



# MEDICAL AND PHARMACEUTICAL PACKAGING SOLUTIONS



GLOBAL PACKAGING

# Discover safe and reliable packaging for your products

ULMA's packaging machines have been designed with and for the customers.

Its outstanding operating performance and advanced features ensure high productivity rates with the highest quality and safety of packaging.

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# PACKAGING SOLUTIONS FOR MEDICAL AND PHARMACEUTICAL

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## Specialists in Medical and Pharmaceutical

Medical and Pharmaceutical industries, require reliable, reproducible and traceable packaging solutions to offer maximum protection for Healthcare devices and products.

ULMA offers packaging solutions fulfilling all of the standards required by those industries. Using plastic films, Tyvek®, medical grade paper, aluminized materials, etc. to protect products and avoid contamination.

### Sterilised packages

Our packaging solutions can provide packages suitable for a wide range of sterilization processes:

- Steam-heat treatments.
- Use of gases (e.g., ethylene oxide).

The package is gas permeable through the pores on the lidding material (thermoformed) or a band that partially covers the packaging (flow pack/thermoformed).

- Gamma or E-Beam radiation.
- Others.

### Easy-open packages

We can design different customised packages to be ease-opened, such as Chevron type, Notch, zig-zag, finger hole, flat area, etc.

### Assistance with standards

ULMA offers assistance in the qualification and validation processes based on GMP, GAMP 5 and ISO practices, focusing on critical aspects for patient safety, product quality and data integrity.

The FAT protocol ensures the veracity of the measurement of the results, such as calibrated instruments or official protocols and regulations.

We are qualified to assist you in the Installation Qualification (IQ) and Operational Qualification (OQ) protocol, including the installation and operation aspects that are relevant to the equipment.

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# ULMA SERVICES DURING THE LIFE CYCLE OF THE PROJECT

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## Unique customer-oriented service

At ULMA Packaging we believe that developing a close working relationship with our customers is the best way of ensuring their satisfaction, always providing a unique customer-oriented service.

### Validation

Through our experts, we offer you advice on your validation processes in accordance with the GAMP 5 guidelines issued by the ISPE (International Society for Pharmaceutical Engineering).

We are able to help you to generate the necessary documents in each of the different qualification and validation phases required by these processes and, more specifically:

- The **specification phase** in which your URS is used to define the functional and design specifications of the ULMA packaging equipment.
- The **verification phase** helping you to create your own protocol for the FAT, SAT, IQ (Installation Qualification) and OQ (Operational Qualification).

### IOV Protocol

The aim of the IOV protocol is to provide documented evidence of the detailed checks and tests that have been performed, the documented results, the deviations recorded and the changes controlled.

These verifications are carried out in ULMA's facilities, as part of the FAT (Factory Acceptance Test).

### Calibration of the packaging

The machines have systems that can be calibrated so that the packaging parameters and critical processes are fully certified and approved.

### Project management

From devising the packaging idea and subsequently defining the project, at ULMA you will find a team of specialists who will advise you and accompany you throughout the process until the start-up of the packaging solution in your facility.

Our project managers represent our customers on the production line, keeping them regularly informed of the status of the project, handling any new requirements and leading acceptance and validation processes.

# Data Integrity to meet FDA's requirements

You can count on ULMA, which ensures that its systems make it easier to comply with the GMP and GAMP 5 guidelines and 21 CFR Part 11.

## Data Integrity

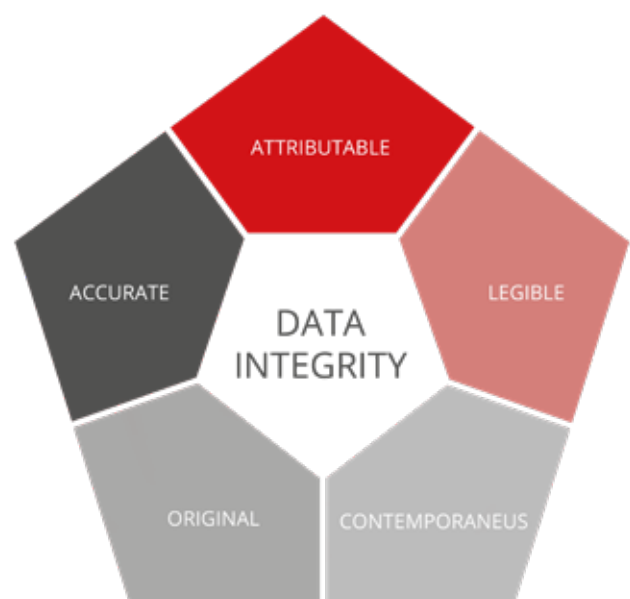
Through our control system, we offer you the optional **Data Integrity I** and **II** packages so that you can ensure the integrity of your electronic data.

