ATEX 94/9/EC Directive

Declaration of Conformity: Tips and FAQ’s

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Introduction

This technical white paper clarifies some of the basic concepts within every “New Approach” European Directive. As a Notified Body, Intertek deals with the technical and legal aspects of the ATEX Directive on a day to day basis. Thanks to the experiences we’ve had with our clients and by means of responding to their most frequently asked questions we have written this white paper and hope the following will help you to prepare your documents in a way that is clear, concise and as legally correct as possible.

Key words
EC Declaration of Conformity = ATEX Declaration of Conformity = DoC
Single market
New approach

ATEX Directive and the EC Declaration of Conformity (DoC)

The 94/9/EC Directive is a Directive of the New Approach: it requires the CE Mark and the EC Declaration of Conformity (DoC).
The DoC, accompanies the product during its placing on the market. Signing this document, the manufacturer declares to be the sole and ultimate person responsible for:

- The design and manufacture of the product in accordance with the Essential Health and Safety Requirements (EHSR) listed in the Directive
- Carrying out conformity assessment in accordance with the procedures described in the Directive

What is the single market?
It is the economic space, included in the European Union, where goods, services, capital and labour can circulate freely.

Prior to the creation of the single market, it was more difficult for manufacturers to sell their products in other European countries.
In fact, for each one, it was necessary to be in compliance with National, and sometimes regional, laws.
This cost time, economic and intellectual resources.
The need for a common set rules moved the Community to create the Single Market removing the barriers to trade between the European member states.

What is the New Approach?
The terms “New Approach” and “New Approach Directives” indicate the product regulations relating to the European Single Market.
As reported on the European Commission official web site (www.ec.europa.eu), “The new approach is a regulatory technique for technical harmonisation whereby
product legislation is restricted to the requirements necessary to protect the public goals of health and safety”.

The New Approach has more recently been referred to as “New Legislative Framework”, and is described on the EC website (http://ec.europa.eu/enterprise/glossary/index_en.htm) as:

**New Legislative Framework (NLF)**

- Regulation (EC) 764/2008 on the free circulation of products in the non harmonised area
- Regulation (EC) 765/2008 on the accreditation of conformity assessment bodies and on the organisation of market surveillance
- Decision 2008/768/EC on general principles that the Parliament & Council should follow in the future for legislation covering the free circulation of products (definitions, rights and obligations of the various players, and conformity assessment modules)

**Which are the “New Approach” Directives?**

Since the development of the “New Approach” concept, several European Directives have been adopted throughout Europe.

ATEX 94/9/EC, Machinery 2006/42/EC and PED 97/23/EC are included and they require the CE marking.

Other directives are listed on the official European web site.

**What are the main advantages following the adoption of the “New Approach” Directives?**

This kind of Directive defines only basic concepts and schemes to demonstrate the compliance of a product to the Directive itself. Avoiding dealing with technical aspects they are not subjected to become obsolete as the state of the art changes.
If you are a Manufacturer

As a manufacturer, what do I have to write in my DoC?
The ATEX Directive dedicates ANNEX X – part b to the elements of what a DoC must contain.
Note that in an EC DoC, the logo “CE” must appear.
The following bullet points explain the text of Annex X:

- the name or identification mark and the address of the manufacturer or his authorised representative established within the Community;
  The address must be clear and specifies the European Country.

- a description of the equipment, protective system, or device referred to in Article 1 (2);
  The subject of the EC Declaration of Conformity must appear:
  - name (e.g.: pump, reciprocating compressor, level gauge, flame proof enclosure, etc.)
  - type or model number (in case of ATEX Unit Verification certificate, the Serial Number must appear on the DoC)
  - any other relevant supplementary information, such as lot, batch or serial number, sources and number of items
  - It is permitted to write only one document for several types or series of equipment, but they must be clearly specified.

- all relevant provisions fulfilled by the equipment, protective system, or device referred to in Article 1 (2);
  Even if this part is not immediately interpretable, it means that the marking of the equipment must appear on the document, including the EX logo and all other information present on the ATEX name plate

- where appropriate, the name, identification number and address of the notified body and the number of the EC-type-examination certificate;
  “Where appropriate” has the meaning of “where Notified Body intervention is mandatory, e.g. Annex III – EC Type Examination”. In other words, if a certificate is present, the DoC must contain a clear reference to it. All the data needed to identify the Notified Body who issued the EC-type certificate can be found on the certificate itself.

