



# SOLUTIONS TO COMBAT PRODUCT PIRACY

TAMPER-PROOF AND  
COUNTERFEIT-RESISTANT.

## SOLUTIONS TO COMBAT PRODUCT PIRACY

According to FDA estimations, ten percent of all medicinal products worldwide are counterfeit and cause harm to patients and pharmaceutical companies. The European Directive 2011/62/EU – also known as the Falsified Medicines Directive (FMD) – is putting a stop to these counterfeits: on the basis of serialization combined with tamper-evident pack closure. In the case of serialization, machine-readable codes for the stipulated end-to-end verification are generated and transferred to higher-ranking systems for posting in the EU database. Tamper-evident pack closure allows visual verification of the integrity of the medicine pack. Traceability also plays a major role outside the European Union. This is ensured by applying Track & Trace solutions.

A pharmaceutical manufacturer very appropriately referred to compliance with current and future regulations to combat product piracy as the “license to sell”, because manufacturers without appropriate solutions by the respective deadlines can potentially forfeit their ability to supply, which has a detrimental impact on their reputation. Uhlmann already offers customized solutions to meet all requirements – suited to respective national specifications, your product, and your packaging process.



Be prepared: The specifications of the Falsified Medicines Directive 2011/62/EU have to be implemented by **February 9, 2019**.

## DIVERSE REQUIREMENTS – CUSTOMIZED SOLUTIONS

### 1 **Serialization**

Software generates and manages unique, up to 20-digit serial numbers. These are recorded, transferred to the corporate IT system, and forwarded to the external EU database as required by the FMD.

### 2 **Tamper-evident closure**

Different technology allows various forms of tamper-evident pack closure. The consumer immediately recognizes whether a pack has already been opened.

### 3 **Track & Trace**

Also referred to as e-pedigree, aggregation, or full serialization. The unique serial numbers are aggregated, recorded, and transferred to higher-ranking systems.

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## SERVICES THAT ENSURE PRODUCT INTEGRITY

### Tamper-evident closure

- Hot-melt carton closure.
- Flaps sealed with a label (label technology).
- Mechanical carton closure (suitably designed carton/flap geometry).
- Information on alternative types of technology tested in a feasibility study. For example, the 2-shot process using hot and cold glue, or PUR gluing.
- Consultation on the selection of the most suitable option.
- All types of closure technology are available both for new cartoners and those already in operation.
- Retrofits on site – including necessary electrical and mechanical modifications.

#### **Uhlmann Serialization Platform:**

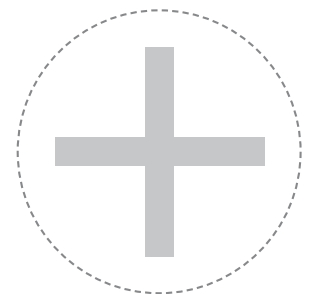
Compact, modular standalone unit. Allows tamper-evident labeling, also in combination with Track & Trace functions such as printing and inspection.

### Marking and traceability

- Various types of printing technology and label application.
- Intelligent OCR/OCV inspection systems, as well as printing/ marking systems suited to the application.
- Uhlmann software to record, aggregate, and manage serialization data relevant to the machine, line management, and the site server.
- Standalone systems for manual packaging processes, or when the revalidation of machines and lines is not desired.
- Solutions for primary, secondary, and tertiary packaging, as well as for warehousing and distribution processes.
- End-to-end marking and serialization solutions from the packaging line to higher-ranking systems, and to the corporate IT system.
- Complete turnkey project management.
- Full integration of serialization and Track & Trace systems into new as well as existing machines and lines from Uhlmann and other manufacturers.

## YOUR BENEFITS

- Compliance with serialization and marking specifications for reliable, traceable, and cost-optimized production.
- Comprehensive protection against counterfeiting; product and process reliability.
- Reliable supply chain from the packaging line to the pharmacy or the consumer.
- One partner: Uhlmann assumes overall responsibility for the line, site server, and the higher-ranking systems.



THE **HEARTBEAT** OF PHARMA PACKAGING

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