This will make it easy for you to meet the requirements of **21 CFR Part 11** monitoring and recording the packaging process: data backup, personalized user administration (password), audit trail, recipe changes, etc.

Thanks to our advanced data acquisition and recording system, all of our UPC and Rockwell control systems are capable of creating exportable files with multiple data.

Our Data Integrity I package will allow you to record data on events, change parameters, recipes, etc., while always recording the user responsible for doing this.

Additionally, our advanced Data Integrity II package will also allow you to sort the data recorded with Data Integrity I by production batch.



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## ULMA MAKES IT EASY FOR YOU

At ULMA Packaging we have extensive experience in quality system compliance processes according to the GMP and GAMP 5 guidelines.

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# SAFE AND FUNCTIONAL PACKAGES

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## Tailored design

The design of our packaging solutions is tailored to suit the product's specifications and functional requirements.

Custom shapes, materials suitable for sterilisation, mechanical protection, easy-to-open systems, batch number, expiry date, printing of information for traceability, etc. Features that provide product functionality and protection.



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### Customised shapes packages

Certain products require custom shapes or packages with multiple cavities to form medical kits.

Our packaging machines incorporate great flexibility and rapid setup features to quickly change formats.



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### Wide range of materials

The possibility of using different materials on the same machine or even on the same package offers our solutions a wide range of possibilities.

As part of our **WeCare** sustainability project, we ensure that we use less material, mono-materials, paper and even our own technologies, e.g. BETTER-SEAL™.



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### Easy-open packages

Being easy to open is an essential feature for packages that need to be handled with gloves.

Without reducing the required airtightness, there are different options to enable the package to be opened easily and quickly: unsealed flaps, grip holes, pre-cut, thumb holes, zig-zag, Chevron seals, etc.



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### Traceability

Traceability is essential across the entire logistics chain. Our equipment enables the incorporation of labelling and coding systems based on different technologies: thermal printing, inkjet printing, pad printing, etc.

The variable information (name, batch, serial number, bar codes, expiry date, etc.) can be cleanly printed on the label or directly onto the packaging material.



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### Vision systems

Vision systems add advanced functionalities to the packaging line. These include:

- Product presence verification
- Dimensional checks
- Legibility and correct position of the traceability information

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# PACKAGING TECHNOLOGIES

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## Wide solutions portfolio

ULMA has a wide packaging solutions portfolio, suitable for the Medical and Pharmaceutical industries, with seven different technologies: Flow Pack (HFFS), Thermoforming (flexible and rigid), Vertical (VFFS), Traysealing, Shrink and Sleeve wrapping.



### FLOW PACK (HFFS)

Packaging is accomplished through a roll of film, forming a tube that is sealed along all the package length and two more transverse sealing areas on the head and foot of the package.

Plastic films, medical grade paper, Tyvek®, aluminised films can be used.

Designed for manufacturers who need affordable packaging with highly flexible formats and mass medical devices production.



### THERMOFORMING

Trays are formed by means of heat and pressure (thermoforming), allowing manual or automated product filling on their cavities, sealing of the tray with a lidding material is the next process stage to finally enter into longitudinal and traverse cutting to obtain individual packages.

Material commonly used are: plastic films for both, bottom and lidding; permeable materials for the lid as medical grade paper, Tyvek®; aluminium, metallic materials and others.

This technology is mainly used on mass medical devices production.





### VERTICAL (VFFS)

The pack is formed by vertical wrapping machines. A tube of film is formed around a product and sealed with one longitudinal and two transversal seals.

