In vitro diagnostic medical devices: security requirements

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1) OBJECTIVE To ensure the free movement of in vitro diagnostic devices by harmonizing the national laws on the reliability of these products and on the protection of the health and safety of patients, users and third parties. 2) CONTENTS 1. This proposal applies to in vitro diagnostic medical devices. 2. These devices are products used for the in vitro analysis of tissues or substances from the human body. The types of analysis covered are as follows: * state of health; * congenital diseases or anomalies; * checking the progress of courses of treatment; * determining compatibility in the case of organ or blood donations. 3. The proposal lays down the objectives or "essential requirements" of safety, health, design and manufacture which must be met by in vitro diagnostic medical devices when they are manufactured and placed on the market. 4. Harmonized European standards on the prevention of risks relating to the design, manufacture and packaging of products are drawn up by the European standards bodies on the basis of the essential requirements. These standards, which are not mandatory, are published in the Official Journal of the European Communities in the form of national standards with identical contents. 5. Any product manufactured in accordance with harmonized standards is presumed to conform to the essential requirements. 7. The product conformity assessment procedures and the essential requirements are based on the modular approach set out in Council Decision 93/465/EEC. Conformity assessment is the responsibility of: * manufacturers or their authorized representatives themselves; or * more rarely, bodies which may be designated by the Member States in accordance with joint evaluation criteria and notified to the Commission and the other Member States. 8. Before they can be placed on the market, devices must bear the CE marking of conformity which: * confirms that they conform to the provisions of this proposal; * consists of a single graduated drawing the "CE" mark, accompanied by the identification number of the notified body responsible for following the procedures; * is affixed by the manufacturer or his authorized representative established in the Community. 9. If a device is subject to other Directives which require "CE" marking, the affixing of the mark also indicates that the device conforms to the requirements of those Directives. 10. Any other mark may also be affixed to the devices provided there is no risk of it being confused with the conformity mark. 11. Penalties must be imposed by the Member States if they find that the mark has been unduly affixed. 12. There is a safety clause which allows any Member State, in an emergency, to withdraw the devices, when correctly installed, maintained and used for their intended purpose, from the market if they may compromise the safety of property and the health and/or safety of users or third parties. 13. Administrative cooperation and the exchange of information between the Member States are necessary to guarantee conformity with this proposal. 14. There is a transitional period of four years during which the Member States will authorize the placing on the market and/or putting into service of devices confirming to the rules in force in their territory from the date of adoption of this proposal. Source : European Commission - Info92 - 02/96