the appropriate tests as set out in the relevant standard(s) referred to in regulation 4(2) of these regulations, or equivalent tests, to ensure its conformity with the relevant requirements of the regulations.

The notified body must affix, or cause to be affixed, its identification symbol on the approved explosive and draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documents is to enable conformity with the requirements of the regulations to be assessed and the design, manufacture and operation of the explosive to be understood.

The documents must contain, in so far as is necessary for the assessment:

- a general description of the type,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of the said drawings and schemes and the operation of the explosive or protection system,
- a list of the standards referred to in regulation 4(2) of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in regulation 4(2) of these regulations have not been applied,
- results of design calculations made, examinations carried out, etc.,

- test reports.

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### SCHEDULE III

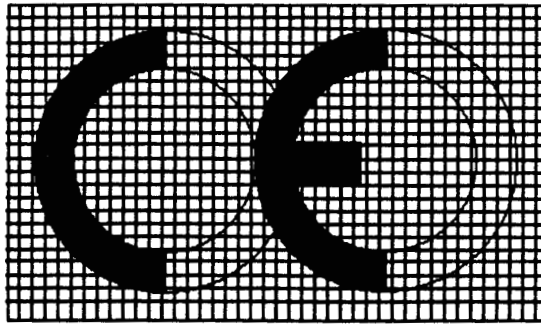
#### MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of explosives which they inspect, nor the authorized representative of any of these parties. They shall not become either involved directly or as authorized representatives in the design, construction, marketing or maintenance of such explosives. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
  2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
  3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.
  4. The staff responsible for inspection shall have:
    - sound technical and professional training,
    - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
    - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
  5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
  6. The body shall take out civil liability insurance unless its liability is assumed by the State in accordance with national law, or the State itself is directly responsible for the tests.
  7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except *vis-a-vis* the competent administrative authorities of the State in which its activities are carried out) under these regulations or any provision of national law giving effect to it.
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SCHEDULE IV

CONFORMITY MARKING

The CE conformity marking shall consist of the initials "CE" taking the following form:



If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

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