

## Ex PROOF KOMBİNE EKİPMAN (Ex ASSEMBLY)

(Birden Fazla Ekipmanın bir araya getirilmesi, yani montajı ile oluşturulmuş "Kombine"; (yani monte edilmiş birden fazla ekipmandan ve elektriksiz kısımlardan oluşan kombine (=Bütünleşik Ekipman) ASSEMBLY için Teknik Dosya İçeriği şunlardan oluşmalıdır:

- 1- Teknik Çizimler (Belgesi olanlar ve diğerlerinin bağlantılarını ve yerleşimini gösteren çizimler)
- 2- ATEX 2014/34/AB Ek 2 ye göre Risk Analizi (Assembly içinde yer alan Tüm Elemanlar için)
  - a. Rulman
  - b. Halat
  - c. Vana (valf)
  - d. Hidrolik Teçhizat
  - e. Pnömatik Teçhizat
  - f. Kayış vb. için herbirinin ateşleme tehlikesinin analiz edildiği
- 3- Elektrikli Ekipmanın;
  - a. Sertifikaları ve X işareti (Özel Şartlar)açıklamaları
  - b. Ex İşaretlemeleri (Ex Marking)
- 4- Kullanım (Operasyon) Montaj ve Bakım Talimatları
- 5- Bileşen Listesi (Kombine Ekipman içinde bulunan Elektrikli Ekipman Listesi)
- 6- Test Raporları:
  - a. Plastik Malzeme veya
  - b) Kayış varsa Antistatiklik Test Raporu
  - c) Hidrolik veya Pnömatik Bileşen varsa bunların Test Raporları
- 7- Standartlar Listesi (Ekipmanın tabi olduğu Ex standartların tamamı ve versiyonları )
  - a) TS EN 80079-36 Elektrikli Olmayan Teçhizat Standardı
  - TS EN 80079-37 Elektrikli Olmayan Teçhizat Standardı "c"(Yapısal Koruma )
  - "b"(Ateşleme Kaynağının Kontrolü) "k" (yağa Daldırma) Koruma tiplerinin birleştirildiği ve "h" olarak belirlendiği standart
- 8- Kombine (Assembly) Ekipmanın Etiket tasarımı
- 9- Kombine (Assembly) Ekipmanın Uygunluk Beyanı (Declaration of Conformity)

### ATEX 2014/34/EU GUIDELINES 2017

#### **§ 44 Combined equipment (assemblies)**

#### **Başlığı Altında Aşağıdaki Açıklamalar Vardır:**

From the term "jointly" in the definition of equipment in the Directive (Article 2(1)) it follows that a product, formed by combining two or more pieces of equipment, together with components if necessary and together with other parts as necessary, that are electrically and mechanically interconnected to create a complete functional assembly, has to be considered as a product falling under the scope of Directive 2014/34/EU. This

combined product or assembly must be placed on the market and/or put into service by a responsible person (who will then be the manufacturer of that assembly) as a single functional unit.

Such assemblies may not be ready for use but require proper installation. The instructions (Annex II, 1.0.6.) shall take this into account in such a way that compliance with Directive 2014/34/EU is ensured without any further conformity assessment provided the installer has correctly followed the instructions.

In the case of an assembly consisting of different compliant pieces of equipment as defined by Directive 2014/34/EU which were previously placed on the market by different manufacturers these items of equipment have to conform with the Directive, including being subject to proper conformity assessment, CE-marking, etc. The manufacturer of the assembly may presume conformity of these pieces of equipment and may restrict his own risk assessment of the assembly to those additional ignition and other relevant hazards (as defined in Annex II) which become relevant because of the final combination. If there are additional ignition hazards, a further conformity assessment of the assembly regarding these additional risks is necessary. Likewise, the assembler may presume the conformity of components which are accompanied by a written attestation of conformity issued by their manufacturer (Article 6(2)) (see also section § 74 on obligations of manufacturers).

However, if the manufacturer of the assembly integrates parts without CE marking into the assembly (because they are parts manufactured by himself or parts he has received from his supplier in view of further processing by himself) or components not accompanied by the written attestation of conformity, he shall not presume conformity of those parts and his conformity assessment of the assembly shall cover those parts as required.

