

DECLARATIONS OF CONFORMITY AND STANDARDS AMENDMENTS

All “New Approach” European Directives require products placed on the market to be accompanied by a “Declaration of Conformity” (DoC) which claims compliance with the directive. Components for Incorporation (only conforming with some of the requirements of the directive) are provided with an “Attestation of Conformity” which follows the identical principles to the full DoC. Although this document is written specifically in the context of the European ATEX Directive 2014/34/EU, it also applies to the equivalent UK legislation that came into effect at the end of the Brexit transition period on 1 January 2021. The UK legislation is UKSI 2016:1107 (as amended by UKSI 2019:696). In this document, reference to a requirement in the Directive can also be taken as a reference to the equivalent part of the UK legislation. Reference to a European harmonised standard should also be taken as a reference to a UK designated standard. Separate Declarations of Conformity are required for Europe and for the UK, as shown in the examples in the Annex to this document.

It is important to note that the declaration is made on the day the product is placed on the market. Each individual example of a product is treated separately in a legal sense, so the declaration must relate to the way the directive is implemented on the date the individual product is placed on the market, not the date the first example of the product was placed on the market. Although the directive itself may not change, the new approach allows related aspects, such as harmonised standards, to change. It is not always easy for the manufacturer to follow such second level changes and to calculate the impact on the DoC over the lifespan of a particular product range.

This publication outlines responsibilities in this area and indicates where information is available that will help a manufacturer keep his declarations up to date in the most cost effective manner. Example declaration are provided in the Annex. Although what follows is applicable in principle to all the new approach directives, it is described solely in relation to the ATEX Directive 2014/34/EU. Annex X of the directive (reproduced here) lists exactly what must be included in the Declaration of Conformity:

1. Product model/product (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative;
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of product allowing traceability; it may, where necessary for the identification of the product, include an image):

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) performed (description of intervention) and issued the certificate:
8. Additional information:
Signed for and on behalf of:
(place and date of issue):
(name, function) (signature):

Note that paragraph 227 of the ATEX Guidelines document (available from http://ec.europa.eu/growth/sectors/mechanical-engineering/atex_en) provides additional commentary on these requirements.

Annex II of the directive “The Essential Health and Safety Requirements” (EHSRs) has the following statement right up front:

“Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilized immediately.”

It therefore follows that a manufacturer must maintain awareness of changes in technological knowledge and any impact that this may have on the continuing validity of the form of a declaration. Fortunately we have a fairly common understanding of “current technological knowledge” (also known colloquially as “state of the art”), based on the European standards that have been given “harmonised” status for the directive by having their number published in the Official Journal of the European Union (the OJ).

Particularly, the declaration is required to list the use of harmonised standards and other standards at item 6, with the implication that there is a clear distinction between the two types of documents.

It therefore follows that, throughout the lifetime of a product range, the relevant declaration may have to change up to twice in respect of each standard listed; if it had not been harmonised when the product range was launched, it subsequently became harmonised, and then ceased to be harmonised while the product range was still being manufactured.

This may sound far-fetched but, as a historical example, consider a Category 3G product where EN 50021 was used as the basis of conformity.

- a) The product range was first manufactured in 2000 and the declaration relied on referencing EN 50021: 1999 as “state of the art” for Category 3G electrical equipment, although it was not yet harmonised.
- b) EN 50021:1999 was harmonised in 2001.
- c) EN 50021:1999 ceased to have harmonised status in 2006.

The move from (a) to (b) was a comparatively simple clerical exercise, merely requiring an editorial reworking of the Declaration of Conformity. The move from (b) to (c) is not so simple.

The essence of the directive is compliance with the EHSRs at the time the individual product is placed on the market. If the reason that the standard ceases to be harmonised is that it no longer fulfils the criteria of being based on current technological knowledge, then it cannot stand alone as justification of compliance.

In such a case, the whole set of technical documentation for the product needs to be reviewed and a new justification of compliance prepared.

It may be that changes in the standard, brought about by revision or replacement, do not impinge on the particular product (changes applicable to electric motors, for example, do not impinge on luminaires made to the same standard), in which case a straightforward statement to this effect will be sufficient justification for continuing to use the de-harmonised standard.

However, if the replacement standard has more stringent technical requirements applicable to the product, it will be necessary to prove compliance to those new requirements or to prepare a very careful technical justification as to why the updated requirement should not apply to the product.

