



## Fully automated packaging line with Track & Trace solution for Phytopharm By Romaco and SoftGroup

Phytopharm Kłęka S.A. is part of The Nature Network® Holding. As a subsidiary based in Poland, the company is a cutting-edge pharmaceutical manufacturer of active substances and plant extracts to produce drugs and dietary supplements, as well as finished products made primarily from natural ingredients. Phytopharm Kłęka S.A. is recognized as one of the most advanced production facilities in the country and provides the European and Russian markets with high-quality products.

The modern facility reaches its high-volume production goals by introducing high levels of process automation on a plant level involving innovative software technologies and the most advanced equipment available. To become compliant with the most complex Track & Trace requirements so far (the Russian regulations), Phtyopharm Kłęka S.A. equips its production with a fully automated packaging line with Track & Trace solution by Romaco and SoftGroup – a winning combination between high-efficient hardware and highly reliable software.



Phytopharm Kłęka S.A. has been operating in the market since 1949. It started as a producer and seller of herbal raw materials. Nowadays, the company offers its customers private label finished products as well as contract manufacturing services, such as formulation preparation, raw material sourcing, active substance manufacture, and finished drug liquid form manufacture together with registration documentation.

In 2019, Phytopharm Kłęka S.A. put into service the new, modern pharmaceutical department herbafin® together with fast, fully automated continuous motion filling line with an efficiency that amounts to 40 M packages per year.

### Full set of Automations for maximum efficiency

Implementing high automation levels of manufacturing and packaging processes were considered as one of the highest priorities of the Senior Management of Phytopharm Kłęka S.A. The company has opted for a fully automated production and packaging line with serialization and aggregation to maintain the highest possible throughput. This highly specific demand has been achieved with minimum footprint by choosing the equipment of ROMACO and software by SoftGroup.

This combination ensures Phytopharm with a complete non-aseptic liquid filling, capping, labeling, cartoning, and case packing line for syrups by Romaco (automatic bottle depacker, Blower section machine, Macofar LF 200 Liquid filler and capper, labeling machine and Promatic PC 4250 continuous motion cartoning machine, and PAK 320 fully automated case packer) and serialization and aggregation software for management of the data on all levels (machine, packaging, site, enterprise, network) by SoftGroup.





## Project essentials

For achieving the complex modernization was established integration into the fully automated Romaco packaging line with zero effect on its current architecture, capacity, efficiency. Meanwhile, a customized ERP integration was in place for ensuring an automated connection to SoftGroup® SaTT software as well as an automated export to the customer's warehouse system.

Despite the fast-changing Russian Track & Trace requirements in 2020, and up to date with the latest regulations cryptographic protection codes request/receive/import/report process was established via SoftGroup® SaTT Cloud solution, connected to OMS and MDLP systems.

The 2D Data Matrix with necessary higher hardware and software requirements for printing and verification was set with verification of dynamic elements using Romaco and SoftGroup's camera vision systems simultaneously. Additionally, the

company was provided with a fully automated aggregation solution with Russian 2D codes and automated label printing.

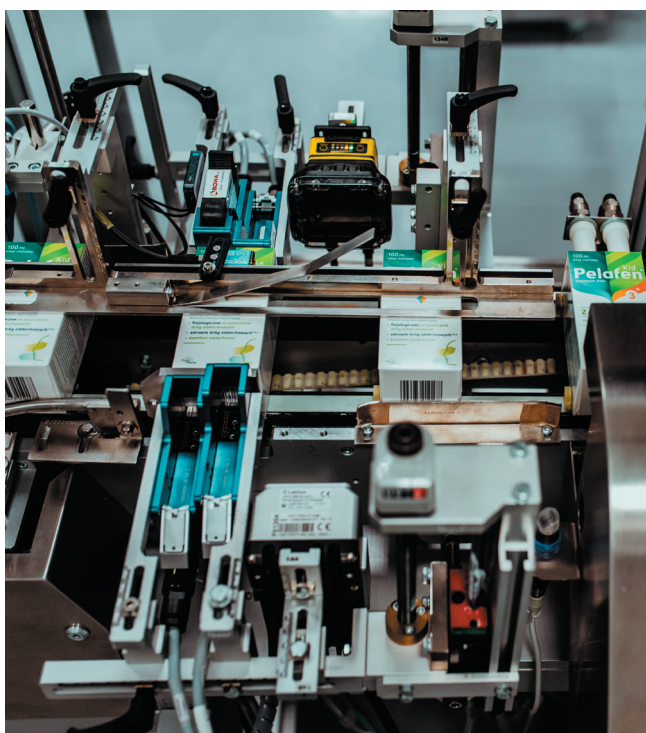
Despite the intuitive and high functionality software, by choosing SoftGroup, the Phytopharm management team requests also customized reports that can facilitate the monitoring of the business processes for smarter decisions.

