

AMPO From design to EC marking

AMPO wanted to make sure that its new stretcher complied with European regulations as from the design stage, in order to obtain EC marking, as this was necessary to market the stretcher.



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OUR CLIENT

Corporate name
AMPO (Ateliers Mécanique Précision Outillages - tooling precision mechanical workshops)

Activity
General mechanics, welding, milling, free machining

Turnover
2 million Euros

Workforce
17

AMPO (Ateliers Mécanique Précision Outillages – tooling precision mechanical workshops), a company located in Fleurines (Oise - France), wanted to market a stretcher for the rescue services, ambulance companies and hospitals. The product is subject to the European Medical Device Directive, which sets out essential requirements in terms of safety, health, protection of the environment and consumer protection.

Report on regulations and standards in force

“We hold a patent on automatic crutch unlocking,” said Frédéric Brique, AMPO

manager. “Cetim assisted us throughout the design process in order to make sure that the product would comply with the regulations in force, so that we could safely affix the EC Marking compulsory for marketing purposes.”

The first stage consisted of drawing up a report on the regulations and standards in force. The AMPO stretcher needs, in fact, to meet the provisions of two standards, which give rise to presumption of conformity with Directive NF EN 1865 on general stretcher systems, and NF EN 1789 on road ambulances. Furthermore, the products can be used by French fire-fighters subject to NF approval.

A comprehensive assistance

The second stage consisted of making sure that regulatory provisions were complied with. Cetim assisted AMPO and coordinated the assignments of the different certifying bodies – the UTAC (Union Technique de l’Automobile, du Motorcycle et du Cycle – technical union for the automobile, motorcycle and cycle industries), in charge of approval tests, and Afnor, which carried out an audit of the AMPO workshop in order to check the reproducibility of the process.

Cetim also drew up the documents to be supplied with the product in order to obtain EC marking and to complete the subsidy application form, because the project was conducted within the framework of a joint innovative project conducted by the Creati network (local technical support and innovation centres).

Cetim’s asset

Our regulatory watch allows us to remain up-to-date regarding all the texts governing product marketing.



Companies can then rely on us to assist them in procedures which are often complex.