MDD
COUNCIL DIRECTIVE 93/42/EEC
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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;
Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to ‘minimizing’ or ‘reducing’ risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety;

I interpret this to mean any product designed and manufactured prior to the introduction of the CE system
The Microstim was originally designed by MRI Manchester Royal Infirmary by a team of Medical Physics Technicians headed by Malcolm Purnell.
CE marking did not exist.
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The current file can therefore only be re-written as a product already designed and manufactured with a 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

Many of the original design team and clinical evaluation team are now retired or deceased. Any organisations that employed them as consultants need legally only retain documentation fo 11 years. This assumes those organisations still exist.
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 and have used theses standards as a guide but have not submitted the products to 3rd party test or to be audited against Harmonised Standards
J.S.Lamb
09/04/17