Background Notes for Tomb Thumb

Tom Thumb Design

The Tom Thumb design was originally instigated by clinicians in Princess Mary Hospital Newcastle (Hospital now closed inventors, now deceased) Dr E Hay.

It was passed on to Viamed to manufacture.

External specialist consultants were used (in design files).
At the time CE marking did not exist.

ISO9000 (BS5750) was not in operation and it was not until the mid-1990s that Viamed achieved ISO9000 for design.

The current Tom Thumb file can therefore only be re-written as a product already designed and manufactured with a 10 + year track record before the current legislation.

We can only update the files as long as we do not falsify information not originally existing.

Essential requirements
Changes to design etc.
We can complete the risk assessment assuming we were starting now, but still ending up with the current design. Unless the current protocol is unsafe.

New information can be added to the file so long as it adds to its value and does not have the effect of reducing product credibility. This would certainly mean a product withdrawal and re-design. Probably not economic.

There will be no changes to the proven design of the Tom Thumb unless driven by the end user (possible future standards).

The MDD addresses this problem in several areas

MDD
COUNCIL DIRECTIVE 93/42/EEC
1993L0042 EN 11.10.2007 005.001 1
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Whereas, in order to demonstrate conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices; whereas such

harmonized European standards are drawn up by private law bodies and should retain their status as non-mandatory texts; whereas, to this end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines on cooperation between the Commission and these two bodies signed on 13 November 1984;

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Whereas medical devices should, as a general rule, bear the CE mark to indicate their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose;

EN Standards
I believe (I can find no direct statement in MDD) that EN standards are mandatory, and in fact infer the opposite. I also interpret that they are suggested as a means to justify the comply statement (ER) without extra supplementary explanation.

Other ways were found and accepted on BSI audits in the past.

We categorically state we build to these standards, but have not submitted the products to 3rd party test or audit. I do believe EN 62366-1 on usability is not a mandatory standard to MDD. Usability can be proved in other ways.

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