QNET BV – Authorized Representative Notice: Status of New Medical and IVD Regulation Discussions in the EU

Dear Authorized Representative client,

The trilogue meetings between the European Council, European Parliament and European Commission that are being held behind closed doors, are moving slowly.

At this time the negotiations/discussions have not yet produced a final text for the new Medical Device Regulation or the In Vitro Diagnostic Device Regulations.

At present mostly political issues remain and here are some examples of what they include:

- Genetic testing
- CMR substances
- Scrutiny/Special Notified Bodies
- Device reprocessing
- Manufacturer and Authorized Representative mandatory Product Lability Insurance
- Classification rules affecting: rule 6 (reusable surgical instruments), Nanotech and substance based devices.
- Transition period from old directive to new regulation
- Clinical Investigations
- In-house (hospitals) manufacturing of medical devices
- Notified Body and Competent Authority resources, especially in the IVD area.

Etc. etc.

Several of the intelligence sources that we regularly track are estimating that the final new regulation texts may become available mid to end 2016. However since these meeting are being held behind closed doors we are all guessing.

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