The reason EN 50021:1999 was de-harmonised in 2006 is because it had already been replaced by EN 60079-15:2003 and Cenelec Standards Committee TC31 agreed that EN 50021:1999 should be withdrawn in 2006, allowing the normal three year overlap. De-harmonisation normally follows automatically.

Although there are many detailed differences between EN 50021:1999 and EN 60079-15:2003, the one major difference affecting virtually every product is that the standard impact test level was doubled from 3.5J to 7J. (The other impact levels, e.g. applicable to transparent parts, were also increased.)

Did this mean every product requires a new type test? Possibly, yes. Possibly, no.

The existing test report will have given details of the test performed. It may well be that if the product has been certified by a body, such as SGS Baseefa, which was aware of developments in the standards, the test would already have been done at the enhanced level, in order to "future proof" the certification. Relief all round.

The existing report may give justification for "deeming" compliance with the impact test, rather than performing it. This is often done with thick cast iron constructions. A new justification for "deeming" compliance at the higher impact level will be required.

If all else failed, it would be necessary to do the test!

Once the technical justification is sorted out, the necessary compliance modules of the directive have to be followed.

And, of course, EN 60079-15:2003 did not remain harmonised because, with the publication of the next edition in 2005, the normal three year overlap lead to the 2003 edition losing its harmonised status in June 2008. In turn, the 2005 edition lost its harmonized status in 2013, just three years after publication of the 2010 edition. The 2010 edition resulted in a more stringent environmental pre-conditioning for non-metallic enclosures and non-metallic parts of enclosures, as well as a number of other less major changes.

This historical example is given, as it is a very clear cut case of how changes in the standards can be said to reflect a change in the "state of the art". Other comparison of standards may not be so clear cut.

It is not often that a new standard doubles a test requirement, but extra requirements are often introduced. For example, for increased safety, as EN 60079-7 replaced EN 50019 (harmonisation status ceasing in 2006), proof became needed for the new terminal pull test on plastic bodied terminal blocks.

Moving between different editions of a standard used to be a significant problem but, now, as we move from one edition of an EN 60079 series standard to another, life is simpler as the IEC published version of the standard carries a list of the major differences as part of the foreword to the document itself. The IEC has been very kind to us and the information can be downloaded free from the IEC Webstore (<http://webstore.iec.ch/>) as part of the service designed to encourage the direct purchase of the IEC version of the standard.

Cenelec repeats the same information in a similar (hopefully identical) way, when publishing the EN version, in a special "ATEX" Annex ZY which reflects that the standard supports the EHSRs of the ATEX Directive.

So where do the responsibilities lie? SGS Baseefa had always accepted the previously stated view of the UK DTI (now BEIS) and the European Commission that Declarations of Conformity are a purely legal matter for the manufacturer and that Notified Bodies are solely responsible for providing the compliance confirmation in accordance with the modules of the directive. However, during 2004, it was suggested that Notified Bodies might have a legal responsibility to inform manufacturers of relevant changes to standards and how they impinge on the Declaration of Conformity for particular certified products. This was roundly rejected by all the European Notified Bodies at their meeting in Brussels in November that year. The cost of putting a foolproof system in place to monitor all certificates on behalf of manufacturers and ensure that manufacturers would be advised of every change that was applicable to each of their products, would be prohibitively expensive. It also begs the question about responsibilities in respect of equipment declared in accordance with the "Internal Control of Production" module, where there is no Notified Body involvement.

The situation was resolved such that Notified Bodies are considered to have a generalised duty to inform their certificate holders of the nature of changes. However, the responsibility for specific action lies with the manufacturer.

The information in this document, together with the detailed information provided in document DS08 (Harmonisation Status of Common Electrical Standards) and DS67 (Revision and Change of Harmonisation Status of ATEX DIRECTIVE Standards), both available on-line from www.sgs.co.uk/sgsbaseefa, is how SGS Baseefa is fulfilling this responsibility.

The prime document for determining harmonisation status is the list published in the OJ. It would be remarkable if any normal manufacturer monitored the OJ as a matter of routine, so the European Commission makes the latest version.

The equivalent list of UK designated standards is available at <https://www.gov.uk/government/publications/designated-standards-atex>. The two lists are identical on first publication of the UK list and are likely to remain identical for some time, as there is no current intention for the UK to diverge technically from the rest of Europe in respect of Hazardous Atmospheres.

However, the OJ list can never look ahead to show the position of standards

which have not yet been harmonised. It is for this reason that SGS Baseefa regularly publishes an updated list of the most common standards, in BAS-PS-010, to confirm their position in relation to harmonisation issues. Manufacturers therefore have an opportunity to look at future standards and consider the most appropriate document to use for their product.

