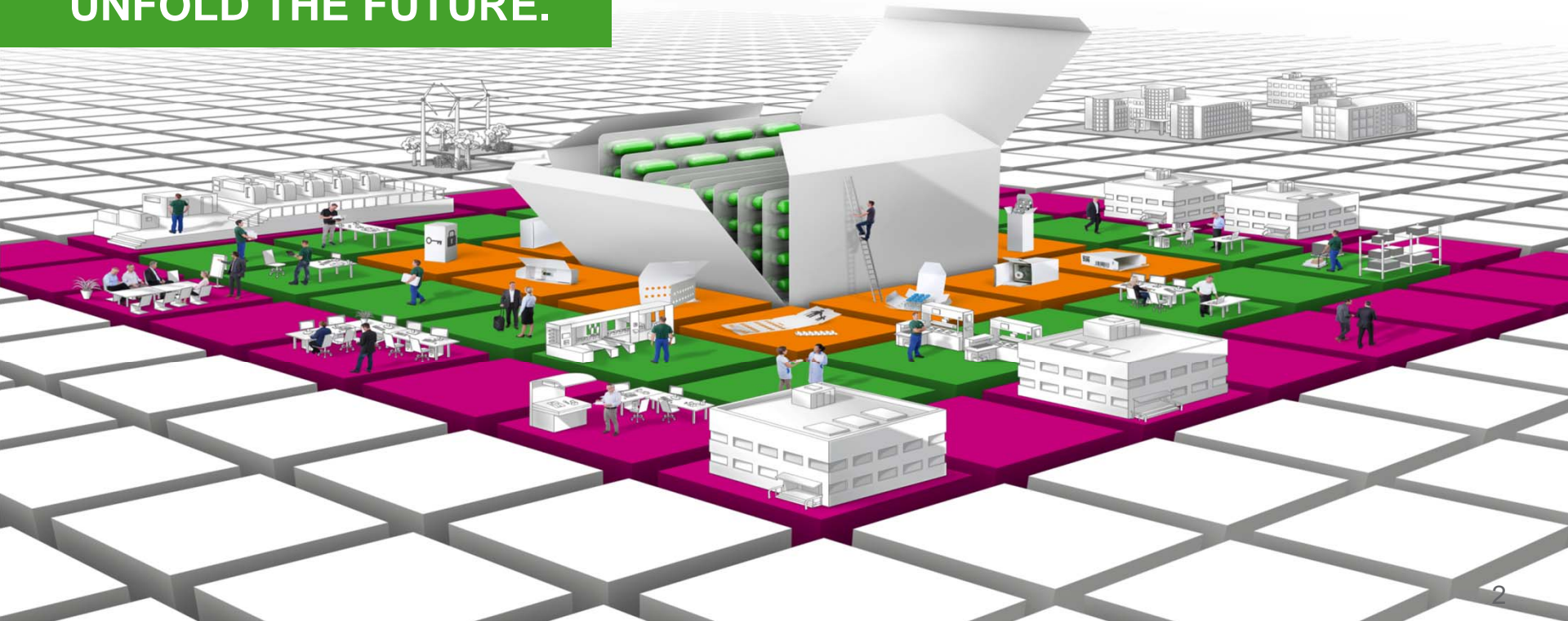


REGULATORY IMPACT ON SECONDARY PACKAGING.

