

Product Information Bulletin

December 2012

Comark Policy re 21CFR Part 11

Dear Customer,

RF500 has been designed with the requirements of 21 CFR in mind, e.g. Full password protection, Audit Trails, Electronic Signing of data etc. However, Comark does not undertake to tell you that a deployed RF500 installation will meet the requirements of 21 CFR Part 11.

Comark understands that you are the expert in 21 CFR and that you will undertake to validate RF500, and its components, by way of IQ OQ PQ in order to confirm suitability for your application.

Comark is aware that many RF500 systems installed over the past 6 years have been validated to meet 21 CFR and therefore we are confident that you will find your installation meets your requirements.

If you have any questions please contact your Distributor or Comark representative who can advise you further.

Best Regards,

Andy

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