This is fully hygienic technology with high production requirements.

Designed for gravity-fed or vertical feed products.



### TRAYSEALING

Sealing of preformed rigid trays in automatic machines called traysealer machines.

Designed for medium-batch manufacturing.



### SHRINK AND SLEEVE WRAPPING

Automatic and manual machines that work with shrink film and provide a high-quality wrapping that is free of folds, flaps, etc. after passing through a shrink oven which adapts the film to the shape and dimensions of the product.

In the case of sleeve wrapping, two rolls of film are used, welded crosswise to obtain a shrink wrap around the product.

Provides perfect wrapping for distribution and transportation.

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# PACKAGING SOLUTIONS

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## Comprehensive package

Unlike other suppliers, ULMA is able to offer a wide range of solutions for the packaging of medical products. Packaging solutions designed for sterile medical, pharmaceutical and laboratory products that meet the sector's strictest requirements, maintaining their sanitary conditions and integrity until they are opened.

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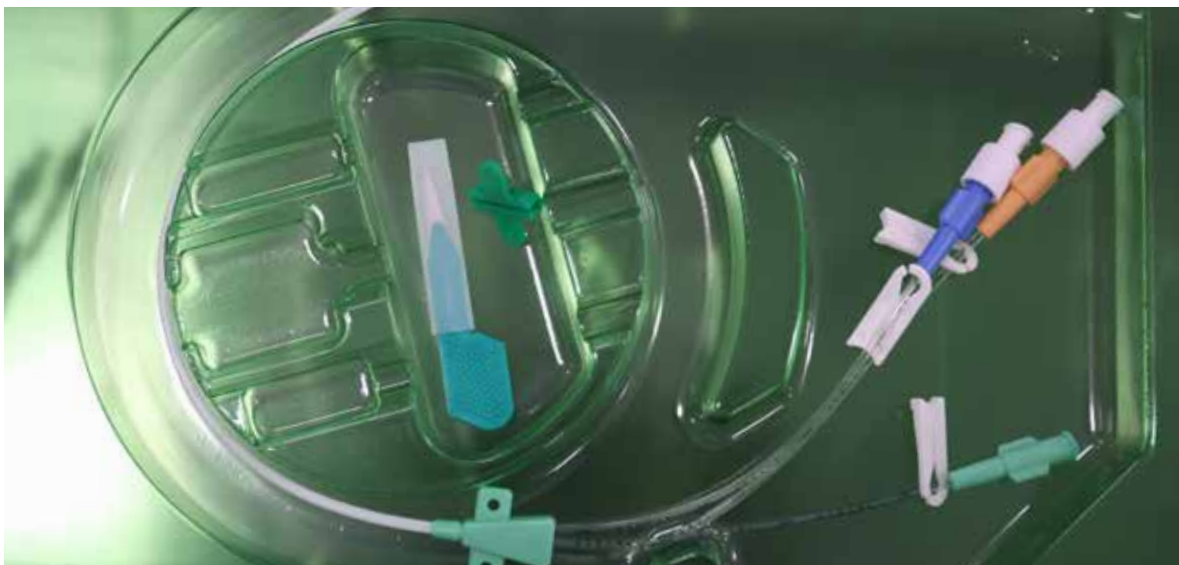
### Medical products

- Single-use devices
- Surgical supplies
- Suture materials
- Implants and prostheses
- Syringes and needles
- IV bags

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### Products for pharmacies and laboratories

- Ampoules
- Blisters
- Petri dishes
- Diagnostic kits
- OTC (over the counter) products





