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Practical Checklist 2026

Is Your Pharma Packaging Line Serialization-Ready?

Practical Checklist for EU FMD / EMVS Compliance

The EU Falsified Medicines Directive (FMD) has fundamentally changed the pharmaceutical supply chain. Serialization is no longer an optional feature – it is a business-critical process that connects IT systems, printing technology, data management and logistics.

In practice, many projects fail not because of hardware, but due to unclear processes, poor data quality and missing system integration.

This checklist was developed by experts in packaging and automation technology. It helps you quickly assess whether your line is not only formally compliant, but also operationally EMVS-ready – and where concrete action is required.

Goal: identify risks early, ensure compliance and avoid costly rework.

1. Regulatory & Legal Basis

- ☐ FMD (2011/62/EU) and Delegated Regulation (2016/161) understood
- ☐ Products correctly classified as subject to verification
- ☐ Responsible NMVO (e.g. securPharm) connected
- ☐ Audit and authority processes defined
- ☐ 21 CFR Part 11 / EU Annex 11 considered

2. Serialization Data & Number Logic

- ☐ Serial numbers are randomly generated
- ☐ Uniqueness ensured over legal retention periods
- ☐ Product code correct (GTIN, NTIN or PPN)
- ☐ LOT and expiry date validated by the system
- ☐ National reimbursement number (if required) included
- ☐ Human-readable text and code are always synchronized

3. DataMatrix Coding & Print Quality

- ☐ Code according to ISO/IEC 16022 (ECC200)
- ☐ Sufficient module size and contrast
- ☐ Suitable printing technology (TIJ, laser, label, etc.)
- ☐ Camera verifies every pack (code + text)
- ☐ Defective codes are automatically rejected
- ☐ Code grading according to ISO/IEC 15415

4. EMVS / NMVS Connectivity

- ☐ Serialization software connected to the EMVO Hub
- ☐ National systems correctly addressed
- ☐ Data uploaded before the product leaves production
- ☐ Reconciliation mechanisms in place
- ☐ Error messages are processed automatically
- ☐ Test environment has been used

5. Decommissioning & Special Scenarios

- ☐ Export processes with correct timing defined
- ☐ Parallel import processes correctly mapped
- ☐ Returns within the 10-day window handled correctly
- ☐ Damaged packs are immediately and permanently decommissioned
- ☐ SOPs for special cases documented

6. Aggregation & Logistics

- ☐ Pack → bundle → case → pallet linked correctly
- ☐ Aggregation data available in the system
- ☐ Serial numbers traceable throughout the supply chain
- ☐ Automated scanning at goods-in

7. IT, Security & Compliance

- ☐ Audit trail available
- ☐ User roles and access rights defined
- ☐ Data backup and recovery concepts in place
- ☐ System validation documented
- ☐ Cybersecurity considered

Evaluation

0–10 checks: High risk – urgent action required
11–20 checks:: Partially compliant, increased audit risk
21–30 checks:: EMVS-ready
>30 checks:: Best-practice level

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We support pharmaceutical manufacturers and contract packers in planning, integrating and validating serialization systems – modular, EMVS-compliant and seamlessly integrated.

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