

Data Sheet

Serialization solutions

Scalable solutions: offline, inline, stand-alone.

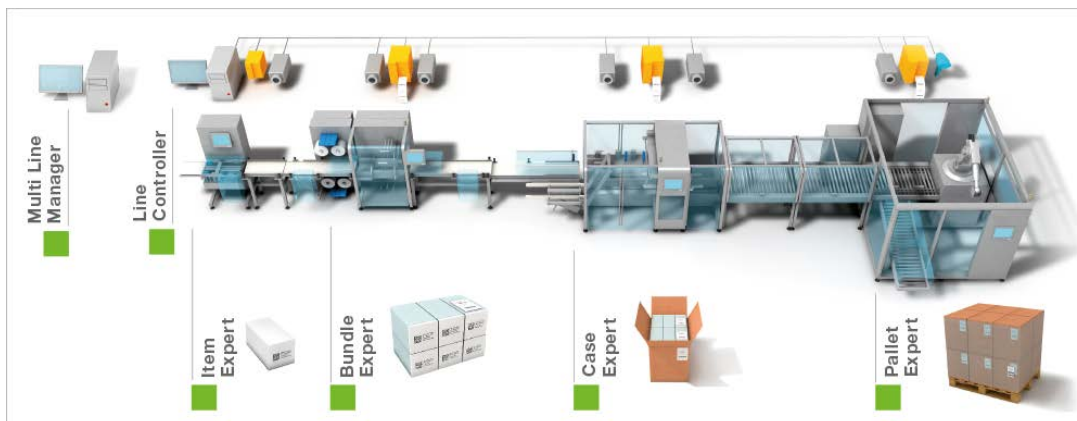
By means of Directive 2011/62/EU, the European Union has drawn up a mandatory standard for preventing the penetration of falsified medicines into the legal supply chain and to increase patient protection. According to this Directive, all prescription medicines – with the exception of those on the "White List" – as well as those medicines for self-medication cited on the "Black List" must be provided with an individual distinguishing feature (serialization) and protection from manipulation (tamper evidence). The Directive enters into force on 9 February 2019. Businesses have various options for applying individual detection features to their products. Consequently, flexible Track&Trace solutions based on customers' requirements are in greater demand than ever before.

Approaches to finding solutions

The Medipak Systems companies have been busy from the start with the requirements relating to serialization and tamper evidence for the packaging of medicinal products. Using this knowledge, they provide prompt support for their customers in respect of fulfilment of the requirements and guarantee, together with their customers, smooth application of the statutory provisions. Rondo, Seidenader and Werum IT Solutions provide their customers with flexible solutions for secure, efficient serialization of their products. From offline serialization during the production of folding boxes through stand-alone solutions to integrated concepts - customers can find the solution which best suits their existing and future packaging and logistics processes.

Seidenader provides customers with a modular **Track&Trace solution which guarantees compliant serialization and aggregation of each individual packaging level** (single packs, bundled packs, cartons and pallets). Stand-alone solutions as well as integration of components into third-party systems at each secondary packaging level are available.

Seidenader's ItemUnit provides serialization of individual packs (Items), plus, if required, application and verification of tamper evidence labels. Depending on the applicable regulations, in addition to batch-specific information in clear text and a random, unique serial number, Seidenader also prints a Data Matrix code with all the this information on the folding box. Both clear text and Data Matrix code are checked for content, print quality and consistency of the information.



In the downstream processes on the packaging line, there follows - again depending on the applicable regulations - aggregation of the serialized individual packs: they are first (where applicable) combined into bundles. The serial numbers of all Items in a bundle are recorded. Then a serialized bundle label is printed, applied and verified. Finally, the Item serial numbers within the bundle are linked to the serial number of the bundle. An identical operational sequence is repeated - if required - both at the case packing level and at the end

of the packaging line at the pallet level. This means that within the supply chain the content at each packaging level can be traced back to the manufacturer and to the individual folding box.

Werum IT Solutions offers a **vendor-independent Track & Trace solution** to comply with the anti-counterfeiting requirements of any country around the globe. It is available as standalone solution or can be seamlessly integrated into the packaging solution with EBR and KPI/OEE or the PAS-X MES (Manufacturing Execution System).



