QNET BV – Authorized Representative Notice: New Guidance documents from the NBOG

Dear Authorized Representative client,

The Notified Bodies Operations Group (NBOG) consisting of: a) representatives from the designating and competent authorities of the EU member States; b) EFTA countries; c) Mutual Recognition Agreement Partners (i.e. Switzerland); and d) the European Commission, have finalized 3 important new guidance documents for manufacturers and notified bodies.

They are:

1) Guidance on Renewal of EC Design-Examination and Type Examination Certificates: Conformity assessment procedures and general rules.
You can find it here: http://www.nbog.eu/resources/NBOG_BPG_2014_1.pdf

2) Guidance on the information required for Notified Body Medical Device Personnel involved in Conformity Assessment Activities.
You can find it here: http://www.nbog.eu/resources/NBOG_BPG_2014_2.pdf

3) Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System.
You can find it here: http://www.nbog.eu/resources/NBOG_BPG_2014_3.pdf

Kindly download these guidance documents for your future use.

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