Jürgen Nowak, Rondo AG

**RONDO.
UNFOLD THE FUTURE.**





MEDIPAK SYSTEMS
KÖRBER SOLUTIONS

BU Machinery



BU Software



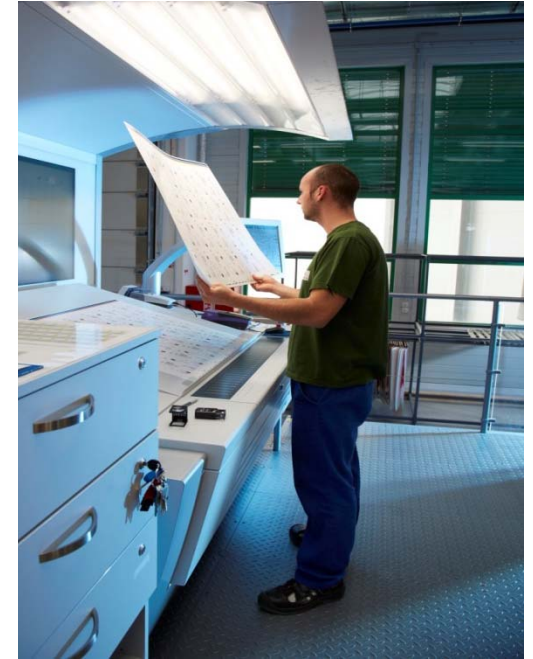
BU Materials



Company Profile

Solutions & Services for the
Pharmaceutical Industry.

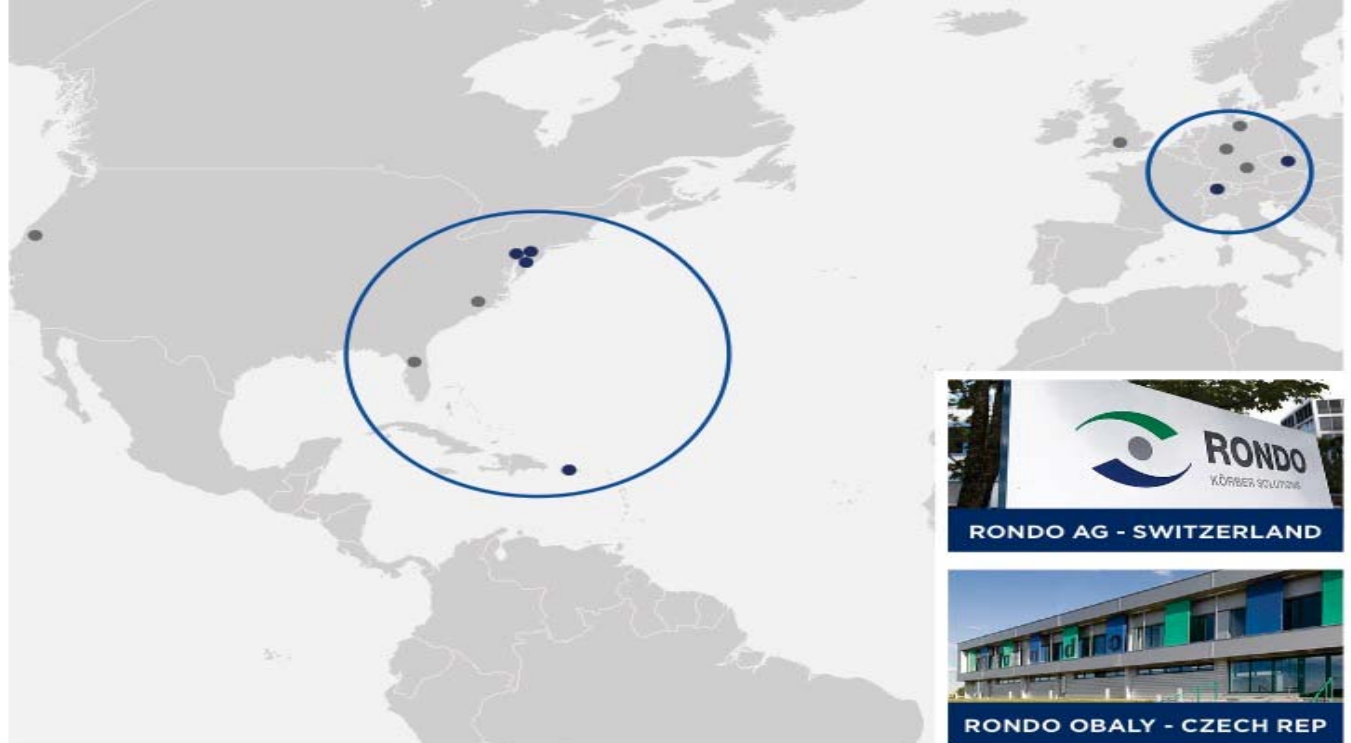
- High technology standard.
- Production capacity up to 1.15 billion folding boxes/year.
- Part of Medipak Systems, the Körber Group's business area pharma systems.
- Presence in Europe and North America.