## Highest functionality on every level

On the machine level, to satisfy the serialization needs an integration was done into the existing fully automated Romaco PC 4250 continuous motion cartoning machine through a serialization module to provide dynamic carton marking as well as printing and verifying of 2D Data Matrix codes and human-readable part including specific requirements for cryptographic protection.



As it's required by the Russian requirements and it is widely discussed to be implemented in Europe, the aggregation has many advantages. Even more so if it is an end-to-end automated aggregation and labeling process which is exactly the solution in Phytopharm provided from a high-efficient Romaco Promatic PAK 320 fully automatic case packer through to the case packed item with sealed aggregation label, ready for shipment. The system can aggregate standard and custom case sizes and scans, verifies, and aggregates a single pack into a case just in a few seconds. Different types of labels are precisely printed and applied with the required aggregation information following the EU & RU regulations.



The SoftGroup software on the machine level (SoftGroup® SaTT line controller) manages the serialization process on the line and controls the entire packaging line. The system is connected to Site-level serialization management, again provided by SoftGroup.

On the other side, via SoftGroup® SaTT Aggregation software the aggregation processes are fully controlled including management of SSCCs, scanning of serialization data, and printing of aggregation labels. It includes aggregation/

de-aggregation and re-aggregation processes a bundle, case, and pallet levels.

The centralized management system for serialization and aggregation processes on multiple production lines and sites (SoftGroup® SaTT Line Controller) has a key role in the process with its core functionalities as electronic batch management; generation of unique random/sequential SNs and SSCCs; report's management; automatic communication with the line machine's software.

Hence the external interface communication with ERP and WMS was provided according to highly demanding Phytopharm's requirements, the company has established fully automated.



Following the external interface communication with ERP and WMS was provided according to highly demanding Phytopharm's requirements, the company was a step closer to its fully automated system with serialization. As a finishing touch, Phytopharm introduced an on-premise installed SoftGroup® SaTT Communication Cloud services. The services provide Product Master Data management and Product Pack Data management and secure communication among the business partners.

As CRPT officially listed partner and integrator, SoftGroup has the capabilities to provide a live connection between the Manufacturer/MAHs and IS MDLP (Chestny ZNAK track & trace digital system). By choosing SoftGroup for this specific communication, Phytopharm can upload the product information, request, and receive the cryptographic protection (crypto keys and crypto signatures), and report SNs and SSCCs to IS MDLP.





### Final thoughts

By choosing the winning combination between high-efficient hardware and highly reliable software by Romaco and SoftGroup, Phytopharm can benefit from:

- Fully adapted services to the existing production processes without affecting the production capacity
- Secured communication between the business partners and all existing systems (ERP, Warehouse, etc.)
- Fully compliant with Russian and European regulations

- One point of contact for all issues, related to serialization and aggregation
- High production speed with no negative impact
- Low rejection rate: less than 1%
- User-friendly bilingual software, available in Polish and English
- 24/7 Customer Support service

Fully compliant with the official regulations and supported by Romaco and SoftGroup, Phytopharm is ready to Track and Trace medicines and contribute to the safety and transparency of the Polish drug market. Contact us to support your next expansion plan.