Note that the manufacturer's own risk assessment does not necessarily preclude the use of notified bodies in the applicable conformity assessment procedure(s).

In order to clarify the concept of "assembly" in the sense of Directive, a pump/electric motor combination intended for use in potentially explosive atmospheres can be used as an example.

1. For the purposes of Directive 2014/34/EU, a split tube motor pump constitutes a single item of equipment with respect to the ignition hazard, i.e. the pump and electric motor cannot be considered separately for the purposes of assessing explosion risk(s). In this case, the unit as a whole has to undergo the conformity assessment procedure of electrical equipment. The same applies e.g. for an electrical ventilating fan where the fan is an integral part of the motor.

2. a) In some cases the pump and electric motor can be considered separately although they form a functional unit. If in this case there is no additional ignition hazard as a result of assembling the pump and motor, this functional unit as a whole does not constitute a single item of equipment which falls within the scope of Directive 2014/34/EU. It is then to be considered a combination of "individual items of equipment" in terms of explosion protection. In this case, therefore, the manufacturer of pump and electrical motor must supply an EU declaration of conformity for each of both items.

2. b) A manufacturer may nevertheless choose to supply pump and motor as described in 2. a) with one EU declaration of conformity for the assembly as a whole. In this case further clarification is required as to the obligation of the assembler where only ATEX compliant products (such as equipment and autonomous protective systems) are used. Here it is clear that the assembler needs to undertake an ignition risk assessment to ensure that the nature of the incorporation and assembly has not altered the explosion characteristics of the products with respect to the essential health and safety requirements of the Directive. If the assembler is in any way uncertain as to how to undertake such an assessment, technical advice should be sought and taken into account. This might be the case, for example, if a manufacturer of mechanical equipment needs to connect different pieces of ATEX electrical equipment together as part of the assembly. Once the assembler has successfully undertaken such an assessment and no additional ignition risk has been identified, the general agreement is that he then draws up a technical file, affixes the CE and Ex marking

according to Annex II 1.0.5 of the Directive to the assembly, indicating intended use, signs the EU declaration of conformity covering the whole of the assembly indicating the technical specifications/ standards applied (for example, for electrical inter-connection) and provide instructions for safe use. The assembler therefore takes complete responsibility for the assembly. This procedure does not require the involvement of a notified body.

2. c) If there is an additional ignition hazard as a result of assembling pump and motor, or if one item is not already in full conformity with the Directive, the assembly has to undergo the complete conformity assessment procedure appropriate for the category.

Assemblies may be placed on the market in different ways: with specified configurations of parts or with various configurations.

Combined products (assemblies) which are fully specified configurations of parts

In this case the manufacturer has already defined one or more invariable combination(s) of parts and places them on the market as a single functional unit / single functional units.

An example could be instrumentation consisting of a sensor, a transmitter, a Zener barrier and a power supply if provided by one manufacturer.

The above mentioned parts are put together by the same person (the manufacturer of the assembly), and placed on the market as a single functional unit. This person assumes responsibility for the compliance of the combined product with the Directive.

The EU declaration of conformity, as well as the instructions for use must refer to the assembly as a whole. It must be clear (e.g. by enclosing a list of all parts and/or a list of the safety related data) which is/are the combination(s) that form(s) the assemblies. The manufacturer assumes responsibility for compliance with the Directive, and must therefore, in accordance with Annex II 1.0.6, provide clear instructions for assembly/installation/operation/maintenance etc. in the instructions for use.

Combined products (assemblies) with various configurations

In this case the manufacturer has defined a whole range of different parts, forming a "modular system". Either he or the user/installer selects and combines parts out of this range to form an assembly, which serves the specific task.

An example could be a modular system for flameproof switch- and control gear, consisting of a range of flameproof enclosures of different size, a range of switches, terminals, circuit breakers etc. Although in this case the parts are not necessarily put together by the manufacturer of the assembly, and placed on the market as a single functional unit, the manufacturer is responsible for the compliance of the assembly as long as the parts are chosen from the defined range and selected and combined according to his instructions.

