Background Notes for Tomb Thumb

Tom Thumb Packaging

ER5,7.2,8.6 The only way to test packaging is to send a package and examine on return. This was done then instruments were sent out and returns (0) monitored. With many thousands now having been without mishap or complaint the data is zero failures in packaging. This can be proven by access to our QA system records.

Tom Thumb Sterility

Iddoc 13285 MAC Manual part 1 Principles
Iddoc 12384 MAC Manual part 1 Principles section 3-1
Iddoc 12386 MAC Manual part 2 Protrocols
Iddcoc 13287 MAC Manual part 3 Procedures
The Tom Thumb is not suitable for sterilisation as It contains O rings
However after barrier nursing if the unit is sterilised in accordance with MAC and MHRA protocols and certified. as it is brass it is possible to be dismantled and rebuilt by a trained technician.
This is trying to cover any eventuality which may be raised by users.
Because of national edicts on decontamination no sterility tests or microbiology tests are required. The units when delivered are not sterile

Tom Thumb ingress of water.

The Tom Thumb is subjected to gas flows through it. The gas may be humidified to 100% RH. Condensation may them take place inside the Tom Thumb. Once humidity stops the residue will evapourate. This has not proven to be a problem since 1993 with its introduction.
The gas is supplied via a EN standard component logged by a recognised 3rd party. No acces unless it is removed. Blood and other contaminents have no method of entry due to construction. Positive pressure gas input ensures any dust is expelled,

Tom Thumb life

Initial Investigation ER4 DocID 3306 Estimated life. Based on the components and materials used. If user life (now proven to be in excess of 10 years) is estimated at 10 years then storage life must be more.

Tom Thumb Accessories

Apart from the bracket all other accessories are supplied /or procured from recognised CE certified manufacturers each having their own CE Technical files.

Background Notes for Tomb Thumb

Tom Thumb Design

The Thumb was originally instigated by +clinicians in Princess Mary Hospital Newcastle (Hospital now closed inventors now deceased) It was passed on to Viamed to manufacture. External specialist consultants were used
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 .
I believe we can only update the files as long as we do not falsify information not originally existing.
We can upgrade software
Essential requirements
Changes to design etc.
We can complete the risk assessment assuming we were starting now but still ended 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 ??)

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;

Background Notes for Tomb Thumb

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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. I believe they are suggested as a means to justify the comply statement without extra explanation .
Other ways were found and accepted on BSI audits in the past. We state we build to these standards but have not submitted the products to 3rd party test
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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