**For 80 years:
Secure, Efficient
Packaging for Your
Products.**

- 1934 Foundation of Rondo AG in Basel
- 1998 Takeover by Disetronic Holding
- 2002 Takeover by the Körber Group
- 2006 Foundation of the subsidiary company Rondo Pak Inc. (USA)
- 2006 Foundation of the subsidiary company Rondo Obaly s.r.o.(CZ)
- 2012 Extension Site Rondo Obaly s.r.o. (CZ)
- 2013 Rondo Pak Inc. (USA) starts to operate a site in San Juan / Puerto Rico
- 2016 Joint Venture between Rondo Pak Inc. and CGS in the US

Global Footprint



Our USPs

- 100% focus on pharmaceutical customers
- Good presence in Europe and North America / Caribbean
- Good company size in EU and NA
- High focus on quality and delivery performance
- Strong innovation power
- High level of process and system integration with our customers
- Strong partnership with leading pharmaceutical customers
- Integrated in Medipak Systems as system solution supplier for pharma packaging (Software, Machinery, Material)
- Strong financial background with Körber AG



Joint development Rondo/Roche

- Packaging for liquid pharmaceuticals
- Shock and vibration resistant and reduces glass breakage
- The folding box consists of an insert and a double-wall construction
- 100% cardboard as mono-material
- Compatibly with automated and manual processes



Joint development Rondo/UCB

- HCPC Europe Columbus Award for Patient Compliance
- Cimzia® (used for rheumatoid arthritis): packaging developed for easy handling
- Close development based on a cooperative partnership between UCB Pharma and Rondo



Packaging Requirements according to 2011/62/EU („Falsified Medicines Directive“)



Supply Chain:
→ **Serialization**

Experts:
→ **ACF Features**

All:
→ **Tamper Evidence**

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Serialization

Regulations for Pharmaceuticals

- TURKEY
- CHINA
- BEGIUM / ITALY

- USA
- BRASIL
- EUROPE(Directive 2011/62/EU)



Datamatrix
EAN 128 barcode
EAN 128 barcode (label)

Datamatrix
Datamatrix
Datamatrix

Serialization

EU Code (2D Datamatrix)

1. Article number GTIN (Global Trade Identification Number)
2. Batch number
3. Expiry date
4. Serial number (14 digits randomized)



China Code (1D Code 128)

1. Product code
2. Serial number
3. Check number



Serialization with Digital Printing

- Codes are integrated directly into the artwork before printing
- Different codes can be printed (e.g. China code, 2D Datamatrix)
- Security through coating after printing enhancing resistance to wear.
- High degree of freedom in placing the code onto the folding box



Serialization Offline (planned)

- Codes can be printed both on the flat blanket or the glued folding carton
- Different codes can be printed (e.g. China code, 2D Datamatrix)
- Camera control for readability and quality of codes
- High degree of freedom in placing the code onto the folding box



Packaging Requirements according to 2011/62/EU („Falsified Medicines Directive“)

