

personal protective equipment

certification

The European Directive 89/686/EEC imposes CE-marking of personal protective equipment (PPE) for professional and private use.

It is illegal to sell in Europe any PPE not properly CE-marked.

European Directive 89/686/EEC

The European Directive 89/686/EEC aims at facilitating the free movement of goods and services throughout the internal European market, while respecting the minimum regulations ensuring the consumer's safety and health (basic health and safety requirements).



The manufacturer is obliged to affix the CE mark onto his products. This label visually states that the product meets the directive's basic requirements and that all procedures have been duly respected.

How to market PPE ?

PPE are divided into **3 categories** according to the complexity of the design and the degree of risk against which they are intended to offer protection. The PPE category determines the procedure which has to be followed prior to marketing a PPE.

Since the manufacturer has to prove that his product is in harmony with the basic requirements he has to draw up a **technical file** providing this proof. This file shall contain such data as the manufacturer's identification, a description of the product, the conformity claims, laboratory results, examples of marking, and the information notice (in the language of the country of destination). A technical file has to be drawn up for all PPE.

In general such a file will be drawn up on the basis of **harmonised standards**, which are considered as a technical translation of the basic requirements and which provide a presumption of conformity. However, the harmonised standards only determine the performances of PPE and not their design or composition, still leaving the manufacturer a high degree of freedom to design his products.

For **PPE category I** (low risk - simple design) a technical file suffices and the manufacturer may affix the CE mark without intervention of a third party.

PPE categories II (medium risk) **and III** (mortal hazards or serious and irreversible damage to health - complex design) require a **CE type examination by a notified body**. A demand for CE type examination may only be submitted once.



Notified bodies

For a number of tasks within the framework of the European Directive 89/686/EEC one needs to make an appeal to notified bodies. Notified bodies are designated by the individual European Member States, but their operation is not limited to the territory of the Member State by which they have been designated.

The notified bodies must have the necessary technical skills and professional integrity. Their staff and management have to be independent from any possible interest groups and are bound to professional secrecy.

Notified bodies shall also engage in systematic consultation with their colleagues and follow up the standardisation and regulations in their field.

Since 1994, CENTEXBEL has been notified by the Belgian Federal Public Service of Employment, Labour and Social Dialogue (European notification number 0493) for protective clothing and gloves.

The application has to be accompanied by the technical file and product specimens. The notified body will perform the necessary testing, and examine whether the technical file actually proves conformity with the relevant basic requirements of the directive.

PPE category III takes the certification system one step further. In addition to the type examination the production quality has to be monitored by a notified body, either by periodical sampling and testing (system 11A), or by the periodical auditing of the quality management system (system 11B). The manufacturer may choose between both systems.

When all procedures have successfully been completed, the manufacturer affixes the **CE mark** onto his product.

The manufacturer also has to draw up a CE declaration of conformity stating the PPE meets the basic requirements and mentioning the harmonised standard(s) used to establish the conformity.

For PPE categories II and III, he moreover confirms that the PPE is identical to the one for which an CE type approval certificate, issued by a notified body, has been obtained.

In the case of PPE category III, the manufacturer also declares that the PPE is submitted to a permanent monitoring of the production quality, according to either system 11A or system 11B, under the supervision of a notified body.



