Guidance document for the Conformity Assessment and Certification of 'complex' products

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SUSTA-SMART
supporting standardisation for smart textiles

CENTEXBEL

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1 Executive Summary

This document contains guidelines for the inclusion of conformity assessment and certification aspects in research and development projects, since proving conformity with legal (and other technical) provisions is often a major (but underestimated) factor in bringing newly developed products to the market.

In many cases products will have to comply with legal European (and national) provisions, coming from several separate legislations. This creates additional problems for product developers and manufacturers to find out which legislations apply and how to find competent conformity assessment bodies to handle this complex situation.

This document is intended for anyone who is involved in the conformity assessment and certification of products which fall under more than one EU law. This includes Notified Conformity Assessment Bodies and laboratories as well as manufacturers of these products, but also researchers and policy makers may find this information useful for their work.

This document represents a first draft and will be further developed in the future.

2 Foreword

This document is a first draft, which in the future shall be developed further into a guidance document. It will be made available to interested researchers and other relevant stakeholders and any feedback for improvements is welcome[1].

3 Acknowledgements

This document was prepared as a result of the work performed under the EU FP7 project SUSTA-SMART, grant agreement no: 319055 It is intended to make this document available to researchers via the website of the SUSTA-SMART project and the website of the SUSTA-SMART partners

[1] Feedback can be provided to the SUSTA-SMART coordinator Karin Eufinger (ke@centexbel.be)

4 Standardisation, certification and conformity assessment – definition of terms

The terms *standardisation*, *certification* and *conformity assessment towards EU legislation* are used quite often as interchangeable terms by researchers, without realising that they actually have a very different meaning and implications. In order to provide the reader of this document with a basic understanding and distinction of these three terms they will be described in more detail below.

4.1 Standardisation

Standardisation refers to the development and implementation of normative documents, e.g. for product requirements and product testing, but also for services and terminology. Standards are voluntary documents developed as means to be able to compare test results, have common evaluation criteria, ensure compatibility of components (cables, software, etc.). Standards can be developed by National, Regional (e.g. European), or International standardisation organisations or by a group of companies (industrial standards, e.g. USB, IEEE).

4.2 Certification

Certification is the process of attestation that a product (or service or person) complies with the provisions of a certification scheme. Certification is usually carried out by an independent third party (certification body). To obtain a certificate the product has to fulfil a set of requirements, which are assessed by testing or other evaluation criteria.

The certification process is more transparent for all parties involved if it refers to technical specifications laid down in standards. This is why the reference to standards is preferred in certification schemes, but not legally compulsory.

Certificates often support mandatory or voluntary labels or markings, which are used as a visual indication that the product fulfils the requirements of the certification scheme. Certificates may or may not be linked to conformity assessment imposed by EU legislation.

4.3 Conformity assessment (in support of EU legislation)

Although the term "conformity assessment" applies in principle to both voluntary and mandatory assessments, it will be used in these guidelines only in relation to mandatory assessment procedures in support of EU legislation, usually leading to CE marking of products.

Products being sold on the EU market must comply with the provisions of the EU legislation applicable to these products. Manufacturers need to prove that their products comply with these legal provisions.

A large range of products (construction products, personal protective equipment (PPE), medical devices, machinery, etc.) are covered by so-called "new approach" legislation. This legislation specifies the essential requirements, with which the products shall comply, and the route to be followed to demonstrate compliance. This route comprises the design and manufacturing stages of the product and may include self-assessment by the manufacturer, type approval or systematic follow-up by external conformity assessment bodies or a combination of these elements.

New approach legislation supports the principle of "presumption of conformity". This means that conformity of a product with the provisions of a harmonised European standard gives that product the presumption of conformity with relevant essential requirements of the legislation. A table in the standard indicates which essential requirements are covered. Lists of harmonised standards are published in the Official Journal of the EU. This mechanism makes standardisation a preferential tool

in proving compliance with the law. This is especially the case for products where safety and reliability are very important like construction products and personal protective equipment.

4.4 CE marking

The CE marking is a visual indication of a product's compliance with EU legislation. CE marking is compulsory if it is explicitly imposed by the specific legislation applicable to that product. CE marking is forbidden if there is no such legislation. It is the manufacturer's responsibility to affix the CE marking on his products. More information is available on the website of the European commission[2].

