SECTORIAL NATIONAL MARKET SURVEILLANCE PROGRAMME – MEDICAL DEVICES

Member State:
Lithuania

Planning for: 2014

Surveillance Authority:
State Health Care Accreditation Agency under the Ministry of health of the Republic of Lithuania
Jeruzales st. 21
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EU legislation	Sector	Description of the product or category	Type of monitoring	Monitoring motivation	Monitoring activity	Priority	Starting period or date	Outcomes or further initiatives	Contact s (persons or functional mail boxes)
Directive 93/42/EEC 98/79/EC 90/385/EEC	Medical Devices	-Medical devices -*In vitro* diagnostic medical devices -Active implantable medical devices	Reactive	Vigilance notifications	Verification of information, assessment of corrective actions, checking the availability of concerned medical devices on the national market, information of concerned persons (if necessary)	High	All year	Verification whether corrective actions are done	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaite: jolanta.karavackate@vaspvt.gov.lt
Directive 93/42/EEC 98/79/EC 90/385/EEC	Medical Devices	-Medical devices -*In vitro* diagnostic medical devices -Active implantable medical devices	Reactive	Complaints received from the consumers and other third parties	Verification of information, documents inspection, review of the labelling, laboratory testing (if necessary), site visits of the market operators (if necessary), information of the conclusions, defined non-conformities and actions which must be taken	High	All year	Corrective actions, vigilance notifications (if necessary), national measures (suspension of further distribution/use, withdrawal of unsafe medical devices, administrative penalties)	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaite: jolanta.karavackate@vaspvt.gov.lt
Directive 93/42/EEC 98/79/EC 90/385/EEC	Medical Devices	-Medical devices -*In vitro* diagnostic medical devices -Active implantable medical devices	Reactive	Notifications received from customs	Site visits to customs offices, checking labelling, conclusions regarding the release of medical devices	High	All year	National measures regarding the release of medical devices	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaite: jolanta.karavackate@vaspvt.gov.lt
Directive 93/42/EEC 98/79/EC	Medical Devices	-Medical devices -*In vitro* diagnostic medical devices	Proactive	Surveillance of national manufacturers	Site visits of manufacturers, review of technical documentation and the labelling of the finished medical devices, information of the conclusions, defined non-	Medium	All year	Corrective actions, vigilance notifications (if necessary), national measures (suspension of further distribution/use,	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaite: jolanta.karavackate@vaspvt.gov.lt

					conformities and actions which must be taken			withdrawal of unsafe medical devices, administrative penalties)	
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Directive 93/42/EEC 98/79/EC 90/385/EEC	Medical Devices	-Medical devices -*In vitro* diagnostic medical devices -Active implantable medical devices	Proactive	Surveillance of the users (health care providers) of medical devices	Site visits of the users, evaluation of the labelling, review of the maintenance documents	Medium	All year	Corrective actions, vigilance notifications (if necessary), national measures (suspension of further use, administrative penalties)	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaite: jolanta.karavackate@vaspvt.gov.lt
Directive 93/42/EEC 98/79/EC 90/385/EEC	Medical Devices	-Medical devices -*In vitro* diagnostic medical devices -Active implantable medical devices	Proactive	According to the national law all users (health care providers) have to register information about medical devices used by the user. This information must be sent to the national competent authority	Registration of the data into national data base	Medium	All year	Awareness of medical devices used on the national market, traceability of medical devices (vigilance cases)	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaite: jolanta.karavackate@vaspvt.gov.lt