- where appropriate, reference to the harmonised standards;
  In this case, “Where appropriate” means that if harmonised standards have been adopted (totally or in part), they must appear in the document. The reference will be the European Reference, including the year of issuing.
E.g.: Correct form EN 60079-1: 2007
Incorrect form BS 60079-1: 2007

• where appropriate, the standards and technical specifications which have been used;
Other technical documents than the harmonised standards can be adopted during designing and production of the equipment. They must be listed and it will be better to keep them separately from the harmonised standards. Other technical documents can be applied during the design and manufacturing. They will be listed in the DoC even if they do not confer the presumption of conformity to the equipment or are listed in the Official Journal as Harmonised Standards.

• where appropriate, references to other Community Directives which have been applied;
An ATEX product is often subjected to other directives (PED, Machinery, RTTE, etc). This must be stated in the ATEX Declaration of Conformity (which itself may be a DoC covering several directives, not just ATEX).

• identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorised representative established within the Community.
“Identification” means that a person must be identified. A printed name and surname is sufficient, without the specification of the role within the company. The term “signatory” means that a signature is required. A digital signature is allowed, due to the fact that for bulk products it is not reasonable to hand-sign every EC Declaration of Conformity.

Other than the contents listed in the ANNEX X – part b of the ATEX Directive, is there any other information that can be written in the EC Declaration of Conformity?
Yes. It is quite common and well considered to write on the DoC the number of the Production and Product Quality System certificates (ANNEX IV and VII) and the data related to the notified body that has issued it. In case of equipment subjected to the procedure of logging of the technical file, it is recommended to write in the DoC the reference to the number of logging of the technical file and the reference to the Notified Body that is filing it.

I am a manufacturer but I did not design the equipment. May I share the responsibility of the product?
No. In any case a manufacturer can discharge himself from his responsibility. If some of the productive phases had been subcontracted, the manufacturer must retain the overall control of the product.
I am a manufacturer based in a Country which is not part of the European Community. Do I have to write an ATEX Declaration of Conformity?
Yes. Even if you are not based in a Member State, as soon as your products are placed onto the European Market they must comply with the European regulations. You must comply with all applicable Directives.

I have an ETL (or other NRTL) listing/certificate. May I sell my product in Europe?
No. Even if NRTL listings/certificates are technically comparable to an EC Certificate, the European Market does not admit the placing on the European Market (and the consequently put into service) of product not in compliance with the European Regulations. The suitable ATEX conformity assessment procedure must be applied, the CE and ATEX logos must be reproduced on the equipment and the DoC must be drawn up.

I have an IECEx certificate. May I sell my product in Europe?
No. The product must be submitted to the ATEX Directive conformity assessment procedures, it must be consequently marked and the EC Declaration of Conformity must be drawn up.
It is extremely important to note that IECEx scheme offer a Fast Track procedure to obtain an ATEX certificate: a Notified Body can issue an ATEX certificate based on the IECEx Test Reports/Certificates issued by an IECEx Test Laboratory/Certification Body.

I have an EC type ATEX Certificate (or an ATEX Unit verification certificate) issued by a Notified Body. Do I have to give a copy of it to my clients? Do I have to give them an EC Declaration of Conformity?
It is always mandatory to give the DoC to the clients.
To give to the clients a copy of the EC ATEX Certificate is often a contractual requirement, but not compulsory.

Do I have to retain a copy of my EC Declaration of Conformity?
Yes. The DoC must be kept for at least ten years from the last date of manufacture of the product.
The manufacturer must make available to the Relevant Authorities immediately upon request, all documents pertaining to the manufacture of product placed on the European Market for up to 10 years after the last manufacture of that product.

Do I have to insert the DoC in my ATEX technical file?
No. The text of the ATEX 94/9/EC Directive describes thoroughly the contents of the Technical File and does not list the DoC. This means that the EC Declaration of Conformity must be drawn up once the Conformity procedure has been completed:
- after receiving certification or other such documentation from the Notified Body.
- after completion of the requirements of Internal Control of Production (per Annex VIII of the ATEX Directive) and receiving the attestation of lodge of the technical file by a Notified Body, for non-electrical equipment of Category 2
- after the completion of the requirements of Internal Control of Production (per Annex VIII of the Directive), for equipment of Category 3 (Electrical)

Is there a mandatory format or a suggested template that I have to use to drawn up my Declaration of Conformity?
No. The mandatory requirements are related to the contents only.

