In vitro diagnostic medical devices: security requirements

1995/0013(COD) - 27/10/1998 - Final act

OBJECTIVES: to harmonise and improve the safety standards of in vitro diagnostic medical devices with a view to completing the internal market in this sector; to safeguard the health and safety of patients, users of the products in question and third parties.

COMMUNITY MEASURE: European Parliament and Council Directive 98/79/EC on in vitro diagnostic medical devices.

CONTENT: in vitro diagnostic medical devices are a sub-category of the medical devices defined in Directive 93/42/EEC. These devices are used in medicine for in vitro analysis of samples taken from the human body. The medical applications include analyses to evaluate the state of health (e.g. cholesterol, pregnancy), diagnose congenital diseases or anomalies, check the progress of a course of treatment (e.g. dosage and effect of drugs) or determine safety and compatibility in the case of organ or blood donations (e.g. to check for HIV or hepatitis).

The directive lays down the conditions under which in vitro diagnostic medical devices may be placed on the market. It sets out the main requirements in terms of reliability of the devices, taking account of their purpose, and in terms of the protection of users and third parties. In addition, it harmonises the procedures for evaluating compliance to be applied by manufacturers before placing devices on the market.

The directive requires Member States to implement a vigilance procedure so that any information which comes to their attention in relation to incidents involving devices carrying the CE mark is registered and evaluated centrally.

In order to monitor the market, the directive makes provision for the implementation of a European database containing data relating to registration of manufacturers and devices, certificates and data obtained in accordance with the vigilance procedure. It states that Member States have an obligation to monitor the safety and quality of devices placed on the market.

Finally, the directive makes it possible to take transitional national measures or Community measures to prohibit or restrict the placing on the market of certain products or groups of products on grounds of public health.

ENTRY INTO FORCE: 7 December 1998.

DEADLINE FOR TRANSPOSITION: 7 December 1999. Provision applicable from 7 June 2000.