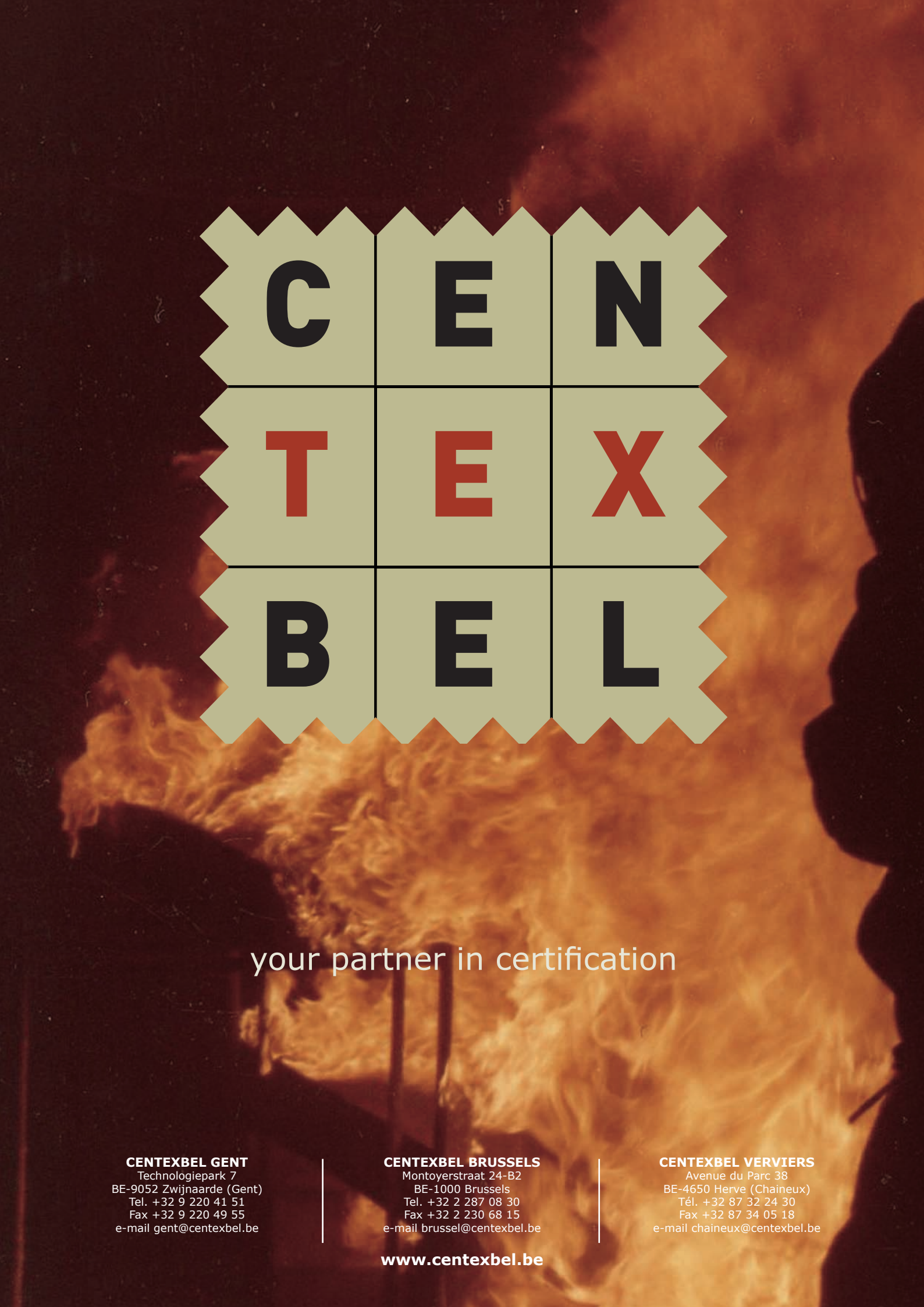
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CENTEXBEL is an innovation-driven service centre for the entire textile production and distribution chain, from fibre to final product.

CENTEXBEL supports the textile chain by carrying out research projects, by promoting innovation, performing a wide range of laboratory tests^(*), by giving technological advice, organising training sessions, auditing, certifying, etc.

You may find a complete survey of the CENTEXBEL products and services on www.centexbel.eu

^(*) the CENTEXBEL laboratories are ISO 17025 accredited



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B E L

your partner in certification

CENTEXBEL GENT
Technologiepark 7
BE-9052 Zwijnaarde (Gent)
Tel. +32 9 220 41 51
Fax +32 9 220 49 55
e-mail gent@centexbel.be

CENTEXBEL BRUSSELS
Montoyerstraat 24-B2
BE-1000 Brussels
Tel. +32 2 287 08 30
Fax +32 2 230 68 15
e-mail brussel@centexbel.be

CENTEXBEL VERVIERS
Avenue du Parc 38
BE-4650 Herve (Chaineux)
Tél. +32 87 32 24 30
Fax +32 87 34 05 18
e-mail chaineux@centexbel.be

www.centexbel.be