Market surveillance programme

Medical devices

Directive	Authority	Surveillance	Communications	Development	Training	Other
Active Implantable Medical Devices 90/385/EEC Medical Devices 93/42/EEC In Vitro Diagnostic Medical Devices 98/79/EC	National Supervisory Authority for Welfare and Health (Valvira)	Evaluation of the appropriateness and correctness of marketing. Supervision of the safety and compliance of products on the market. Inspections of Finnish manufacturers. Inspections of the professional use of medical devices. Supervision of the notified body.	Communications relating to device safety aimed at the development of safe use and prevention of incidents. Monitoring of uniform practices and surveillance-related functions in the European Economic Area and related information provision.	Assessing amendments to EU legislation, anticipating their impacts and creating capacities. The main focal areas are the pan-European harmonisation of the surveillance of the activities of the notified body (NB) and the further development of registers maintained by authorities as well as the gradual introduction of EU registers in surveillance work. The development and launch of the document inspection procedure.	Provision of information and training for actors in the entire surveillance sector, particularly concerning the responsibilities and obligations of professional users. Aiming at proactive prevention of safety risks . Providing information about amendments to EU legislation.	Implementing the shared objectives of medical device market surveillance and Valvira's social welfare and health care supervision programmes. Further development of international cooperation and harmonisation of practices aiming at increased surveillance efficiency. Participating in the planning and implementation of the product sector specific implementation of EU's changing market surveillance legislation.
RoHS 2011/65/EU	See the separate RoHS market surveillance programme for medical devices					