

Procurement of Medical equipment for Emergency Centre-Clinical Centre of Serbia

IOP/23-2018/RD

Issued on February 8, 2019

Question 1

Will be accepted to submit equivalent license for registration for selling medicines and medical devices on different territory of Serbia, which is member of the EU? For equipment with ionizing radiation source, will be accepted to submit equivalent license for registration for selling equipment which produce ionizing radiation on different territory of Serbia, which is member of the EU?

Answer 1

Medical devices sale is regulated by The Law on medical devices (“Official Gazette of RS”, No. 105/2017), Paragraph XI Medical devices Marketing. This Law prescribes license for wholesale medical devices marketing which is issued by the Ministry of health of the Republic of Serbia.

For joint ventures it is sufficient that one member of joint venture is registered for selling medicines and medical devices.

Also, selling devices with ionizing radiation source is regulated by The Law on radiation and nuclear safety, (“Official Gazette of RS”, No. 95/2018), Paragraph X Marketing of ionization sources. Importer should have License for marketing of such devices which is issued by Serbian Radiation Protection and Nuclear Safety Agency. Holder of license should have permission for import of each particular device(or for ionization source).