PAS-X Track & Trace provides serialization and aggregation functionalities for packaging processes. It integrates the ERP and the Global Repository with the shop floor packaging equipment and line controllers. PAS-X Track & Trace is a smart option to get started with Werum's manufacturing IT solutions and can easily be extended to a full-scope PAS-X MES. Drug manufacturers can thus benefit from the additional advantages of comprehensive production control and documentation, including equipment management.

Rondo offers Medipak Systems' customers an alternative to inline serialization on the packaging line: **offline serialization on the premises of the folding box manufacturer**. Consequently the integration of printing technology, camera and ejection into the customer's packaging lines and the training of employees to manage printing technology become superfluous. The basis



for workable off-line serialization is secure data exchange with the folding-box manufacturer and adaptation of processes to the special requirements of the pharma industry.

For offline serialization Rondo has invested in an Atlantic Zeiser DIGILINE Single Pharma 450, which covers all the requirements for reliable offline serialization.



Importing of data from the customer is also automated, as is data export of the result files. Assignment of serial numbers to the production order is performed using unique naming with automatically generated file names. For production, the data is provided automatically via an enhanced master data management system. For quality assurance, a second camera which checks the correctness and quality of the codes is installed in the equipment. The production results report and the balance file can be generated in different data formats according to the customer's wishes and sent to the customer via electronic data exchange.

interpack exhibits

Seidenader provides **Track&Trace solutions** for serialization and aggregation of each individual packaging levels which meet all regulatory requirements: for single packs, bundled packs, cartons and pallets. At interpack, Seidenader is presenting its solution in conjunction with the Mediseal blister line: the **ItemUnit-Tamper Evident**, complemented by the CaseUnit and the PalletUnit. On Seidenader's ItemUnit, codes are applied and verified on folding boxes, depending upon the applicable regulations: e.g. in addition to batch-specific information in clear text and a random, unique serial number, also a Data Matrix code ,which contains all the above-mentioned information.

Werum IT Solutions provides a supplier-independent **Track & Trace solution**. The solution provides functions for serialisation and aggregation in packaging processes and integrates ERP and Global Repository with packaging technology and line control at production level. On the Medipak Systems booth, Werum is demonstrating data exchange with a **Seidenader Line Controller for serialization**.

Visitors can obtain information on the use of **preserialized folding boxes** using the **NeoTOP x** cartoner from **Dividella**. The **Topload boxes**, which are 100% monomaterial, have been provided by **Rondo** with a **China code**. The China code is checked by an **integrated Seidenader Track&Trace system**.

Further information

Rondo:

- „Serialization during folding box production“, April 2017

Werum IT Solutions:

- <http://www.werum.com/en/it-solutions/track-trace/>

Seidenader:

- <https://www.youtube.com/watch?v=jBcl2bCGH6I>



Offline solutions, where the secondary packaging is serialized directly by the folding box manufacturer, are, in combination with sophisticated data flow architectures, an alternative to inline serialization.



Seidenader ItemUnit-Tamper Evident for serialization of folding boxes and application of tamper evident seal



Seidenader can put together a tailored solution for its customers according to the requirements imposed by specific tasks (serialization, aggregation, reworking and production data collection).



PAS-X Track & Trace for serialization independent of line controller

These images and texts can be downloaded at:

<http://www.interpack.medipak-systems.com/en/press-center>



Contacts for the press

**Seidenader Maschinenbau
GmbH**

Christian Gamperl

Lilienthalstr. 8
85570 Markt Schwaben
Germany

Tel.: +49 8121 802-253
christian.gamperl@seidenader.de

Rondo AG

Kerstin Höhn

Gewerbestrasse 11
4123 Allschwil
Switzerland

Tel. +41 79 840 70 16
k.hoehn@rondo-
packaging.com

Werum IT Solutions GmbH

Dirk Ebbecke

Wulf-Werum-Str. 3
21337 Lüneburg
Germany

Tel. +49 4131 8900-689
dirk.ebbecke@werum.com