CE Label does not apply to Biochrom AG products

Information from Biochrom AG

Most everyday items such as toys, household appliances or pyrotechnical items carry the CE label. This is a manufacturer's label for product safety according current regulations in the European Union (EU). This does not automatically mean that a "CE" labelled product is certified by an independent body. With the CE label, manufacturers confirm that their products meet European guidelines.

There are European guidelines for medical devices and *in vitro* diagnostics as well. It is for this reason that customers always ask whether Biochrom AG products are CE certified. CE labelling is necessary for products that are subject to the Medical Devices Act (MDA). This does not apply to Biochrom AG products. From our point of view, currently no additional advantage or benefit to our customers can be derived from CE labelling, thus Biochrom AG abstains from it.

On the other hand, Biochrom AG products and their manufacture is ISO 9001 certified, a certification that is checked and confirmed by a nominated body; for Biochrom AG this is the German Association for Management System Certification (Deutsche Gesellschaft zur Zertifizierung von Managementsystemen - DQS)

ISO Certification of Biochrom AG

With certification, a company proves that it meets set standards for products with its production processes. Certification is the foundation of a company's quality management, and guarantees a specific and reliable quality. There are various types of certifications, for example the ISO certification. In the case of ISO certification following DIN EN 9001, standards are specified for companies which provide goods and services. These goods must meet the specifications of customers and regulatory requirements. At the same time, the objective is constant improvement of processes and customer satisfaction. These corporate goals of Biochrom AG are, through ISO 9001:2000 certification, complied with and documented. Biochrom AG will extend this certification in 2010.

Aside from the ISO certification, there are more certifications for enterprises, e.g. a certification for training standards, computer safety certification in the software industry, or a certification tailored to the needs of the food industry. The CE label was created on the other hand to guarantee the free movement of goods, and ensure product safety for the end customer within the EU. It is for this reason that the CE label has been described as a 'passport' for the European internal market. Products thus carry the CE label when they meet EU guidelines. The EU guidelines define mandatory minimum requirements for numerous products in terms of safety and health.

Products with CE certification

As an example, European guidelines exist as a basis for CE labelling for the following product groups: Household cooling and freezing devices, toys, as regards electromagnetic compatibility of electrical and electronic products, gas appliances, or water heating appliances.

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Additionally, there are guidelines for medical products (93/42/EWG, revised under 2007/47/EG, in effect as of 21 March 2010) and i*n vitro* diagnostics (98/79/EG). The former applies to placing medical products and accessories on the market, and putting them into service. This applies to products like instruments, apparatuses, appliances, material, or other items that are intended by the manufacturer to be used by the public. *In vitro* diagnostics include reagents and reagent products, calibrators, control materials, kits, instruments, apparatuses, equipment or systems, used individually or in combination that are specifically intended by the manufacturer to be used for *in vitro* diagnostic examination of specimens derived from the human body. Manufacturers of such products in Germany are required under current law to use these guidelines in their production processes.

To date, Biochrom AG has not been producing or marketing products of that kind. A CE label is therefore currently not needed.