

How to achieve compliance, mitigate risk and manage costs by implementing regional serialization.

Leading global brands are making massive investments in serialization infrastructures, although those may lack the capabilities required to meet existing regulations and the flexibility to adjust to evolving future requirements. Extensive reinvestment, unpredictable production downtime and restricted market access can be the fallout of mismanaged serialization strategies.

As part of Systech's global serialization offering, Systech UniScope™ is designed for manufacturers that require line serialization solution that maps directly to a single country or regional mandate.



UniScope is a module of the UniSeries™ platform that is pre-configured to map directly to a single country or regional serialization mandate.

Rapid Implementation

Systech's UniScope enables manufacturers to rapidly and easily comply with regional regulatory requirements. Pre-configured with everything needed for compliance, Systech UniScope is easy to integrate, dramatically reducing overall implementation time, line downtime and cost.

Future-Proofed Compliance

As regulations are revised, Systech UniScope assures ongoing protection of investment by delivering regular, cost-effective upgrades. Systech UniScope can be upgraded at any time within the Systech UniSeries suite of serialization solutions and integrates seamlessly with Systech UniSecure authentication platform.

BENEFITS

- Supports Regional Compliance
- Rapid Implementation
- Reduce Line Downtime
- Efficient Design and Configuration
- Future-Proofed Compliance
- Upgradable within Systech's UniSeries Suite
- Compliance with Changing Regulations

FEATURES

- Meets Regional Regulatory Requirements
- Supports In-Lot and Post-Lot Rework Operations
- Integrates Into Legacy Platforms
- Customized to Specifications
- Packaging Use Cases
- Scalable as Part of the UniSeries Suite
- Master Data and Package Order Support
- Built-in test and simulation environment
- Non-Serialized Quality Vision Inspection
- Suspend and Resume Lot Selections
- Reporting Capabilities
- Advanced Configuration Options
- Use Authentication - On Existing Action Directory

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System UniScope Compliance Models

Each regional model is pre-configured and ready to deploy to meet pre-designed regional regulatory compliance requirements.

Unit Level. Compliance readiness for the EU Falsified Medicines Directive and regulations that require only unit-level serialization, such as Argentina, South Korea and Saudi Arabia.

Configuration formats

- Carton/tray only
- 1 serialized and 1 non-serialized configuration

Printing & Inspection

- Human Readable Lot Number, Expiry Date, GTIN, Serial Number
- Data Matrix following the GS1 formats

USA DSCSA. Compliance readiness for the Drug Supply Chain Security Act (DSCSA) for 2017.

Configuration formats

Solution for the US supports two (2) levels of serialization for Unit and Homogeneous case.

- Carton/tray and case serialization
- Label web (bottles) and case serialization
- 1 serialized and 1 non-serialized configuration

Printing & Inspection

- Human Readable Lot Number, Expiry Date, GTIN, Serial Number, Case Qty.
- Data Matrix or 1D barcode following the GS1 formats

Brazil ANVISA. Compliance readiness for the ANVISA RDC-54 regulation.

Configuration formats

Solution for Brazil supports unit level serialization with two (2) levels of aggregation to the case and pallet. It utilizes the Pack-By-Layer (PBL) solution to guarantee case packaging accuracy and data integrity.

- Carton, Manual PBL, and Manual Pallet Aggregation
- Carton, Semi-Automatic PBL, and Manual Pallet Aggregation
- Carton, Manual Case and Pallet Aggregation (Hand-Scan)
- 1 serialized and 1 non-serialized configuration

Printing & Inspection

- Human Readable Lot, Expiry Date, ANVISA Reg. #, GTIN, SN, Case Qty.
- Data Matrix or 1D barcode following the ANVISA IUM and SSCC formats

China CFDA

Configuration formats

- Unit carton, Manual or Automatic PBL Case
- Unit carton, Bundle and Manual or Automatic PBL Case

Systech is the global technology leader in anti-counterfeiting, product safety, consumer and brand protection. Systech pioneered serialization and is defining the future of authentication.

Systech unifies and optimizes authentication, enterprise serialization and track-and-trace technologies to ensure regulatory compliance, mitigate risk, and drive efficiency and profitability.

For 30 years, Systech's innovation has led best practices for key brands representing industries across consumer packaged goods, food and beverage, aviation and automotive and life sciences. Systech works globally with 19 of the top 20 pharmaceutical companies.

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