



THE SUPPLIER'S DECLARATION OF CONFORMITY (SDoC) IN THE EUROPEAN REGULATORY FRAMEWORK

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SDoC (1) - What it is

- **Defined under Decision 768/2008 “on a common framework for the marketing of products”**
- **It means that the fulfillment of legislative requirements applying to a product has been demonstrated**
- **The essential objective is to enable public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the sectoral legislation**
 - **Consequently, the primary reader of the SDoC are the public authorities**
 - **Yet, the consumer or user is also an intended reader in many cases**
- **No Conformity Assessment Bodies involved for Modules A, C**

SDoC (2) - Drafting

- **SDoC is always drawn up by the manufacturer for each product model:**
 - **Upon successful assessment of the conformity of the product against the legislative requirements that apply to it and**
 - **Independent of the fact if a conformity assessment body has intervened (or not) during the conformity assessment process – the conformity assessment is carried out (in many cases) by the manufacturer**
- **The procedures for conformity assessment are laid down in the sectoral legislative act(s) that apply to the product**
 - **All procedures are set out in Decision 768/2008 serve for the sectoral legislator as a simple, coherent and complete menu to select the most appropriate ones for the specific area of activity.**

SDoC (3) – Stakeholders obligations

- When drawing the declaration of conformity, the manufacturer must also always affix the CE Marking on the product
- By drawing up the EC declaration of conformity and affixing the CE Marking, the manufacturer shall assume responsibility for the compliance of the product.
- The manufacturer or importer must keep it at the disposal of the national authorities for ten years after the product has been placed on the market.
 - However according to art 4.5.b of the Decision 768/2008, the legislator may alter this period

SDoC (4) – Stakeholders obligations

- **A copy of the declaration of conformity shall be made available to the relevant authorities upon request**
- **Moreover, some Directives (e.g. relating to machinery) require that individual products are accompanied by the SDoC**

SDoC (5) – Stakeholders obligations

- **The SDoC must be translated into the language or languages required by the Member State in which market the product is placed or made available**
- **The non-drawing or the incorrect drawing of the SDoC constitute a case of non-compliance of the product to legislation and are subject to sanctions according the relevant national legislation**
- **The manufacturer's obligations regarding SDoC and CE Marking may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate**

SDoC (6) - Content

The content and the format of the EC declaration of conformity are laid down in Annex III of the Decision 768/2008 and are based on EN ISO 17050-1:2004[1] that has replaced EN 45014:1998

- This standard has been drawn up with the objective of providing the general requirements for the declaration of conformity and addresses first-, second- (not relevant in the European Regulatory Framework) and third-party attestation of conformity
- EN ISO 17050-1:2004, §6 specifies the content (minimum and additional optional information) of the declaration of conformity, while EN ISO 17050-1:2004, Annex A gives a format example and provides guidance for completing it.

[1] “Conformity assessment - Suppliers declaration of conformity – Part 1: General Requirements”

SDoC (7) - Content

- **Where several directives apply to a product, the manufacturer can, basically, merge all the declarations into a single document.**
- **Consequently, the SDoC should also provide information on whether or not it covers only one directive.**
- **In such a case the declaration should include a reference to all directives in order to verify whether the manufacturer has followed all the Community legislation**

SDoC (8) - Content

- **Unique identification of the product**
- **Name and address of the manufacturer or his authorised representative**
- **Object of the declaration (identification of product allowing traceability - it may include a photograph, where appropriate)**
- **Relevant Community harmonisation legislation to which the compliance of the product has been demonstrated**
- **References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared**
- **Additional information**
 - **(place and date of issue)**
 - **(signature)**

SDoC (9) – Technical documentation

- However some Directives, due to sector specificities and order for authorities to be better assisted in their surveillance activities, may be obliged to require additional information to what is specified by EN ISO 17050-1:2004
- Furthermore the acceptance of the declaration of conformity may be enhanced by including such information
- In this respect EN ISO 17050-2:2004[2] (§5) specifies requirements for technical documentation in support of the SDoC

[2] “Conformity assessment - Suppliers declaration of conformity – Part 2: Supporting documentation”.

SDoC (10) – Technical documentation

- **The manufacturer draws up the technical documentation of the product**
- **Technical documentation is the technical file that provides information on the design, manufacture and operation of the product**
 - **A main purpose of drafting the technical documentation is to provide supporting evidence of the conformity of the product in question**
 - **Technical documentation accompanies the SDoC**
 - **The content of the technical documentation as set out in the text of the Decision 768/2008 is based on EN ISO 17050-2:2004 (§5.1) that specifies requirements for documentation in support of the declaration of conformity**

SDoC (11) – Technical documentation

The technical documentation shall contain, wherever applicable, at least the following elements :

- a general description of the product
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied
 - In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied
- results of design calculations made, examinations carried out, etc.
- test reports

SDoC (12) - Examples of sectors

- Electrical / electronic products / machinery
- Radio and telecommunications
- Low voltage
- Electromagnetic compatibility
- Medical devices
- Refrigeration appliances
- Pressure equipment



More under

http://ec.europa.eu/enterprise/newapproach/index_en.htm



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THANK YOU

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