



2011/62/EU

Also outside the line production

In 2011, the EU Falsified Medicines Directive (FMD) 2011/62/EU was published. It applies to all prescription-only and selected OTC drugs in the European Union.

Drug safety is a valuable asset that is repeatedly endangered by falsified drugs. According to an estimate by the US FDA (Food and Drug Administration), more than 10% of all drugs in circulation are believed to be counterfeit. A Community code has therefore been established at EU-level to prevent the entry of falsified medicinal products into the legal supply chain.

The implementation of the Directive concerns not only pharmaceuticals which are produced and packed on large production line but also small batches. In most cases, it is not cost effective to change the production line frequently.

With the udaFORMAXX, Koenig & Bauer offers a sophisticated solution.

Solpharm Pharmazeutische Erzeugnisse GmbH, based in Melsungen in Germany, also relies on this offline solution.

Millions of glass ampoules and glass phials

Solpharm is a modern and efficient family-owned company with state-of-the-art production facilities. The company is a strong and reliable partner for national and international customers. Every year, millions of glass ampoules and glass phials are filled, inspected and packaged.

„Koenig & Bauer Coding, a long-term partner for coding systems, is the first point of contact for Solpharm.“

Kai Theer,

Teamleader Technical Services Packaging

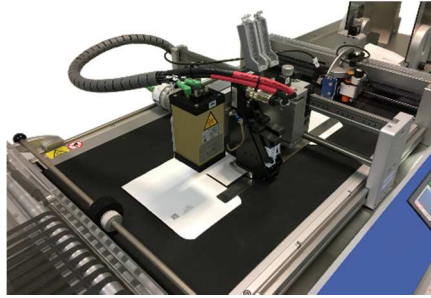




Data Matrix

(01) Product code (e.g. GTIN/NTIN/PPN)
(21) Serial Number
(10) Batch/Lot Number
(17) Expiry Date
National reimbursement number
(applicable to DE, FR, BR, ES, PT,)

Beispiel-Code



01 2011/62/EU

With the udaFORMAXX with its own stack-to-stack processing, Solupharm GmbH separates flat folding cartons – even crash lock cartons, complex formats and insertable flaps – which must be identified with a **serialised, unique code** in accordance with Directive 2011/62/EU.

Each individual pack must be marked with the following information:

- Product identification number, in the format GTIN, NTIN (or PPN for Germany)
- Batch number
- Use by date
- Individual serial number of the single pack
- If necessary, national healthcare reimbursement numbers, NHRN, for reimbursement by national healthcare insurers

02 Track & Trace

Equipped with a DOD inkjet for coding and an inspection system with corresponding Track & Trace software, the udaFORMAXX offers a cost-effective solution that enables **separation, serialisation and aggregation** in the smallest place.

Every printed code is verified with a camera system and recorded in the database.

Folding cartons whose codes were rated as „bad“ during camera scanning are automatically rejected via the udaFORMAXX reject station and subsequently booked out of the database by software.

03 Solupharm GmbH

For more than 40 years, the name Solupharm has been synonymous with high-quality, responsible contract manufacturing of sterile preparations in glass ampoules and glass phials. The new building in Melsungen is one of the **most modern production facilities** in Germany.

Solupharm operates in a market where the highest standards of manufacturing processes and quality standards are essential.

*Kai Theer,
Teamleader Technical Services Packaging*

„The uda concept has been convincing us for decades. The combination of systems from two machine builders in this compact solution is well thought-out and well implemented. In addition, the ergonomic operation of our system implementation is of course a highlight for the operator.“

udaFORMAXX – Offline-Solution

With its own stack-to-stack processing: ideal for flexibly and precisely just-in-time printing of variable data outside of the production line for small and medium batch sizes.

Can be combined with various coding and camera systems to meet the diverse requirements of all industries.



For more information: coding.koenig-bauer.com