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# MEDICAL PRODUCTS

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## MEDICAL PRODUCTS

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# MEDICAL PRODUCTS

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## PRODUCTS FOR PHARMACIES AND LABORATORIES

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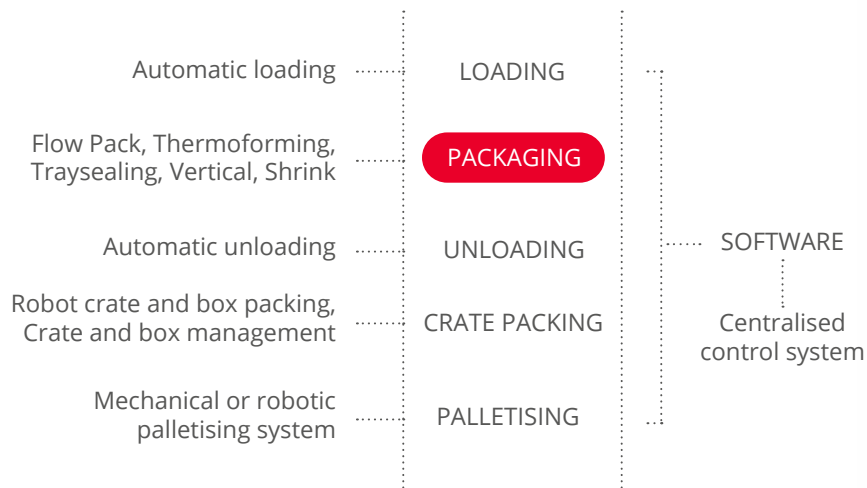


# COMPLETE LINES AND TURNKEY SOLUTIONS

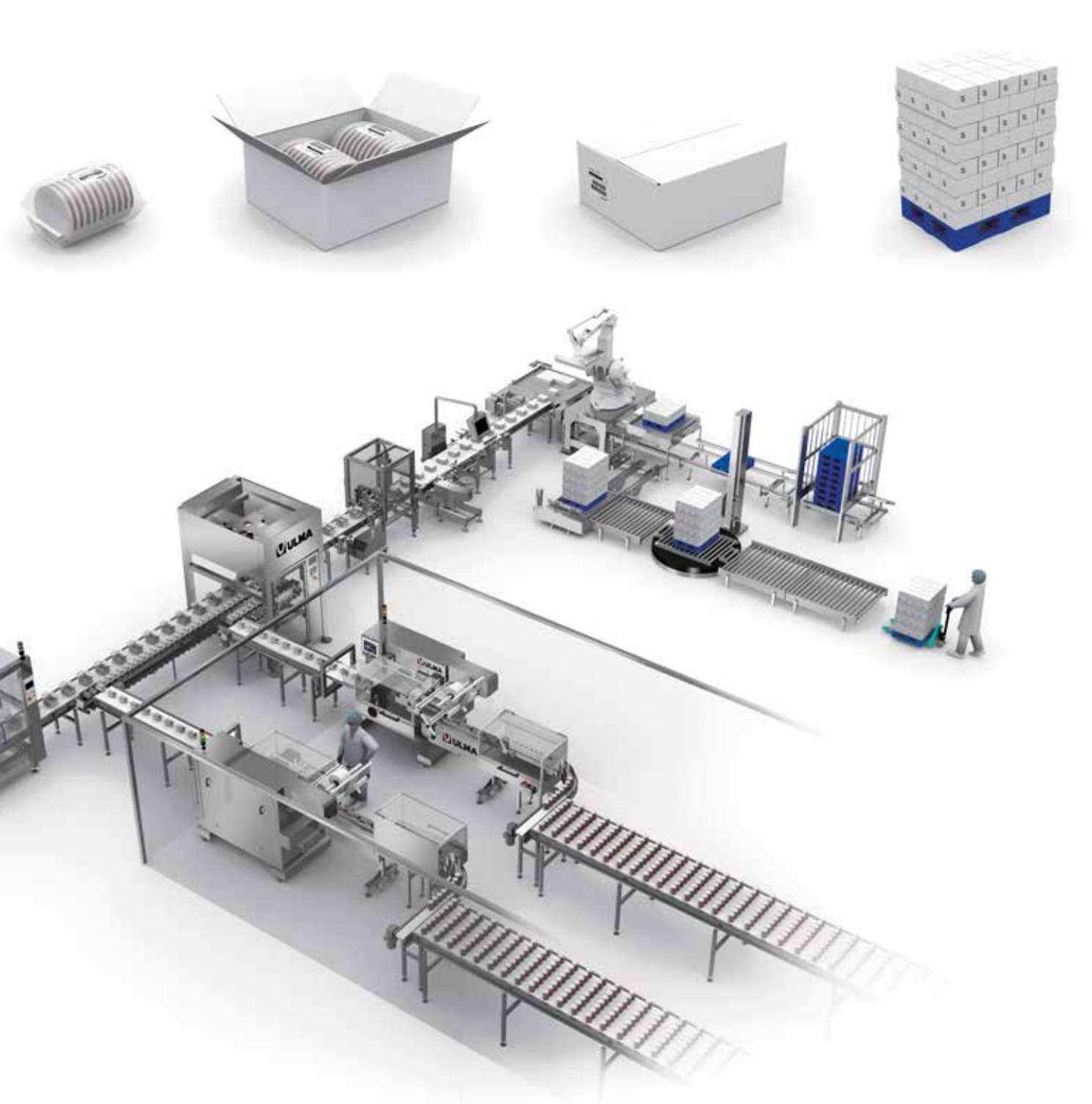
At ULMA Packaging we develop complete solutions with a high level of customisation and which are tailored to meet each customer's needs, either through proprietary technological developments or by integrating our partners' products, while ensuring the optimal reliability of the unit.

