QNET BV – Authorized Representative Notice: De-designation of and Complaints about EU Notified Bodies

Dear Authorized Representative client,

During the last few weeks we have received many complaints about Notified Bodies being tough, rude, expensive and non-value adding.

We suspect that this is a result of the auditing of all Notified Bodies, since 2013, by an auditing team that consists of one European Commission representative and two representatives from other member state regulatory authorities.

This audit team's objective is to ensure that a Notified Body has the necessary competence to carry out the assessment of medical devices as stated in their scope statement.

The outcome of these audits has led to de-designation of Notified Bodies (approx. 20%). Resulting in a large number of manufacturers being forced to change Notified Body.

If you are contemplating a change in Notified Body (as a result of de-designation or voluntary) you need to follow the 'change of Notified Body document': http://www.nbog.eu/resources/NBOG_BPG_2006_1.pdf

If you are informed that your Notified Body has been de-designated following needs to take place:

a) Your Notified Body has to inform you that they were de-designated because they were not fulfilling the requirements of the directive, so you can start the transfer process with a valid certificate, which is much easier than transferring without a valid certificate. Your new Notified Body will be suspicious of the validity of your present certificate and will therefore increase the depth of the assessment.

b) The former Notified Body has to give you an explanation about the reason for their de-designation. You should check this out further with the competent authorities in the hope that they will be extending a reasonable timeframe for the transfer to a new notified body where the certificate is kept valid.

Just understand that you are starting from the beginning and you need to make sure that you select a new Notified Body based on their competence level, clinical and technical resources as it relates to your type of devices. Your new Notified Body should have an internal process for these transfers, please ask for it.

De-designation of a Notified Body will be very expensive for manufacturers, so please make your decisions carefully!

Keeping you informed as a good Authorized Representative should.