Notes on Products designed before CE system

Designs of most medical products was originally instigated by +clinicians or Departments of Medical Physics.They would be passed on to Viamed to manufacture and make into a saleable product
External specialist consultants were often used when the original was just an idea.
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.
Current design 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 due to the onerous current regulation and cost of documentation and clinical trials this will not be not economic

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