In vitro diagnostic medical devices: security requirements

1995/0013(COD) - 20/12/1996 - Modified legislative proposal

The modified Commission proposal on in vitro diagnostic medical devices incorporates a number of amendments adopted by Parliament, and in particular those concerning: - clearer demarkation of the scope in comparison with Directive 89/392/EEC relating to machinery; - the clarification that the aspects concerning medical prescriptions for devices are not affected by the harmonizations; - the tightening-up of the protection requirements with a view, in particular, to minimizing the risks, including the risks relating to the packaging; - the clarification of the powers of the Member States' authorities and the strengthening of their market surveillance powers; - the establishment of a European Union database on the products placed on the market; - extension of the group of in vitro diagnostic devices which must be submitted to third-party certification before they are placed on the market; - the inclusion in the scope of Directive 93 /42/EEC of certain medical devices manufactured using products derived from human tissues or cells; - the amendments to Directive 93/42/EEC to bring it closer into line with this Directive. The Commission has not approved the amendments concerning: the obligation that the information accompanying the products placed on the market must be available in the national language(s); the type of committee; application of the transitional system for notification of devices placed on the market to all Member States.