5 General considerations for Conformity Assessment and Certification of 'complex' products

5.1 Importance of Certification and Conformity Assessment (in the context of EU legislation)

The prime goal of EU new approach legislation is to create a single unified free European market within the 28 EU Member States and other countries, which have aligned their national legislation with the EU. However, this single market should also guarantee the safety and health of citizens and prevent that unsafe or unhealthy products enter the market. This goal is achieved by a general legislative framework for bringing products to the market (EU Regulation 765/2008) and by a number of specific EU regulations and directives. These specific pieces of legislation contain essential requirements and conformity assessment procedures for product families, e.g. construction products, personal protective equipment, medical devices etc.

Hence the importance of conformity assessment and certification comes from the expectations of the consumer, about the performance and the safe use of a product, and the concern of governments, e.g. the EU, for the safety, health and well-being of their citizens/consumers. This concern may extend to the design, manufacturing, use, and disposal/recycling stages of the product's life cycle.

Test reports may be used for conformity assessment though, as they can be used to prove that a product meets the legal requirements. Test and evaluation standards can be used to provide the evaluation criteria for conformity assessment procedures and certificates.

5.2 Complex products and EU law

EU regulations and directives are usually intended for a specific, though sometimes very large group of products. Complex products, in which several technologies are combined, may thus be subject to several legislations, each with specific conformity assessment procedures and supported by separate sets of harmonised European standards.

Smart textiles with integrated electronics and ICT are an example of such complex products from a conformity assessment and certification point of view.

For one, there are the legal requirements of the basic textile product, i.e. without the electronics and ICT features. In the case of the SUSTA-SMART focus domains were Personal Protective Equipment (PPE), Construction Products and Consumer Goods.

Construction Products and Personal Protective Equipment are regulated by EU law (the Regulation (EU) No 305/2011 for Construction Products (CPR) and Directive 89/686/EEC for PPE, respectively), both imposing CE marking. Both CPR and PPE directive provide for several systems of conformity

[2] http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/about-ce-marking/index_en.htm

assessment, dependent on the risks related to the use of the product. In these systems some tasks are allocated to the manufacturer, others to external conformity assessment bodies (notified bodies and laboratories).

The general product safety directive (2001/95/EEC) for consumer goods has some new approach features, but doesn't provide for CE marking. Nevertheless the manufacturer has the obligation to ensure that his product is safe and to collect all evidence to support this claim.

For another, smart textiles with integrated electronics and ICT also can be considered electronics and ICT products, with the textile being part of the casing, functional or non-functional structure. For such products other EU laws apply, for example

- RoHS Directive 2002/95/EC (EU legislation restricting the use of hazardous substances in electrical and electronic equipment)
- Electromagnetic Compatibility (EMC) Directive 2004/108/EC

Additionally, depending on specific functionality added, e.g. for Personal Protective equipment, other directives may apply, e.g.

- Equipment and Protective systems intended for use in Potentially Explosive Atmospheres: (ATEX) Directive 94/9/EC
- Medical device directive (2007/47/EEC) – for monitoring physiological properties of the wearer and drawing conclusion on his health and physiological status
- Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data (95/46/EC)

Although there is now a general legislative framework (EU Regulation 765/2008) for putting products on the EU market and an EU Decision 768/2008 serving as a toolbox for more specific legislation, most manufacturers (and even notified bodies) have little knowledge about regulations outside their core domain. Additionally, notified bodies quite often have a good network to other notified bodies within their scope, but not outside of it.

It is therefore not always obvious for manufacturers to identify, for one, into which other sector the complex product falls, and, for another, how to find a notified body in this sector which can assist with the conformity assessment of the complex product.

The European Commission provides lists of notified bodies and which tasks there are allowed to perform. on the NANDO (New Approach Notified and Designated Organisations) website [3], but it can be cumbersome to identify the necessary notified body if one has no good view on the type of conformity assessment required or on the relevant harmonised standards.

Fortunately notified bodies are also aware that a more cross-sectorial approach is needed and many of them establish interactions with other sectors which are crossing their own. As manufacturer of complex products, but also in the framework of an R&D project it will be important to be in contact and work together with a notified body willing to look into the special needs of complex products.

[3] http://ec.europa.eu/enterprise/newapproach/nando/

6 Suggested procedure

6.1 Identify the applicable EU legislation for complex products

Smart textiles with integrated electronics and ICT, even if limited to Personal Protective Equipment, Construction Products and Consumer Goods, can be used for a large variety of different applications and a similarly large variation of functionalities can be added. It is not the purpose of this guidance document to present a complete list, but rather to provide the reader with a methodology on how to identify the laws applicable to a given product.

As a descriptive example we will look at a fire fighter's jacket worn by the member of an intervention team in urban settings. This jacket has an integrated heart rate monitor. During the intervention this heart rate monitor sends the measured data to a remote base station A team leader (commander) follows the activity of his team, taking into account the heart rate data which he uses to assess the fitness for duty of the wearer (i.e. the team member) during the intervention.