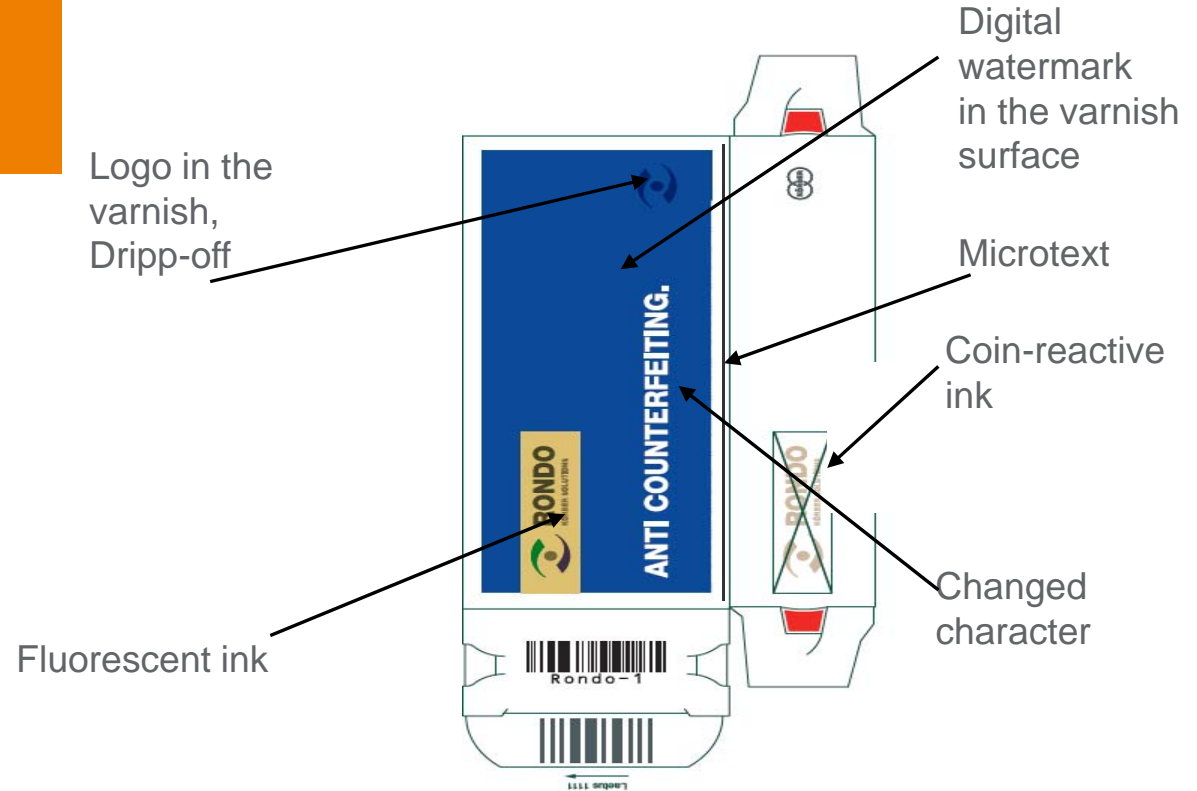


Supply Chain:
→ Serialization

Experts:
→ **ACF Features**

All:
→ Tamper Evidence

Anti-Counterfeiting (ACF) Features



Packaging Requirements according to 2011/62/EU („Falsified Medicines Directive“)



Supply Chain:
→ Serialization

Experts:
→ ACF Features

All:
→ **Tamper Evidence**

Tamper Evidence

- DIN EN 16679:
 - “...manipulation of the outer cover of the pharmaceutical product(folding carton) needs to be indicated...”
 - Technical solution by using
 - Labels
 - Glue
 - Special constructions

Tamper Evidence Solutions



Rondo TE Solution

- EU Directive 2011/62/EU requires that the secondary packaging for prescription drugs has to be equipped with a tamper verification feature.
- Therefore Rondo has developed a **new functionality** for tamper evidence which can be **implemented in standard folding cartons**.
- The solution stands out as ingenious **simple and efficient**.
- Boxes can be **re-closed**.

Rondo TE Solution

- The tamper evidence feature is directly integrated in the carton construction (related to DIN EN16679).
- The half-cut flaps in the lid clearly indicate first opening of the folding carton.
- Neither glue nor labels are necessary for first opening verification.
- Opening and reclosing is as easy as with conventional folding boxes.
- Packaging performance is unaltered.
- OEE is maintained and superior to solutions with glue or labels.

Rondo TE Solution



Closed and activated.



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First opening.



Closing after use.

