FAQ: "Is there anything that documents (certifies) that HunterLab EasyMatch QC-ER software and instruments conform to FDA 21 CFR Part 11 ERES - electronic records, electronic signatures?"

There is a subtle but important point here. Software or hardware cannot be certified as being FDA 21 CFR Part 11 ERES compliant as compliance goes beyond software to include features of the operating system configuration as well as definition of the color measurement method by the user. For this reason HunterLab does not have a specific document that states the software or hardware is inherently CFR Part 11 compliant.

What we do provide is a combination which is better - EZMQC-ER (EasyMatch QC Electronic Records) software, an appropriate sensor, hardware security key and a **Validation and Compliance Notebook** that:

- At the beginning of the notebook, describes in detail how special features of EZMQC-ER meet the specific requirements of FDA 21 CFR Part 11 ERES.
- Describes how the Windows operating system should be configured to assist EZMQC-ER in being CFR Part 11 compliant.
- Describes how EZMQC-ER needs to be installed and configured to be CFR Part 11 compliant.
- Provides the necessary IQ/OQ/PQ protocols associated with the user product measurements that support CFR Part 11 compliance.
- Provides a validation protocol that allows the User to self-certify the CFR Part 11 compliance of product color measurements made on HunterLab equipment using EZMQC-ER software.

FAQ: "Is there any certification from FDA regarding compliance of the HunterLab EasyMatch QC ER software to 21-CFR-11?"

The US Federal Drug Administration does not certify software compliance. Instead the FDA defines the CFR Part 11 requirements and the software manufacturer has to describe how they meet them.

HunterLab does this quite extensively in our **Validation and Compliance Notebook** which lists all the CFR Part 11 requirements for software operating our colorimetric spectrophotometers, and how we meet each of them. Meeting the requirements is based on security features built into EasyMatch QC ER, configuration of the Windows operating system, operational practice or a combination of the above.