

QNET BV – Authorized Representative Notice: Moldova accepts CE Marked Medical Devices

Dear Authorized Representative client,

The country of Moldova has signed a Free Trade Agreement with the EU and is in the process of becoming an EU country. As part of this process it is aligning its medical device regulation with that of the EU. Moldova can be found between Romania and Ukraine, 76% of the populations speaks Moldovan, a dialect of Romanian and Russian. Population is 3.559 Million people (2013).

The Moldovan Competent Authority (Agentia Medicamentului si Dispozit Medicale – AMED) let it be known that the country's new medical device legal framework is to be based on transposing and implementing the EU medical directives and only CE-marked devices are to be present on the market in Moldova.

However local registration still applies and an application for product approval can be found here: http://www.amed.md/tc_userfiles/file/DM/Ordine/ordin%20A07_PS-01_Rg04-177.pdf

We strongly recommend that you contact your Moldovan distributor or agent for assistance with the Moldovan language documents.

Keeping you up-to-date as a good Authorized Representative should.

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