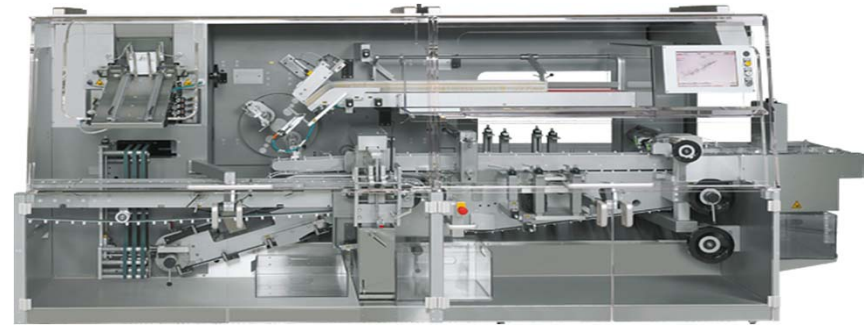


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Rondo TE Solution

The solution is successfully tested on:

- Intermittent cartoning machines
- Continuous cartoning machines
- Dividella Toploading machines



Rondo TE Solution

Learnings during test runs:

- **Visual check - in-process control** from magazine to the stage when manipulating (spreading) flaps before loading the blister
- **Visual check after the cartoner:** Is the Lock-In activated correctly on both sides?



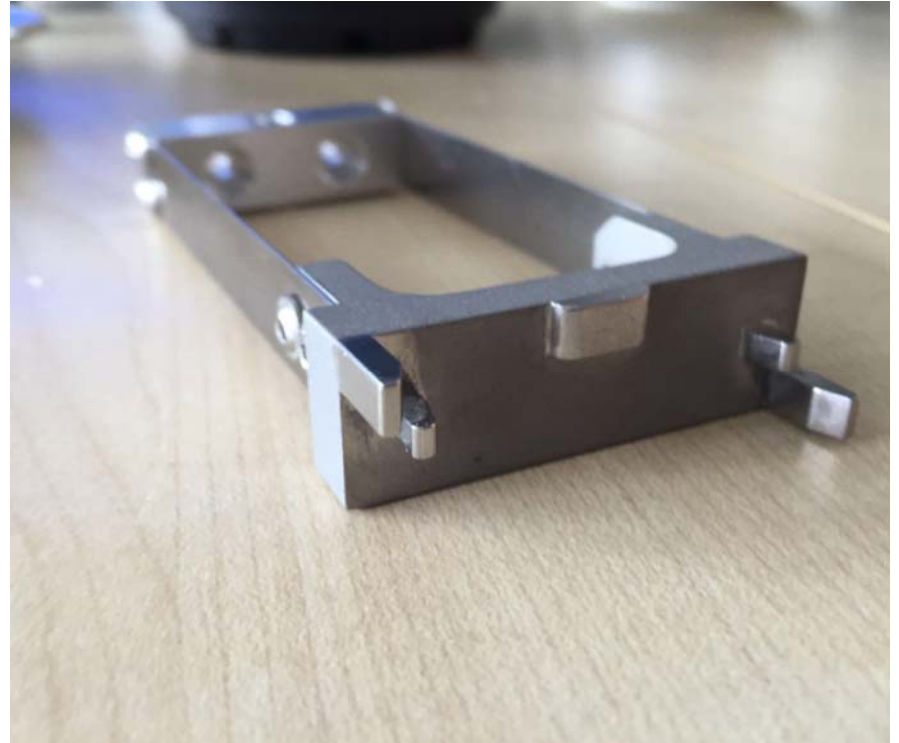
▶ No flap manipulation. ✓

▶ No constant/robust activation of the TE-feature. The presser meets the TE-area not always in the center of the activation area. Few cartons are not activated in all parts, few cartons had destroyed TE-features. There were some parts from the TE-feature in the cartoner. ✗

Rondo TE Solution

Measures after test runs:

- Reworking the activation tool to get a 100% center position



Rondo TE Solution

Technical requirements:

- Minimum height 16 mm.
- No limitation on cardboard quality.
- Tests on further machines possible.
- Tamper Evidence element: position depending on box-size.

**Rondo Tamper Evidence.
Best Cost Solution**



**Thank you for your
attention!**

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