QNET BV – Authorized Representative Notice: RoHs Directive 2011/65/EU – July 22, 2014 deadline – documentation required

Dear Authorized Representative client,

Effective July 22, 2014, it becomes illegal to ship to the EU, electrical and electronic medical equipment/devices unless they comply with two Directives:

1) Medical Device Directive 93/42/EEC
2) RoHS Directive 2011/65/EU

As your European Authorized Representative we therefore request the following new and/or revised documentation, electronic version only, by 22 July 2014:

a) Medical Device Directive 93/42/EEC and RoHS Directive 2011/65/EU combined Declaration of Conformity.
b) RoHS Directive 2011/65/EU technical file documentation in accordance with EN50581:2012.
c) Medical Device Directive 93/42/EEC and RoHS Directive 2011/65/EU, updated Risk Assessment in accordance with ISO14971:2012.

If your device is covered by a RoHS Directive 2011/65/EU exemption kindly send us an officially signed statement referring to the correct exemption number.

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