STATE HEALTH CARE ACCREDITATION AGENCY
UNDER THE MINISTRY OF HEALTH

Budgetary authority, headquarters: Jeruzalės St. 21, LT-08420 Vilnius, tel: (8 5) 261 5177, fax: (8 5) 212 7310
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ON THE MARKET SURVEILLANCE PROGRAMME FOR 2015

The State Health Care Accreditation Agency under the Ministry of Health presents the prepared Programme for Market Surveillance of Medical Devices for 2015. The Programme for Market Surveillance of Medical Devices has also been sent to the e-mail vedas.samukas@ukmin.lt.

ATTACHED: Programme for Market Surveillance of Medical Devices for 2015, 2 pages.

Director /signature/ Nora Ribokienė

J. Karavackaitė, jolanta.karavackaite@vaspvt.gov.lt, 261 5177

MARKET SURVEILLANCE PROGRAMME FOR 2015

MEDICAL DEVICES

Country: Lithuania

Surveillance authority:
State Health Care Accreditation Agency under the Ministry of Health
Jeruzalės St. 21,
LT-08420 Vilnius
Lithuania

Person responsible for the sector:
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Number of EU Directive	Sector	Product category	Type of inspection	Grounds for inspection	Method of surveillance	Priority	Programme launched	Results or follow-up	Contacts
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	Review of the information provided; evaluation of corrective actions taken; verification of the absence on the market of medical devices related to notifications; notification of relevant persons, if appropriate	High	All year round	Monitoring of the corrective actions taken	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaitė: jolanta.karavackaite@vaspvt.gov.lt
93/42/EEC 98/79/EC	Medical devices	- Medical devices	Reactive	Complaints submitted by	Review of the information	High	All year round	Corrective actions; preparation of a vigilance notification (if	General e-mail: vaspvt@vaspvt.gov.lt

90/385/EEC		- *in vitro* diagnostic medical devices - active implantable medical devices		consumers or other persons	provided; assessment of the documents provided; assessment of labelling of medical devices; laboratory testing (if necessary); on-site inspections of market operators (if necessary); notification of relevant persons concerning infringements detected, corrective actions and conclusions			necessary); national sanctions (suspension of further distribution/use, withdrawal from the market of unsafe medical devices, administrative penalties)	Jolanta Karavackaitė: jolanta.karavackaite@vaspvt.gov.lt
93/42/EEC 98/79/EC 90/385/EEC	Medical devices	- Medical devices - *in vitro* diagnostic medical devices - active implantable medical devices	Reactive	Notifications from customs offices	Inspections at customs offices; assessment of labelling of medical devices; drawing up conclusions on market release/suspension of release of medical devices	High	All year round	National measures concerning market release/suspension of release of medical devices	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaitė: jolanta.karavackaite@vaspvt.gov.lt
93/42/EEC 98/79/EC	Medical devices	- Medical devices - *in vitro* diagnostic medical devices	Proactive	Inspections of Lithuanian manufacturers	on-site inspections of Lithuanian manufacturers; assessment of technical dossiers and labelling of manufactured medical devices; notification of relevant persons concerning infringements detected, corrective actions and conclusions	Average	All year round	Corrective actions; preparation of a vigilance notification (if necessary); national sanctions (suspension of further distribution/use, withdrawal from the market of unsafe medical devices, administrative penalties)	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaitė: jolanta.karavackaite@vaspvt.gov.lt

93/42/EEC 98/79/EC 90/385/EEC	Medical devices	- Medical devices - *in vitro* diagnostic medical devices - active implantable medical devices	Proactive	Inspections of health care establishments	On-site inspections of health care establishments; assessment of labelling of medical devices and surveillance documents	Average	All year round	Corrective actions; preparation of a vigilance notification (if necessary); national sanctions (suspension of further use, administrative penalties)	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaitė: jolanta.karavackaite@vaspvt.gov.lt
93/42/EEC 98/79/EC 90/385/EEC	Medical devices	- Medical devices - *in vitro* diagnostic medical devices - active implantable medical devices	Proactive	In accordance with the Lithuanian legislation, health care establishments must register medical devices used and submit these data to the national authorised body	Entry of submitted data into the Information System on Medical Devices	Average	All year round	Traceability of medical devices (for the examination of vigilance notifications)	General e-mail: vaspvt@vaspvt.gov.lt Jolanta Karavackaitė: jolanta.karavackaite@vaspvt.gov.lt