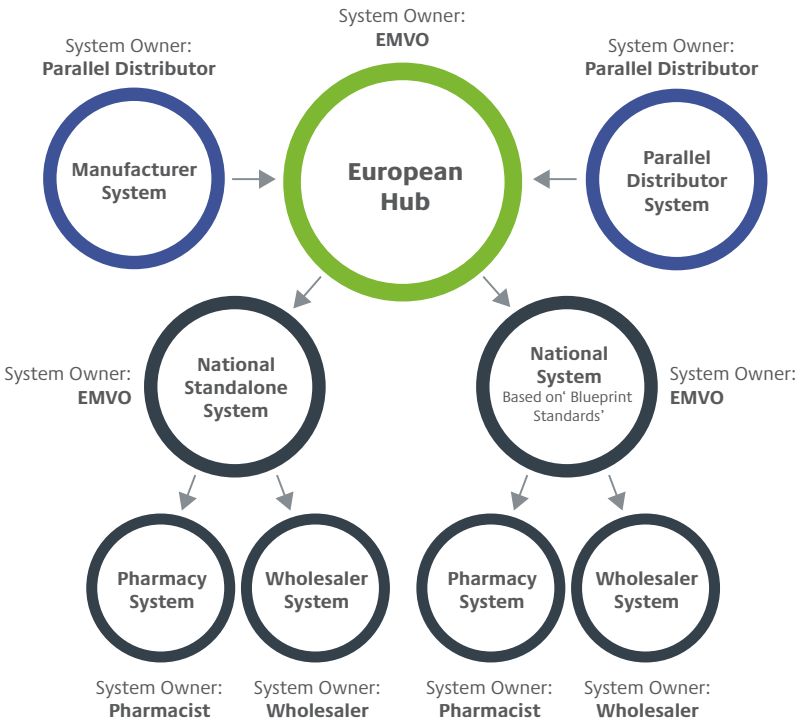
SYSTECH®
connected solutions by Markem-Imaje®

DATA SHEET

EU Falsified Medicines Directive: Simplify compliance with Systech

In force since February 2019, the Falsified Medicines Directive (FMD) requires that every prescription drug have not only an antitamper device, but a unique identifier in both machine- and human-readable forms on the packaging. This requirement goes far beyond just printing a barcode on a box.

Meeting this mandate is not simple. It requires serialization, track and trace and data integrations with regulatory repositories . It is important for manufacturing companies to understand how each of these elements contribute to meeting the regulation. In many cases, this involves evaluation of multiple vendors, supplying individual parts of the solution. The risks of such an approach often outweigh any potential benefit. For expediency, flexibility and implementation ease, a holistic solution is the best approach to getting and staying compliant with all your production lines.



The manufacturer must send the following information to the EU Hub:

1. The Unique Identifier data elements, including the product code, the serial numbers, lot number, expiration date and the reimbursement code (where required)
2. The coding scheme of the product code, which can be a GS1 Global Trade Item Number, National Trade Item Number or some national code
3. The product master data, which are details describing the product, things like the product name, strength, dosage form, size, etc.
4. The EU member state(s) where the product is intended to be placed on the market. Remember, this is the list of national repositories that the EU Hub will send the data to
5. The name and address of the manufacturer placing the safety features on the product
6. The name and address of the Marketing Authorization Holder (MAH) for this product
7. The list of wholesalers authorized by the MAH to distribute the product
8. And where applicable, the code identifying the entry corresponding to the product in the database referred to in Article 57(1)(l) of EC Regulation No 726/2004

Systech's total solution

Systech provides a complete solution for FMD compliance—from on-package serialization through to data integration with the EMVO Hub. With implementations across the globe, Systech is the world's most trusted serialization and track-and trace expert—leveraging decades of experience to enable quick trusted compliance. As an advisor and partner, Systech deploys and implements software solutions designed to meet any regulation requirements, regardless of packaging hardware, new requirements or labels, or even as you expand to new regions. This holds true on new or retrofitted lines, owing to our ability to configure our solutions instead of customizing.

Regulatory hub connectivity

Systech has established the connections required to exchange data with the regulatory bodies (EMVO) in the EU that host the serializaed product data.

Seamless integration

Our flexible, scalable software platform offers unbeatable ease of implementation and speed to compliance. Equipment-agnostic, configurable solutions give you flexibility to adapt to new regulations cost-effectively without customizing for every change, wherever you do business. Systech enables seamless and secure data exchange for traceability throughout the entire supply chain. This—combined with the ability to connect with master data systems and regulatory databases—creates a compliant system of record for your products.

Unmatched support

As one of the few technically certified solution providers to access EMVO, Systech's trusted platform delivers value beyond compliance with unmatched support to guide you through the process.

As the world leader in serialization for decades, Systech's local European-based teams can leverage that expertise to simplify deployment, enabling straightforward FMD compliance with a flexible solution designed to fit your new or existing lines. Our solutions will guide you to compliance and beyond, now and in the future.

LEVEL 4| ENTERPRISE

Connectivity – Comprehensive track-and-trace and compliance integrations

LEVEL 3| SITE

Site Management – Provides site-level master data, serial number management, event reporting and manages offline serialization packing operations

LEVEL 2| LINE

Line Management – Sets up line equipment and maintains serialization data integrity throughout the packaging lot/batch

LEVEL 1| DEVICE

Equipment Interfaces – Works with existing or new packaging equipment

	Systech Solution	Our Competitors
Full Stack (L1–L4)	Single Vendor	Multiple Vendors
Configurable Solutions Library	Yes	No
Package Equipment Agnostic (capacity to retrofit)	Yes	No
Reusable Validation Packages (templates, assessments, traceability)	Yes	No
Transparency in Pricing	Full project scope pricing	Partial project scope pricing

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Eliminate supply chain risks!
Integrated, actionable data to drive efficiency, achieve compliance and protect your brand.

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