Important to note in this case is that possibly a medical decision is taken here: the commander is assessing the fitness for duty of the wearer by interpreting his heart rate date. Here it must be checked if there are any national laws regulating such medical decisions, e.g. whether they can be taken by any (trained) person or only by a medical doctor.

Concerning the conformity assessment the following steps are suggested to gather the necessary information:

(1) Identify the primary function(s) of the product e.g. "*a jacket worn by a firefighter in urban settings*", and list the applicable EU law(s).
(2) Identify the secondary function(s) of the product, e.g. "*a built-in heart rate monitor for following the fitness of the wearer of the jacket*", and identify the applicable EU law(s).
(3) Identify which other EU laws could apply to the components of the system: the electronic and ICT components in the jacket, the wireless transmission, the reception of the signal by the remote infrastructure, the processing of the data in this infrastructure, the interpretation of the data by the commander, the collecting of private data during working hours, etc..
(4) Identify if there are any specific requirements coming from the complexity of the product, i.e. the integration of electronics and ICT into a textile product: components will be used in ways which are not 'standard', e.g. the electronic components being washed, soaked in water or firefighting chemicals, being exposed to elevated temperatures, etc. It should also be investigated of the added components contribute to the risk, e.g. increased flammability of the equipment or risk of explosion.

Note that the above list may need to be expanded depending on the nature of the product and/or the application it is intended for.

Most of the above legislation aims at preventing unsafe products from entering the EU market. However, it is the employer's responsibility to ensure the safety of his employees, in this case the fire fighters. One important aspect of this is to make a thorough risk assessment, i.e. to identify the risk, and to estimate the probabilities and consequences of an accident.

For the above example we will focus on the monitoring system. It is being used to check the fitness of the wearer, i.e. to judge when he has to leave the site of the intervention and get some rest. The consequences of the system failing is that the wearer will work longer than is good for him, with possibly detrimental consequences. On the other hand, the commander will know approximately how long his people can remain at the intervention site, so that he can provide a back-up for the system failure. This can reduce the risk for the wearer of the jacket. If additionally a check-up and warning system is installed that can warn the team leader and (optionally) the wearer that the

system has failed, then the commander can choose to fall back on an alternative system, e.g. (1) using a safe maximum time a person may stay at the intervention site or (2) decide to withdraw the person immediately.

6.2 Identify the Notified Bodies needed for conformity assessment

A good starting point is to contact the notified body one is used to working with (e.g. a Research Partner who is also Notified Body for the envisaged application).

If this is not possible or if the Notified Body contacted is not able to provide assistance, the second step can be to look into ones broader network for possible contacts and if this is also not successful, to look on the website of the EC as mentioned earlier or to contact the horizontal coordination of notified bodies or the national market surveillance authorities.

This needs to be done for all the EU laws identified using the steps proposed in the previous section. It is also advised to identify a lead Notified Body which can manage the complete portfolio for the conformity assessment.

6.3 Certification

It can also be interesting to obtain test reports and certificates stating the e.g. the performance level of the product or that is safe against certain risks or fulfils specific requirements of voluntary labels, e.g. Oekotex. In this case it can also be interesting to work with a test laboratory which can perform the necessary testing and issue the related reports or certificates.

7 Implementing these steps in Research and Development projects

Similarly to implementing standardisation into Research and Development projects, the implementation of Certification and Conformity assessment requires to plan the necessary steps in the work programme and to either have the necessary partners in the consortium or foresee the necessary budget for external assistance, e.g. via subcontracting.

8 Follow up and further development of these Guidelines

For Centexbel as Notified Body for PPE it is becoming more and more important to acquire the knowledge and skills to assist customers with conformity assessment and certification of complex products with EU law. This first draft Guideline therefore serves as a first document to evaluating smart textile products with integrated electronics and ICT.

For Centexbel the concrete steps will be:

1) Learning to identify better the necessary steps and applicable laws for different complex products, as outlined in this guide.
2) Working together with other Notified Bodies:
   Centexbel has experience with working together with other Notified Bodies in the PPE sector and the construction sector and is expanding its PPE certification also to the Maritime Sector. Next steps will be to extend its network to include contacts that could assist with the certification and conformity assessment of complex products, including smart textiles with integrated electronics and ICT.

It is also the aim to further develop this draft guide, in conjunction with CEN CLC BT WG 8 and its follow up body, which has proposed the development of this guide in its final report[4].

[4] ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Fields/Health%26Safety/PersoProtectiveEquip/N87_M509_FinalReport.pdf