QNET BV – Authorized Representative Notice: Revision of Medical Device Directive 93/42/EEC: Qualified Person

Dear Authorized Representative client,

The EU proposes a revision of the Medical Device Directive 93/42/EEC into a 'Regulation'. This proposed regulation can be found here: http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

The approval process of the Regulation has been ongoing since 2012 and once approved there will be a transition period of 3 maybe 4 years. Considering the massive changes, this will be a very short period of time. Some of the changes/additions may need more than 3 years of preparation.

For example: Qualified person (QP):

Article 13: Person responsible for regulatory compliance. This may affect your hiring/training decisions during the next 3 years, it states:

1. Manufacturers shall have available within their organization at least one qualified person who possesses expert knowledge in the field of medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC54.

2. The qualified person (QP) shall at least be responsible for ensuring the following matters:
(a) that the conformity of the devices is appropriately assessed before a batch is released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) that the reporting obligations are fulfilled in accordance with Articles:

- 61: Reporting of incidents and field safety corrective actions.
- 62: Electronic system on vigilance
- 63: Analysis of serious incidents and field safety corrective actions
- 64: Trend reporting
- 65: Documentation of vigilance data
- 66: Implementing acts

(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

3. The qualified person (QP) shall suffer no disadvantage within the manufacturer's organization in relation to the proper fulfilment of his duties.

We recommend that you adjust your training and hiring procedures accordingly and, where applicable, prepare for questions by the Notified Body regarding the credentials of your organization’s Qualified Person. This applies to all risk classifications.

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