



# EasyMatch Essentials™-ER

## Electronic Records, Data Security, and 21 CFR Part 11 Readiness

### Description

**EasyMatch Essentials™-ER** (Electronic Records) provides secure, compliant, and fully traceable data management across all HunterLab Essentials-based instruments. Available both on-board and within **EasyMatch Quality Central™**, it ensures every color measurement is protected, auditable, and aligned with international regulatory standards.

### Purpose

EasyMatch Essentials-ER (Electronic Records) is engineered for laboratories that operate in highly regulated environments, particularly within **bio-pharmaceutical**, **nutraceutical**, and **medical device** manufacturing. The software provides a unified, validated platform for color and appearance data acquisition, ensuring that every record meets FDA, EU, and USP expectations for data integrity and auditability. Each measurement record is automatically time-stamped and permanently linked to the **user ID**, **instrument serial number**, and **calibration reference**, creating a continuous electronic trail from data acquisition through export. This framework supports both standalone and networked instrument configurations, enabling QA managers and compliance officers to demonstrate full control over analytical data without manual transcription or re-entry errors.

When connected to **EasyMatch Quality Central**, Essentials-ER extends its compliance framework to multi-instrument networks, enabling centralized configuration,



validation, and data archiving. Together, these systems deliver seamless, user-authenticated workflows—bridging laboratory and production environments within a single, secure ecosystem.

## Secure Data Architecture

EasyMatch Essentials-ER stores all measurement data within a protected file system designed to preserve **data integrity** from acquisition through export. Each dataset includes metadata elements such as:

- **Automatic time-stamping** for traceable record chronology.
- **User identification and role** for accountability.
- **Instrument serial number** and **calibration reference** for verification.

All data files are **write-protected** to prevent overwriting or unauthorized alteration. This ensures that the original analytical record remains intact for audit, re-analysis, or regulatory review.

## Audit Trail and User Accountability

EasyMatch Essentials-ER maintains a **permanent, non-erasable audit trail** that automatically records every system event—including calibration, tolerance updates, method editing, and measurement actions—with corresponding user credentials and timestamps. These audit logs can be reviewed, filtered, and exported in secure electronic formats (e.g., CSV, XML, or PDF) for **regulatory submission or archive**.

Role-based access control provides three operator levels:

- **Administrator** – Full configuration rights, including method setup and tolerance management.
- **Supervisor** – Review and approval rights, with access to data and audit logs.
- **Operator** – Measurement and reporting access only.



User authentication can be managed locally or through network credentials such as **Active Directory**, ensuring consistent enforcement of enterprise security policies across all connected instruments.

## Compliance Alignment

EasyMatch Essentials-ER supports the documentation, verification, and validation expectations outlined in major global regulatory frameworks, including:

- **FDA 21 CFR Part 11** – Electronic Records and Electronic Signatures.
- **EU Annex 11** – Computerized Systems in GMP Environments.
- **USP** – Analytical Instrument Qualification (AIQ) and data integrity guidance.

This alignment ensures that laboratories can integrate appearance data directly into validated systems without additional customization or external validation scripting.

## Regulatory Confidence Through Integration

When operated through **EasyMatch Quality Central**, the Essentials based instruments achieve full network-based compliance readiness. Controlled, user-authenticated workflows maintain **secure data storage**, **method versioning**, and **result traceability**—while allowing approved users to export measurement data to compliant, encrypted environments.

For extended functionality, the Essentials-ER environment integrates seamlessly with **EasyMatch QC**, where advanced compliance tools—such as **e-signatures**, **multi-instrument control**, and **centralized audit verification**—can be implemented under the same regulatory framework.

## Benefits

The EasyMatch Essentials-ER platform delivers more than analytical precision—it delivers **regulatory confidence**.



- **End-to-End Data Integrity:** Ensures every record is traceable, secured, and validated.
- **Regulatory Readiness:** Meets the expectations of FDA 21 CFR Part 11, EU Annex 11, and USP.
- **Scalable Architecture:** Operates seamlessly from standalone instruments to enterprise networks.
- **Efficiency and Trust:** Eliminates manual logging and verification steps while ensuring full transparency for audits and QA review.

From **powder blending and tablet coating** to **capsule color verification**, EasyMatch Essentials-ER guarantees that every color measurement not only meets product specification—but also satisfies the highest standards of **data integrity, traceability,** and **regulatory compliance** required in modern pharmaceutical production.