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October 15, 2020

To: Whom it may concern

Subject: FDA Title 21 CFR Part 11 and HIPAA Compliance Summary for Florence eBinders

Florence eBinders has been authorized for use with HIPAA protected data and for research requiring Title 21 CFR Part 11 compliance at the University of Minnesota (UMN).

The UMN completed initial validation of Florence eBinders for the U.S. Food and Drug Administration (FDA) Title 21 Code of Federal Regulations (CFR) Part 11 compliance in July, 2020. The validation process included reviewing vendor validation materials, developing and executing functional tests, and documenting standard operating procedures. Staff are required to complete training before gaining access to the eBinders system.

A review of the Florence vendor documentation confirmed extensive validation testing materials, a full traceability matrix to the Part 11 regulations, and an independent third-party audit certification for FDA 21 CFR Part 11 compliance. The certification is available for your review.

A letter was sent to the FDA in April 2020, certifying the intent to use electronic signatures at the UMN; a copy is available for your review.

The UMN information security team completed a security review of Florence eBinders and the UMN has a Business Associate Agreement in place with the vendor. HIPAA data protection processes have been established, including but not limited to access management, security monitoring, and security incident handling procedures.

Sincerely,



Signed Electronically by:
Joshua Fehrmann - jaf@umn.edu
16-Oct-2020 @ 02:40 PM CDT Reason: Authorship

Joshua A. Fehrmann

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