My ATEX EC Type Examination Certificate cites a standard edition that is no longer identified by the European Commission as a harmonised standard. Do I have to ask for an update of the Certificate?
Do I have to change my EC Declaration of Conformity?
The issuing of a new edition of a standard, not always represents a change in the "state of the art".
A revised standard can contain three types of changes:
   a. minor and editorial changes
   b. extensions
   c. major technical changes

In case of a. minor and editorial changes and of b. extensions to the standard, the edition cited in the certificate, still represents the state of the art because it still demonstrate compliance to the Essential Health and Safety Requirements of the ATEX 94/9/EC Directive.
The manufacturer is not obliged to change the name plate but he needs to record the correct standard in its DoC.
A justification is required, to explain that the currently harmonised standard and the edition cited on the EC type Certificate has been compared and that no changes to the state of the art are applicable to the product.

The manufacturer is also free to choose to re-submit its product to a Notified Body, requiring a new certificate or a supplement to the existing one. In this case, it will be possible to have a modification of the marking written on the EC Type Examination Certificate (e.g.: "EEx" using by the EN 50014 series, will be corrected in "Ex" used by the EN 60079 series). As a consequence, the manufacturer will need to update the nameplate, the Instruction for use and the DoC.

In the case of c. major technical changes, the EC type Certificate is no longer considered to satisfy the Essential Health and Safety Requirements. A new EC type certificate or a supplement to the existing one is needed.

In all instances, it is the responsibility of the manufacturer, or person placing on to the European Market, to conduct a full and formal risk assessment of how the
changes in standard affect the conformity of the product under declaration.

In which language do I have to write my EC Declaration of Conformity?
The DoC must be written in the official language of the Country where the product will be used. A manufacturer can write the original document in its own language (unless it is one the official languages of the Community) and provide to its clients the translations also.

I want to export my product in a non-European country. Do I have to translate the EC Declaration of Conformity in the official language of that country?
No. The DoC is a document required only within the European Market. Outside Europe it has no legal validity. Manufacturers trading with a non European country must be in compliance with the rules of that country.

My ATEX EC Type Examination Certificate number ends with the letter "U". Do I need to write the EC Declaration of Conformity?
No. You are manufacturing a "component", so you just need to write an Attestation of Conformity. It does not contain any reference to the CE marking. It must declare the characteristics of the components and it must explain how the component can be incorporated in an ATEX certified equipment.
If you are an End User

I have purchased an ATEX certified piece of equipment. What do I have to do with the EC Declaration of Conformity?
You need to store it for as long as you will use that equipment.

I have purchased an ATEX certified piece of equipment. I have not received the ATEX EC Declaration of Conformity and/or I have received a copy of the EC Type Examination (or Unit Verification) Certificate.
Manufacturers are not allowed to put on the market equipment without the DoC. Even if the certificate has been provided, the user is allowed to expect the EC Declaration of Conformity. The manufacturer is not allowed to claim an extra charge.

I can prove to the relevant authorities that I have requested from the manufacturer the ATEX EC Declaration of Conformity, but he did not provide it. May I use the equipment?
Without a DoC issued by the manufacturer, the end user will become the person responsible for declaring the product to be compliant with all necessary directives.

I have designed and manufacturer an assembly, using previously ATEX certified equipment. Do I have to write my own EC Declaration of Conformity for the whole assembly?
This condition shall be discussed with the final client during the definition of the agreement. This is discussed in greater depth in the ATEX guidelines, and comes down to the definition of equipment versus installation. If the assembly being supplied is to be declared as equipment, then a DoC must be supplied for the “equipment”. Is it also possible to consider the assembly as a group of single units previously ATEX marked by different manufacturers. In this case the assembler needs only to collect all the DoC and to incorporate them in the document pack sent to the final user.

I have designed and manufactured an "assembly" that I wish to refer to as “equipment”. I have drawn up my own EC Declaration of Conformity; do I have to give to the final user all the Declaration of Conformity related to the previously certified equipment I have used?
No. With its own DoC the manufacturer of the “equipment” assumes the responsibility of the assembly. It is necessary, instead, that the manufacturer of the "assembly" will retain all the Declarations of Conformity in its Technical File, to be stored for at least ten years after the putting on the market of the skid.
How Intertek can help

Intertek can help with your compliance requirements, from ATEX/IECEEx/ETL, to EMC, Machinery, RoHS, WEEE testing as well as services for compliance with diverse national and international codes, rules and requirements. Our testing and certification solutions for manufacturers help to reduce time to market which directly impacts their bottom line. If you wish to speed up your time to market and would benefit from one of our dedicated engineers working with your engineers at your site, our labs, or any other convenient facility, then please contact us to find out more.

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