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Electronic provision of documentation for components in accordance with the ATEX Directive 2014/34/EU

CURRENT SITUATION

Article 6(2) of the revised ATEX Directive 2014/34/EU requires components satisfying the definition in Article 2(3) of the directive ("any item essential to the safe functioning of equipment and protective systems but with no autonomous function") to be accompanied by an attestation of conformity in accordance with Article 13(3). Article 6(8) of the new directive further contains the requirement for instructions and safety information to be supplied with the *products*. This would include components. However, Annex II, Paragraph 1.0.6, requires instructions to be supplied only with the *equipment and protective systems*.

THE ISSUE

It is important to first clarify what documentation is actually to be supplied with components. The future guidelines on the revised ATEX Directive would be a suitable medium for this purpose. The primary problem concerns the manner in which the documentation is to be supplied. Components are often very small items supplied in a wide range of batch sizes and package quantities. The "batch" solution described in Article 6(2), according to which a single copy of the attestation of conformity per batch is sufficient where a large quantity of products is supplied to a single user, is of some assistance. This provision ceases to apply, however, once individual items have been removed from the batch packaging for further sale or further distribution. In addition, the provision in Article 6(2) concerns only the declaration or attestation of conformity, and not the instructions.

Orgalime believes an alternative to supplying all required documents for components with the components themselves should be permitted, since the conformity assessment procedure for a component differs from those of a device, as, for the component, an additional assessment as part of a device is demanded.

Such a requirement for components is not proportionate for example to:

- The very often small component size,
- small delivery quantities associated with enormous quantities produced and
- large possible variances installed in the final end user application (device).

PROPOSED SOLUTION

An alternative means of satisfying the information obligation is therefore for a reference to be provided in the delivery documentation or on the smallest additional packaging to a website or other source from which the information can be obtained.

Such sources of information include:

Orgalime, the European Engineering Industries Association, speaks for 43 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.3 million people in the EU and in 2014 accounted for more than €1,825 billion of annual output. The industry accounts for over a quarter of manufacturing output and a third of the manufactured exports of the European Union.

- a. A link to the manufacturer's website www.xxyyyz..... in plain text on each packaging unit or on the delivery documentation or
- b. Cross-media information (such as a QR code or RFID chip) on each packaging unit or in the delivery documentation that links to a database or provides the required data directly.

REASONING

A similar solution has proved effective in the past in the R&TTE Directive 1999/5/EC, which has now been replaced by the revised version, 2014/35/EU. Commission Regulation (EU) No 207/2012 on electronic instructions for use (EIFU) of medical devices also enables the supply of documentation to be simplified.

Several particular aspects apply to components under the ATEX Directive that also justify such a simplified arrangement:

- Components are industrial products intended solely for professional and skilled users who must in any case obtain more detailed information on the products to be used.
- Components, such as terminals, must be assessed again in their final application in the equipment, device or installation, particularly with regard to the safety aspect and satisfaction of the essential requirements. The same applies to maintenance and repair.
- Components are items of low complexity; the required instructions can therefore also be presented in a simple format.
- Components are generally small items and mass-produced products. They are sold from opened packages and in small quantities requested by customers, and provision of the entire documentation with them constitutes an unreasonable logistical overhead.
- Multi-format publishing of information as e.g. via QR codes and access from smartphones generally makes the information accessible more rapidly in multiple languages than searching for and retrieving printed documentation from an unknown location.

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