

# **In vitro diagnostic medical devices: security requirements**

1995/0013(COD) - 24/10/1994

CATEGORY OF REFERRAL: Proposal for Directive 2. Expected date of referral: December 1994 3. Previous Community legislation: Directive 93/42 of 14 June 1993 on medical devices excluding devices used for in-vitro diagnosis and active implantable devices. Related legislation 73/23, 87/404, 88/378, 89/106, 89/336, 89/392, 89/684, 90/384, 90/385 amended by 93/68, 90/396, 91/263, and 92/42. PREVIOUS POSITION OF EP: Amendments and legislative Resolution A3-0178/92 on medical devices (OJ C150 of 15/06/1992) and EP decision on medical devices (OJ C150 of 31/05/1993). The EP found the general tenor of the proposal satisfactory but adopted a number of amendments, especially in regard to restricting administrative formalities, increasing consultation opportunities for manufacturers, and making some of the definitions more precise. SITUATION IN THE MEMBER STATES: no national legislation available.