QNET BV – Authorized Representative Notice: Risk Class I EU Market Surveillance Project

Dear Authorized Representative client,

The European Commission is about to announce that they have allocated US$225,000.00 for a small market surveillance project, to be followed by additional funding of US$1.12 Million as 50% of the overall cost of a joint market surveillance project to be rolled out simultaneously in several member states.

Included in this 'intense' joint market surveillance project is a review of the quality of instructions for use, particularly for Risk Class I medical devices. This project will be rolled out simultaneously in several countries.

The medical device market surveillance working group is also interested in discussing the adoption of an existing market surveillance program established by Prosafe- (Product Safety Forum of Europe) a non-profit progressional organization for market surveillance authorities and officers throughout the European Economic Area.

QNET BV did receive a questionnaire from the Dutch Competent Authorities, whose market surveillance focus is presently on medical software. We were asked if we acted as an Authorized Representative and distributor of medical device software. We confirmed that we are an authorized representative only. QNET BV does not act as a distributor or perform any other marketing function.

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

Copyright © 2016 QNET BV – All rights reserved.