DLF
ATTORNEYS-AT-LAW

Changes to the Technical regulations in relation to medical devices

On 1 July 2015, changes to the Technical regulations in relation to medical devices and Technical regulations in relation to active implantable medical devices became effective. According to such changes, which were adopted on 1 July 2014, all medical devices, auxiliary devices, medical devices for in vitro diagnostics shall not be circulated in Ukraine if they fail to satisfy the requirements of the abovementioned Technical regulations and are not labelled with the national conformity mark.

Thus, as of now the customs clearance of imported medical and auxiliary devices will be performed on the basis of declaration of conformity issued by the certification and standardization authority.

The requirements of the Technical regulations are not applied to medical products, cosmetic products, other devices and products that are not classified as medical devices, in vitro devices or active implantable medical devices.

The Technical regulations are not applicable:

before 1 July 2016 – to medical devices the term of validity of the certificate of state registration of which is unlimited or expires after 1 July 2016; until expiry of the certificate of state registration – to medical devices term of validity of the certificate of state registration of which expires before 1 July 2016.

Such medical devices and medical devices for in vitro diagnostics are allowed for marketing and use in the territory of Ukraine before their expiration date without the need to obtain the declaration of conformity and to label them with the national conformity mark.

DLF ATTORNEYS-AT-LAW UKRAINE
+380 44 384 24 54; info@dlf.ua