By reviewing the SGS Baseefa list in BAS-PS-010, and by considering the technical points comparing standards in the published lists of changes (either in the standards or in the ExNB information – see BAS-PS-015 Revision and Change of Harmonisation Status of ATEX DIRECTIVE Standards), manufacturers

can form a view on where changes in harmonisation status affect their products.

We know that not all manufacturers are happy to take such decisions alone, so we provide a basic service to help, and confirm by issuing a supplementary certificate that changes in the state of the art do not affect a product.

For more information visit

www.sgs.co.uk/sgsbaseefa,
alternatively email baseefa@sgs.com

ANNEX – SAMPLE DECLARATIONS OF CONFORMITY

These are fictional examples, intended to show the intention of Annex X of the ATEX Directive, as amplified by Paragraph 227 of the ATEX Guidelines document.

Where a certificate originally issued by SGS Baseefa is used, after transfer to SGS Fimko, the DoC must make the transfer of responsibility clear.

It must be emphasised that the content of the Declaration of Conformity remains the manufacturer's legal responsibility and these examples have been produced solely to assist manufacturers choose appropriate wording.

EXAMPLE 1: DECLARATION OF CONFORMITY IN ACCORDANCE WITH EUROPEAN DIRECTIVE 2014/34/EU ISSUED IN JUNE 2016 FOR AN EQUIPMENT DESIGN FIRST CERTIFIED IN JUNE 2019

The responsibility for the certificate was transferred from SGS Baseefa to SGS Fimko during 2021

EU DECLARATION OF CONFORMITY (NO XXXX)		
Equipment Type: XYZ Widget rated 230V 1.5 A		
Manufacturer:		
Address:		
This declaration of conformity is issued under the sole responsibility of the manufacturer.		
This declaration relates to the XYZ Widget and related variations as described in the certificate, coded:	Group II Category 2GD	Ex db IIB T4 Ex tb IIIC T120°C
The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:	2014/34/EU	
The following harmonised standards and other technical specifications were used in support of this declaration:		
Harmonised Standards:	EN IEC 60079-0:2018 EN 60079-1:2014 EN 60079-31:2014	
Other Standards and Specifications used:	None	
Notified body SGS Baseefa (number 1180) performed EU-Type examination in accordance with Annex III of the directive and issued the certificate: Baseefa19ATEX1234		
Responsibility for the certificate was transferred from SGS Baseefa to SGS Fimko on See related transfer document signed on behalf of both SGS Baseefa and SGS Fimko. The number of the certificate was not changed.		
Notified Body SGS Fimko (number 0598) performed Conformity to type based on quality assurance of the production process in accordance with Annex IV of the directive and issued the QA Notification document: Baseefa ATEX 9999		
Signed for and on behalf of: (manufacturer)	(place and date of issue):	(name, function) (signature):



EXAMPLE 2: DECLARATION OF CONFORMITY IN ACCORDANCE WITH EUROPEAN DIRECTIVE 2014/34/EU MADE IN JUNE 2016 FOR AN EQUIPMENT DESIGN FIRST CERTIFIED IN JUNE 2013

(Note that the original certificate number remains unaltered and the certificate remains valid for the new directive, even though one of the listed standards lost harmonisation status between June 2013 and June 2016)

EU DECLARATION OF CONFORMITY (NO XXXX)		
Equipment Type: XYZ Widget rated 230V 1.5 A		
Manufacturer:		
Address:		
This declaration of conformity is issued under the sole responsibility of the manufacturer.		
This declaration relates to the XYZ Widget and related variations as described in the certificate, coded:	Group II Category 2GD	Ex db IIB T4 Ex tb IIIC T120°C
The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:	2014/34/EU	
The following harmonised standards and other technical specifications were used in support of this declaration:		
Harmonised Standards:	EN 60079-1:2007 EN 60079-31:2009	
Other specifications:	EN 60079-0:2009 – This standard has been compared with EN 60079-0:2012 + A11:2013 (currently harmonised) and no significant changes have occurred which are applicable to this equipment	
Notified body SGS Baseefa (number 1180) performed EU-Type examination in accordance with Annex III of the directive and issued the certificate: Baseefa13ATEX1234		
Notified Body SGS Baseefa (number 1180) performed Conformity to type based on quality assurance of the production process in accordance with Annex IV of the directive and issued the QA Notification document: Baseefa ATEX 9999		
Signed for and on behalf of: (manufacturer)	(place and date of issue):	(name, function) (signature):



