

# The CE Mark: Not Enough?

*Buyers in some of Europe's more regulated countries still require national standard marks in addition to the CE mark.*

by Erika Morphy

The CE mark, once thought to be the exporter's long-dreamed-for solution to Europe's system of country-by-country product standards, may prove to be less of a savior than once hoped.

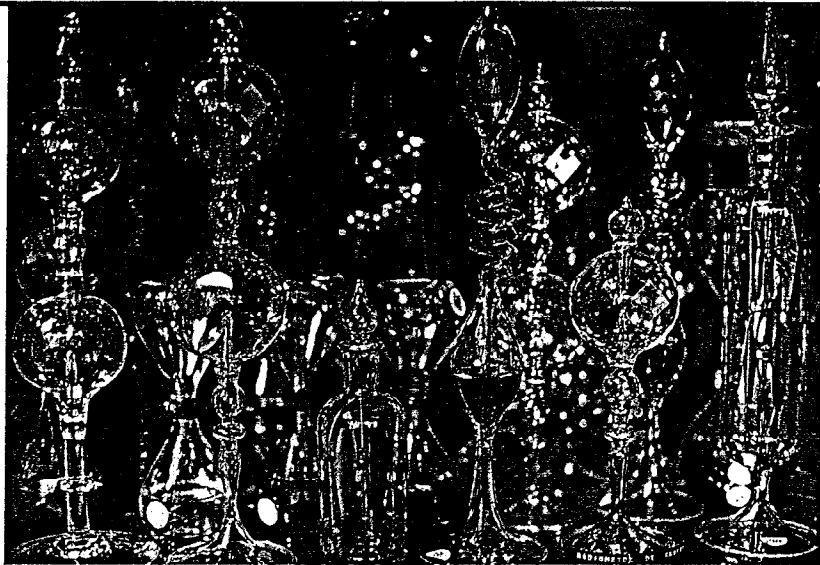
Recently some American firms have found that many procurement officials in Europe still want national marks on the products they buy, even if it has a CE mark.

The problem is especially pronounced in Germany, particularly with exports of medical devices and potentially dangerous machinery. What the problem reveals is that the CE mark is at best a minimal requirement, and by no means the only requirement a company may be asked to meet.

"In principal, private purchasers do have the right to ask for specific requirements," says Charles Ludolph of the U.S. International Trade Administration, who is co-chairman of the Trade Promotion Coordinating Committee Working Group on Product Standards and Certification.

The "Geprüfte Sicherheit" (GS)

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lot of trouble, [marketing products that have only the CE mark],” says Craig Dawson, engineering manager for Introtek International, an Edgewood, N.Y. manufacturer of sensors to measure the level of liquid in a tank.

“We are willing to get the standards they want, because

we are blocked out of the market” otherwise, Dawson says. “Our sales people feel it is worth it.”

**Back Door Certification?** A large part of the problem stems from a mistrust of the CE mark by many officials and businesspeople in individual European countries. Basically, more and more people in the better-regulated countries are questioning the value of testing in countries that have traditionally had lower regulations, according to the director of one U.S. testing laboratory who is involved in the U.S./E.U. trade negotiations.

“People in the United Kingdom, Scandinavia, France and Germany are asking whether testing labs in Greece, Portugal or Turkey are at the same technical level as they are,” says the director, who asked not to be identified. “So they ask for the national marks to be sure the prod-

mark, for instance, has never been officially mandatory for goods sold in Germany — although in many cases an insurance company will require its clients to buy only products that have this mark. But German consumers look for this mark in much the same way as Americans used to look for the “*Good Housekeeping Seal of Approval*.”

The GS mark is very popular “because of its broad commercial application,” says Mary Saunders, assistant to the director in the Office of Standards Services at the National Institute of Standards and Technology. “Products without the GS mark can be placed on the market. They just won’t be bought.”

This has always been true in Germany. Now with the advent of the CE mark, some companies are reinventing the wheel the hard way.

“Our salespeople say they have a

uct is really safe.”

Ultimately, the lab director says, there are fears that the southern tier countries will be used as an easier port of entry for foreign products, and that the northern European states will be forced to accept sub-standard products.

