PRESERVE / PROTECT / NURTURE

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21 CFR Part 11 Statement Regarding Planer Products

21 CFR Part 11 is the FDA's regulation for electronic documentation and electronic signatures. It outlines the administration of electronic records in a medical device company's quality management system.

It is designed to cater to the evolving needs of the medical device industry, with the purpose of helping companies:

- Maintain data safely and securely, and ensure data is not corrupted or lost.
- Ensure that approval and review signatures cannot be disputed.
- Trace changes to data.
- Prevent and/or detect falsified records.

21 CFR Part 11 covers the overall system of hardware, software, and processes and therefore compliance will depend upon the End Users SOP's as much as the specific device(s) used (e.g. if multiple users are sharing the same login for a device, the system will not be compliant regardless of measures taken by the manufacturer)

What does this mean for Planer equipment?

Products supplied by Planer such as DeltaT, PIMS, MR7 and DATAssure are all *"suitable for 21 CFR Compliance*", meaning that they can be added to a compliant system without introducing risk. Without a suitable system in place, they are not automatically "*21 CFR Part 11 Compliant*"