STATUTORY INSTRUMENTS

2016 No. 1107

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016

PART 2

Obligations of economic operators

Chapter 1

Manufacturers

Design and manufacture in accordance with essential health and safety requirements

5. Before placing a product on the market or using a product for their own purposes, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential health and safety requirements.

Technical documentation and conformity assessment

6. Before placing a product on the market or using it for their own purposes, a manufacturer must—

(a) carry out the relevant conformity assessment procedure or have a relevant conformity assessment procedure carried out; and

(b) draw up the technical documentation referred to—

(i) for a product in respect of which the conformity assessment procedure in regulation 39(1)(a) is being carried out, in point 3(c) of Module B of Annex III to the ATEX Directive (as amended from time to time);

(ii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(b) is being carried out, in point 3(c) of Module B of Annex III to the ATEX Directive (as amended from time to time);

(iii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(c) is being carried out, in point 2 of Module A of Annex VIII to the ATEX Directive (as amended from time to time);

(iv) for a product in respect of which the conformity assessment procedure in regulation 39(1)(d) is being carried out, in Point 2 of Module G of Annex IX to the ATEX Directive (as amended from time to time).

EU declaration of conformity and CE marking

7.—(1) Save for where a product is a component, where the conformity of a product with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the product on the market—

(a) draw up a declaration of conformity in accordance with regulation 40 (EU declaration of conformity), and

(b) affix the CE Marking in accordance with regulation 41 (CE Marking).

(2) The manufacturer must keep the EU declaration of conformity up-to-date.

(3) Where the conformity of a component with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the component on the market, draw up a written attestation of conformity in accordance with regulation 39(3) (conformity assessment procedures).

(4) Subject to paragraph (5), before placing a product on the market, the manufacturer must ensure that each product is accompanied by a copy of the EU declaration of conformity or attestation of conformity as appropriate.

(5) Where a large number of products are delivered to a single user, the batch or consignment may be accompanied by a single copy of the EU declaration or attestation of conformity as appropriate.

(6) Where a product is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity, which—

(a) identifies the EU instruments, and

(b) includes references to the publication of those EU instruments in the Official Journal.

Retention of technical documentation and EU declaration of conformity

8. A manufacturer must keep the technical documentation and the EU declaration of conformity (or where applicable, the attestation of conformity) drawn up in respect of a product for a period of 10 years beginning on the day on which the product is placed on the market.

Compliance procedures for series production

9.—(1) A manufacturer of a product which is manufactured by series production must ensure that, before placing a product on the market, procedures are in place to ensure that any product so manufactured will be in conformity with Part 2.

(2) In doing so, the manufacturer must take adequate account of—

(a) any change in the product design or characteristics, and

(b) any change in a harmonised standard or in another technical specification by reference to which the EU declaration of conformity or attestation of conformity was drawn up.

Monitoring

10.—(1) When appropriate, with regard to the risks to the health and safety of end-users presented by a product, a manufacturer must—

(a) carry out sample testing of a product manufactured by the manufacturer made available on the market,

(b) investigate complaints that a product manufactured by the manufacturer is not in conformity with Part 2, and

(c) keep distributors informed of any actions carried out under sub-paragraphs (a) and (b).

(2) A manufacturer must keep a register of—

(a) complaints that a product is not in conformity with Part 2,

(b) products which are found not to be in conformity with Part 2, and

(c) product recalls.

(3) A manufacturer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Labelling and packaging of products

11.—(1) Before placing a product on the market, a manufacturer must ensure that it bears a type, batch or serial number or other element allowing its identification.

(2) If the size or nature of the product does not provide sufficient space for the labelling requirements in paragraph (1), the manufacturer must ensure that the information is provided on the packaging or in a document accompanying the product.

Labelling and packaging of products, other than components

12. Save for where a product is a component, before placing a product on the market a manufacturer must ensure that it—

(a) bears the specific marking of explosion protection as referred to at paragraph 5(1)(f) of Schedule 1, and

(b) where applicable, bears the other markings and information referred to at paragraph 5 of Schedule 1.

Information identifying manufacturer

13.—(1) Before placing a product on the market, a manufacturer must indicate on the product—

(a) the name, registered trade name or registered trade mark of the manufacturer, and

(b) a postal address at which the manufacturer can be contacted.

(2) Where it is not possible to indicate the information specified in paragraph (1) on the product, the manufacturer must indicate that information—

(a) on the product packaging, or

(b) in a document accompanying the product.

(3) The information specified in paragraph (1) must be in a language which can be easily understood by end-users and the competent national authority in the Member State in which it is to be made available to such end-users.

Instructions and safety information

14.—(1) When placing a product on the market, a manufacturer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by end-users in the Member State in which it is to be made available on the market.

(2) The instructions and safety information referred to in paragraph (1) and any labelling must be clear and understandable.

(3) Where the Member State referred to in paragraph (1) is the United Kingdom, the language referred to in that paragraph must be English.

Duty to take action in respect of a product placed on the market which is considered not to be in conformity

15.—(1) A manufacturer who considers, or has reason to believe, that a product which the manufacturer has placed on the market is not in conformity with Part 2, must immediately take the corrective measures necessary to—

(a) bring the product into conformity,

(b) withdraw the product, or

(c) recall the product.

(2) Where the product presents a risk, the manufacturer must immediately inform the market surveillance authority, and the competent national authorities of any other Member State in which the manufacturer made the product available on the market, of the risk, giving details of—

(a) the respect in which the product is considered not to be in conformity with Part 2, and

(b) any corrective measures taken.

Provision of information and cooperation

16.—(1) A manufacturer must, further to a reasoned request from the market surveillance authority, and within such period as the market surveillance authority may specify, provide the authority with the information and documentation necessary to demonstrate that the product is in conformity with Part 2—

(a) in paper or electronic form, and

(b) in a language which can be easily understood by the market surveillance authority.

(2) A manufacturer must, at the request of the market surveillance authority, cooperate with the authority on any action taken to—

(a) evaluate a product in accordance with regulation 55 (evaluation of a product presenting a risk);

(b) eliminate the risks posed by a product which the manufacturer has placed on the market.

Authorised representatives

17.—(1) A manufacturer may, by written mandate, appoint a person established in the EU as their authorised representative to perform specified tasks on the manufacturer's behalf.

(2) A manufacturer who has appointed an authorised representative to perform, on the manufacturer's behalf, a task under these Regulations remains responsible for the proper performance of that task.

(3) The obligations laid down in regulation 5 (design and manufacture in accordance with essential health and safety requirements) and regulation 6(b) (technical documentation and conformity assessment) must not form part of an authorised representative's mandate.

(4) The mandate must allow the authorised representative to do at least the following in relation to a product covered by the mandate—

(a) perform the manufacturer's obligations under regulation 8 (retention of technical documentation and EU declaration of conformity), and

(b) perform the manufacturer's obligations under regulation 16 (provision of information and cooperation).

(5) An authorised representative must comply with all duties imposed on the manufacturer in relation to each obligation under these Regulations that the authorised representative is appointed by the mandate to perform and, accordingly as far as those duties are concerned, as well as the penalties for failure to comply with those duties, references in these Regulations (except in this regulation) to the manufacturer are to be taken as including a reference to the authorised representative.