The lead engineer at another U.S. testing laboratory, who also asked not to be identified, says that, “the CE mark can mean nothing, depending on who did the testing ... Greece and Turkey are the low-point countries, while Germany, France and

England are more rigorous and intent on protecting their markets.”

Part of the problem is that the European Union has not adopted the most recent version of ISO Guide 25, a quality standard that verifies whether a laboratory operation has the capability to produce valid test data. Currently, the European Union follows the 1980 version of ISO Guide 25, which requires merely that a laboratory be certified as a testing lab. The more recent version of ISO Guide 25 — which many labs in the United States are embracing —

requires that a lab state exactly what it is: for example, is it a product safety testing laboratory or an electromagnetic device testing laboratory.

Another factor contributing to the reluctance to abandon national marks is that manufacturers do have the option of simply declaring their conformity using harmonized standards, instead of relying on third-party certification. But these self-declarations are often not accepted by distributors, either for fear of intentional fraud or honest mistakes.

“About four years ago, toys with the CE mark were tested in the United Kingdom to the appropriate standards,” remembers Matthias Bürger, a compliance engineer and lead medical auditor with TUV Rhineland in Chicago. “The majority of the toys failed. They found that the manufacturers self-declared conformity without conducting the appropriate tests.” Most of the toys sampled were imports, Bürger says.

Originally, Bürger says the CE mark was intended for goods manufactured within the European Union, not for imported products. “The GS mark was designed for the consumer, while the CE mark never was.” He adds, “The CE mark does not tell you who has tested the product ... The GS mark means a testing lab has certified the product.”

**No Easy Solution.** Of course, one obvious answer for a non-European manufacturer is to get both a national mark and the CE mark. Testing lab engineers say that once a firm is having a product tested for one mark, it is usually not much more expensive to get it certified for another mark.

“When you test for the GS mark, you have already done about 75% of testing for the CE mark,” says Walter Poggi, president of Retlif Testing Laboratories in Ronkonkoma, N.Y. “It costs about 25% to 30% more to get more than one mark. After all, there are only so many ways you can measure a volt.”

This solution is not applicable for all products though. Bürger, for instance, says that German law is written so that a manufacturer cannot have both a GS mark and a CE mark on a medical device. But when the transition period for medical devices is over in mid-1998, Bürger does not expect the GS mark to simply disappear.

"Because the GS mark carries such a heavy weight with consumers," he says, "German manufacturers are pushing to privatize the mark so it may be used in conjunction with the CE mark."

In fact, private marks are gaining in popularity in Europe. TÜV Rheinland offers a GM mark, which stands for "approved medical product" in English. Underwriters Laboratories, TÜV Product Service in Munich and VDE Testing and Certification Institute in Offenbach,

Germany offer the International "emc-Mark." Daniel D. Hoolihan, vice president of TÜV's Minnesota operations, reports that demand for this mark is increasing every month.

**More Confusion.** Ultimately, most experts in the product standards field tend to agree that several issues need to be clarified before the full value of the CE mark becomes known.

For example, Bill Fuller, a consultant who specializes in CE marks and ISO standards at Grant Thornton LLP in Minneapolis, reports that the United Kingdom is interpreting the machinery directive differently than the rest of Europe.

Fuller says some U.K. industry officials are interpreting the regulation to mean that an authorized representative of the manufacturer must possess a technical construction file, which is the documentation that illustrates the product's conformance

to the directive.

"That is not the way the directive reads," Fuller says. "The directive states the TCF can be held with an authorized representative in the country OR at the manufacturer's headquarters."

Still, many industry experts and U.S. manufacturers don't report any difficulties with the CE mark.

Fuller, for instance, says he has yet to come across the problem, as does Donald Sweeney, president and senior EMC engineer, of DLS Electronics Systems, a testing lab in Glenview, Ill.

But Bob Williams, director of engineering at E-Z-EM Co. in Westbury, N.Y., says his company is trying to sell their medical products "the more traditional way, by going with the national marks." The CE mark, Williams believes, is a goal that still lies in "unchartered waters." **ET**