

Guideline**10/5****CLAP****FORM N°175****Version : 2****Directive 97/23/EC****Keywords :**

Standard

Essential requirement

Conformity

Code

Directive references:

Article 5 - 97/23 EC

16th recital - 97/23 EC

17th recital - 97/23 EC

Adopted by WPG: 28/11/2001**Adopted by CLAP:** 28/11/2001**Subject:**

New approach – Normative references in harmonized standards to other EN and non-EN standards

Question:

Harmonized standards frequently use normative references to other EN and non-EN standards. Do these referenced standards also confer presumption of conformity to the ESRs?

Answer:

1/2.

It depends on the type of reference:

1. When a reference (which is contained in a part of a standard which provides presumption of conformity) to a particular, limited section of another standard, is used as a particular description in the harmonized standard, then the presumption of conformity extends to this reference.

In exceptional cases, an entire standard can be used as a particular description in the harmonized standard (test standards for instance).

In both cases, the referenced standards shall be dated. If it is not dated, the version valid at the time of publication of the standard containing the reference shall be used.

It should be noted, that the presumption of conformity is not valid for the referenced parts or standards independently, but only when applied in the context of the harmonized standard containing the references.

2. Other references, such as:

- references contained in an informative part,
- references with no direct relevance to harmonized normative parts,
- references to informative parts/documents,
- reference to pre-standards (ENV), technical specifications (TS); or other deliverables such as Technical reports (TR) or CEN workshop agreements (CWA),
- references to non EN standards, non ISO/IEC standards which do not comply with the applicable CEN/CENELEC rules (see note 1), do not confer this presumption of conformity.

It should also be noted that the entire reference list, which typically is given as clause 2 of EN standards, does not in itself confer presumption of conformity.

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Answer:

2/2

Note 1: Applicable CEN/CENELEC rules require the following:

- ensure that no suitable CEN, CENELEX, ETSI, ISO or IEC documents are available and confirm that there is a necessity to refer to a document other than those developed by CEN/ CENELEC, ETSI, ISO and IEC;
- confirm that it is impractical to include the relevant text in full;
- justify the need for making reference to a document other than those developed by CEN, CENELEC, ETSI, ISO and IEC;
- ensure and confirm that the referenced document shall:
 - have wide acceptance
 - not be in contradiction with the European legislation, nor create regulatory problems when the EN is implemented by CEN/CENELEC members;
 - have been in accordance with the principles set in ISO/IEC Guide 59 – Code of Practice for Standardization (with the definitions of EN 45020) and in the ISO/IEC Directives;
 - have clearance in respect of possible IPR (Intellectual property rights) issued as prescribed in CEN/CENELEC Memorandum 8;
 - not to be a draft, but shall be an adopted document with an identified and dated issue;
 - be publicly available in official CEN/CENELEC languages, at least in English.

Note 2 : For a harmonized standard whose reference is published in OJEC, the annex ZA gives the relation between the ESR's covered by the standard and the corresponding clauses of this standard.

Modifications compared to the previous adopted version: Editorial correction on 2004-09-16.