Directive 2014/34/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 equipment and protective systems intended for use in potentially explosive atmospheres (recast) (Text with EEA relevance)

CHAPTER 3

CONFORMITY OF THE PRODUCT

Article 12

Presumption of conformity of products

1 Products 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 health and safety requirements set out in Annex II covered by those standards or parts thereof.

2 In the absence of harmonised standards, Member States shall take any steps which they deem necessary to bring to the attention of the parties concerned the existing national standards and technical specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements set out in Annex II.

Article 13

Conformity assessment procedures

1 The procedures to be followed for assessing the conformity of equipment and, where necessary, the devices referred to in point (b) of Article 1(1) shall be as follows:

a for equipment-groups I and II, equipment-categories M 1 and 1, the EU-type examination set out in Annex III, in conjunction with either of the following:
   - conformity to type based on quality assurance of the production process set out in Annex IV,
   - conformity to type based on product verification set out in Annex V;

b for equipment-groups I and II, equipment categories M 2 and 2:

   (i) in the case of internal combustion engines and electrical equipment in these groups and categories, the EU-type examination set out in Annex III, in conjunction with either of the following:
      - conformity to type based on internal production control plus supervised product testing set out in Annex VI,
      - conformity to type based on product quality assurance set out in Annex VII;

   (ii) in the case of other equipment in these groups and categories, internal production control set out in Annex VIII and the communication of the technical documentation provided for in Annex VIII, point 2, to a notified body, which shall acknowledge receipt of it as soon as possible and shall retain it;

c for equipment-group II, equipment category 3, internal production control set out in Annex VIII;

d for equipment-groups I and II, in addition to the procedures referred to in points (a), (b) and (c) of this paragraph, conformity based on unit verification set out in Annex IX may also be followed.

2 The procedure referred to in point (a) or (d) of paragraph 1 shall be used for conformity assessment of protective systems.

3 The procedures referred to in paragraph 1 shall be applied in respect of components with the exception of the affixing of the CE marking and the drawing up of the EU declaration of conformity. A written attestation of conformity shall be issued by the manufacturer, declaring the conformity of the components with the applicable provisions of this Directive and stating their characteristics and how they must be incorporated into equipment or protective systems to assist compliance with the essential health and safety requirements set out in Annex II applicable to finished equipment or protective systems.

4 With regard to the safety aspects referred to in point 1.2.7 of Annex II, in addition to the conformity assessment procedures referred to in paragraphs 1 and 2, the procedure referred to in Annex VIII may also be followed.

5 By derogation from paragraphs 1, 2 and 4, the competent authorities may, on a duly justified request, authorise the placing on the market and putting into service on the territory of the Member State concerned of the products other than components in respect of which the procedures referred to in paragraphs 1, 2 and 4 have not been applied and the use of which is in the interests of protection.

6 Documents and correspondence relating to the conformity assessment procedures referred to in paragraphs 1 to 4 shall be drawn up in a language, determined by the Member State concerned.

Article 14

EU declaration of conformity

1 The EU declaration of conformity shall state that the fulfilment of the essential health and safety requirements set out in Annex II has been demonstrated.

2 The EU declaration of conformity shall have the model structure set out in Annex X, shall contain the elements specified in the relevant conformity assessment procedures set out in Annexes III to IX and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the product is placed or made available on the market.

3 Where a product 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 product with the requirements laid down in this Directive.

Article 15

General principles of the CE marking

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

Article 16

Rules and conditions for affixing the CE marking and other markings

1 The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents.

2 The CE marking shall be affixed before the product is placed on the market.

3 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.

4 The CE marking and, where applicable, the identification number of the notified body shall be followed by the specific marking of explosion protection  , the symbols of the equipment-group and category and, where applicable, the other markings and information referred to in point 1.0.5 of Annex II.

5 The CE marking and the markings, symbols and information referred to in paragraph 4, and, where applicable, the identification number of the notified body, may be followed by any other mark indicating a special risk or use.

Products that are designed for a particular explosive atmosphere shall be marked accordingly.

6 Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.