Regulations applicable to medical devices apply when the device is intended for medical purposes

Judgment of the European Court of Justice (ECJ) of 22 November 2012, Case C-219/11 Brain Products

Background

In this Judgment the European Court of Justice has expressed its position on the interpretation of the definition of "medical device", in a reference for a preliminary ruling from a German Court, in the proceedings between Brain Products and BioSemi.

The dispute between the above mentioned companies occurred in connection with BioSemi's marketing of a system called "ActiveTwo" which, according to this company, enables human brain activity to be recorded. Brain Products considered that the marketing of such product should fall within the scope of the regulations on medical devices and that "ActiveTwo" could only be marketed once the requirements for bearing the CE mark were fulfilled.

On the other hand, BioSemi claimed that "ActiveTwo" is not intended for medical use and, thus, it cannot be classified as a "medical device". Furthermore, BioSemi claimed that the fact that the system "ActiveTwo" can be transformed into a diagnostic device does not imply that it should be classified as a medical device.

BioSemi concluded by claiming that obligatory CE marking would be contrary to the principle of free movement of goods.

The position of the ECJ

The Court analyzes this issue by reminding that Directive 93/42/EEC considers as "medical devices" those products intended by the manufacturer to be used on human beings for certain purposes, among which are the diagnosis, prevention, monitoring, treatment or alleviation of a disease; as well as for the purposes of investigation.

As regards software, Directive 2007/47/EC included it within the definition of "medical device" as long as it is intended specifically for diagnostic and/or therapeutic purposes. The interpretation of this provision that the ECJ makes on the basis of its Preamble is that software shall only be considered as a medical device if its intended purpose, as defined by its manufacturer, is specifically medical.

Consequently, the Court indicates that when a product is not conceived by its manufacturer to be used for medical purposes, its certification as a medical device cannot be required, even though such object enables the investigation of a physiological process as well as to measure, without any medical use, the functioning of certain organs in the human body. The ECJ points out that if such articles were to be classified as medical devices, they would be subject to a certification procedure without any justification for that requirement.