EXAMPLE 3: ATTESTATION OF CONFORMITY FOR A COMPONENT IN ACCORDANCE WITH EUROPEAN DIRECTIVE 2014/34/EU ISSUED IN JUNE 2016 FOR AN EQUIPMENT DESIGN FIRST CERTIFIED IN JUNE 2016

EU ATTESTATION OF CONFORMITY (NO XXXX)		
Component Type: ABC Empty Enclosure Manufacturer: Address:		
This attestation of conformity is issued under the sole responsibility of the manufacturer.		
This attestation relates to the ABC Empty Enclosure and related variations as described in the certificate, coded:	Group II Category 2GD	Ex db IIB T4 Ex tb IIIC T120°C
The object of the attestation described above is in conformity with the relevant Union harmonisation legislation:	2014/34/EU	
The following harmonised standards and other technical specifications were used in support of this attestation:		
Harmonised Standards:	EN 60079-0:2012 + A11:2013 EN 60079-7:2015 EN 60079-31:2014	
Other specifications:	None	
Notified body SGS Baseefa (number 1180) performed EU-Type examination in accordance with Annex III of the directive and issued the certificate: Baseefa16ATEX1234U		
Notified Body SGS Baseefa (number 1180) performed Conformity to type based on quality assurance of the production process in accordance with Annex IV of the directive and issued the QA Notification document: Baseefa ATEX 9999		
Signed for and on behalf of: (manufacturer)	(place and date of issue):	(name, function) (signature):



EXAMPLE 4: DECLARATION OF CONFORMITY IN ACCORDANCE WITH EUROPEAN DIRECTIVE 2014/34/EU ISSUED IN JUNE 2016 FOR A NON-ELECTRICAL ITEM OF CATEGORY 2 EQUIPMENT DESIGN FIRST CERTIFIED IN JUNE 2016

EU DECLARATION OF CONFORMITY (NO XXXX)		
Equipment Type: XYZ Artefact		
Manufacturer:		
Address:		
This declaration of conformity is issued under the sole responsibility of the manufacturer.		
This declaration relates to the XYZ Artefact and related variations as described in the certificate, coded:	Group II Category 2G cb IIB T4	
The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:	2014/34/EU	
The following harmonised standards and other technical specifications were used in support of this declaration:		
Harmonised Standards:	EN 13463-1:2009 EN 13463-5:2011 EN 13463-6:2005	
Other Specification:	EN ISO 4413	
Notified body SGS Baseefa (number 1180) holds a copy of the dossier (number ???) created by the manufacturer in accordance with Annex VIII of the directive, and deposited in accordance with article 13, 1 (b) (ii) of the directive, and has issued receipt number: Baseefa16ATEX1234DR		
Signed for and on behalf of: (manufacturer)	(place and date of issue):	(name, function) (signature):

EXAMPLE 5: DECLARATION OF CONFORMITY IN ACCORDANCE WITH UK STATUTORY INSTRUMENT UKSI 2016:1107 (AS AMENDED BY UKSI 2019:696) ISSUED IN JUNE 2021 FOR AN EQUIPMENT DESIGN FIRST CERTIFIED IN JUNE 2021

UK DECLARATION OF CONFORMITY (NO XXXX)		
Equipment Type: XYZ Widget rated 230V 1.5 A		
Manufacturer:		
Address:		
This declaration of conformity is issued under the sole responsibility of the manufacturer.		
This declaration of conformity is issued under the sole responsibility of the manufacturer.	Group II Category 2GD Ex db	
This declaration relates to the XYZ Widget and related variations as described in the certificate, coded:	IIB T4 Ex tb IIIC T120°C	
The object of the declaration described above is in conformity with the relevant United Kingdom legislation:	UKSI 2016:1107 (as amended by UKSI 2019:696)	
The following designated standards and other technical specifications were used in support of this declaration:		
Harmonised Standards:	EN IEC 60079-0:2018 EN 60079-1:2014 EN 60079-31:2014	
Other Standards and Specifications used:	None	
Approved body SGS Baseefa (number 1180) performed UK-Type examination in accordance with Schedule 3A, Part 1 of the legislation and issued the certificate: BAS21UKEX1234		
Approved Body SGS Baseefa (number 1180) performed Conformity to type based on quality assurance of the production process in accordance with Schedule 3A, Part 2 of the legislation and issued the QA Notification document: BAS UKQAN 9999		
Signed for and on behalf of: (manufacturer)	(place and date of issue):	(name, function) (signature):



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