The EU declaration of conformity, as well as the instructions for use must refer to the "modular system" as a whole. It must be clear which the parts that form the modular system are, and how they are to be selected to form a compliant assembly. Therefore the manufacturer must, in accordance with Annex II 1.0.6, provide clear instructions for selection of parts and their assembly/installation /operation/maintenance etc. in the instructions for use. The conformity assessment of such modular systems may be done (as a minimum) by means of the assessment of those intended configurations which are the most unfavourable regarding the relevant risks (worst cases). If those configurations are considered compliant to the essential health and safety requirements of Directive 2014/34/EU the manufacturer may conclude conformity of all other intended configurations as well. If later on other parts are to be added to the "modular system" it may of course become necessary to identify and assess the worst case scenario again.

**The Table 1: Summary of requirements for combined products (assemblies), on the following page, gives a condensed overview of the various situations regarding assemblies and their requirements under the ATEX Directive 2014/34/EU.**

**Table 1: Summary of Requirements for Assemblies**

<b>SITUATION:</b> <b>1. Parts:</b> <b>Assembly is composed of...</b>	Equipment, protective systems, devices (Art. 1.2) all CE-marked (accompanied by a certificate of conformity) and components accompanied by a written attestation (Art. 8.3). (parts with proven conformity) (*)		Equipment, protective systems, devices (Art. 1.2), including non CE-marked, and components <u>not</u> accompanied by a written attestation (Art. 8.3). (parts without proven conformity)	
<b>2. Configuration:</b> <b>Assembly is placed on the market as...</b>	Exactly defined configuration(s)	A "modular system" of parts, to be specifically selected and configured to serve a specific purpose, maybe by the user/installer.	Exactly defined configuration(s)	A "modular system" of parts, to be specifically selected and configured to serve a specific purpose, maybe by the user/installer.
<b>3. RESULT:</b> <b>Manufacturer may presume conformity for...</b>	All parts	All parts	Only parts with proven conformity	Only parts with proven conformity
<b>4. Conformity Assessment (CA)</b>	CA has to cover the whole configuration regarding all risks, which might arise by the interaction of the combined parts, with respect to the intended use.  See also Note (*)	CA has to cover at least those of the possible and useful configurations, which are assessed to be the most unfavourable regarding all risks, which might arise, by the interaction of the combined parts, with respect to the intended use.  See also Note (*)	CA has to cover: - all parts without proven conformity regarding all risks, and - all configuration(s) regarding all risks which might arise by the interaction of the combined parts, both with respect to the intended use.	CA has to cover: - all parts without proven conformity which are part of the "modular system", regarding all risks, and - at least those of the possible and useful configurations, which are assessed to be the most unfavourable regarding all risks which might arise by the interaction of the combined parts, both with respect to the intended use.
<b>5. Information to be provided:</b> <b>a) by EC-Declaration of Conformity</b> <b>b) by instructions for installation and use</b>	a) identification of the items in the assembly that are ATEX equipment in their own right, and which have been separately assessed;  b) instructions for installation and use, sufficient to ensure that resulting assembly complies with all relevant EHSRs of Directive 94/9/EC.	a) identification of the items in the "modular system" that are ATEX equipment in their own right, and which have been separately assessed;  b) instructions for the selection of parts, to be combined to fulfil the required purpose, and instructions for installation and use, sufficient to ensure that resulting assembly complies with all relevant EHSRs of Directive 94/9/EC.	a) identification of the items in the assembly that are ATEX equipment in their own right, and which have been separately assessed;  b) instructions for installation and use, sufficient to ensure that resulting assembly complies with all relevant EHSRs of Directive 94/9/EC.	a) identification of the items in the "modular system" that are ATEX equipment in their own right, and which have been separately assessed;  b) instructions for the selection of parts, to be combined to fulfil the required purpose, and instructions for installation and use, sufficient to ensure that resulting assembly complies with all relevant EHSRs of Directive 94/9/EC.

(\*) Note: A written attestation of conformity for a component can not guarantee, in general, the safety of the equipment into which the component is to be incorporated, as for a component, all possible use can not be foreseen. In this case, further investigation and evaluation by a Notified Body shall be carried out in the assembly, when required.