Implementing these solutions makes it possible to reduce the number of incidents and increase productivity. Thanks to our comprehensive knowledge of our customers' processes and requirements, we are able to develop turnkey solutions and automated systems for a large number of tasks, so that complete lines are formed with all of their peripherals.

We offer our customers fully automated solutions that cover everything from product handling and loading, to the inspection, labelling, packing and final palletising of products.





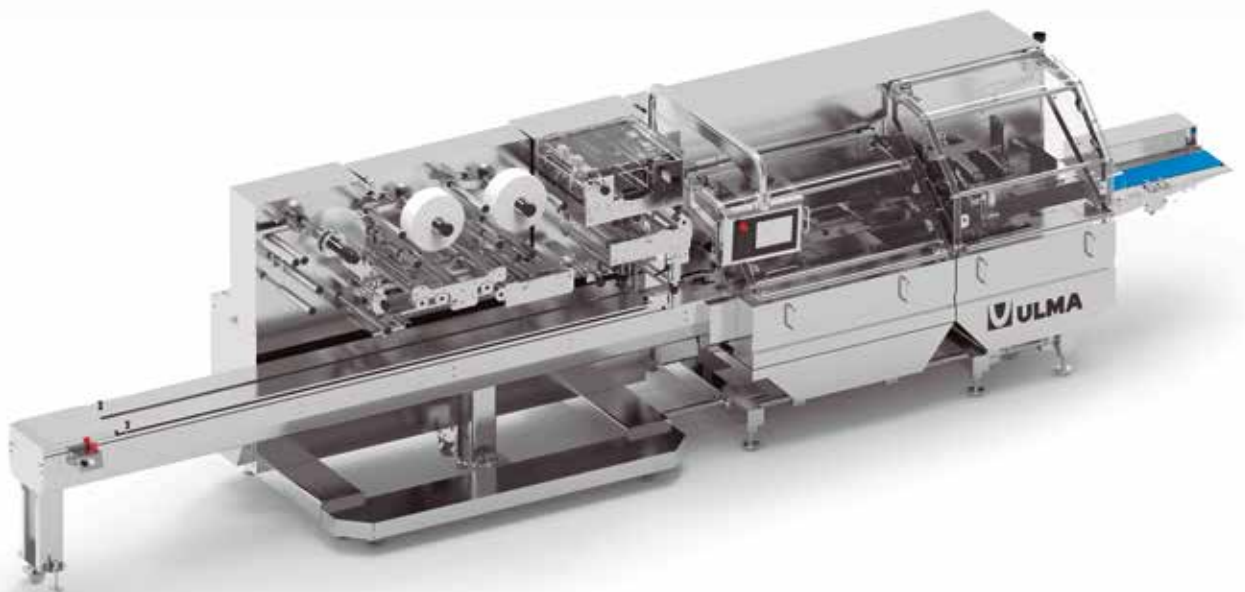


Complete automated solution for packaging and packing Petri dishes, with a robotic palletising and pallet wrapping system.

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## LINES AND TURNKEY SOLUTIONS

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Automatic packaging line for blister packs with leaflet dispensers.



## BLISTER



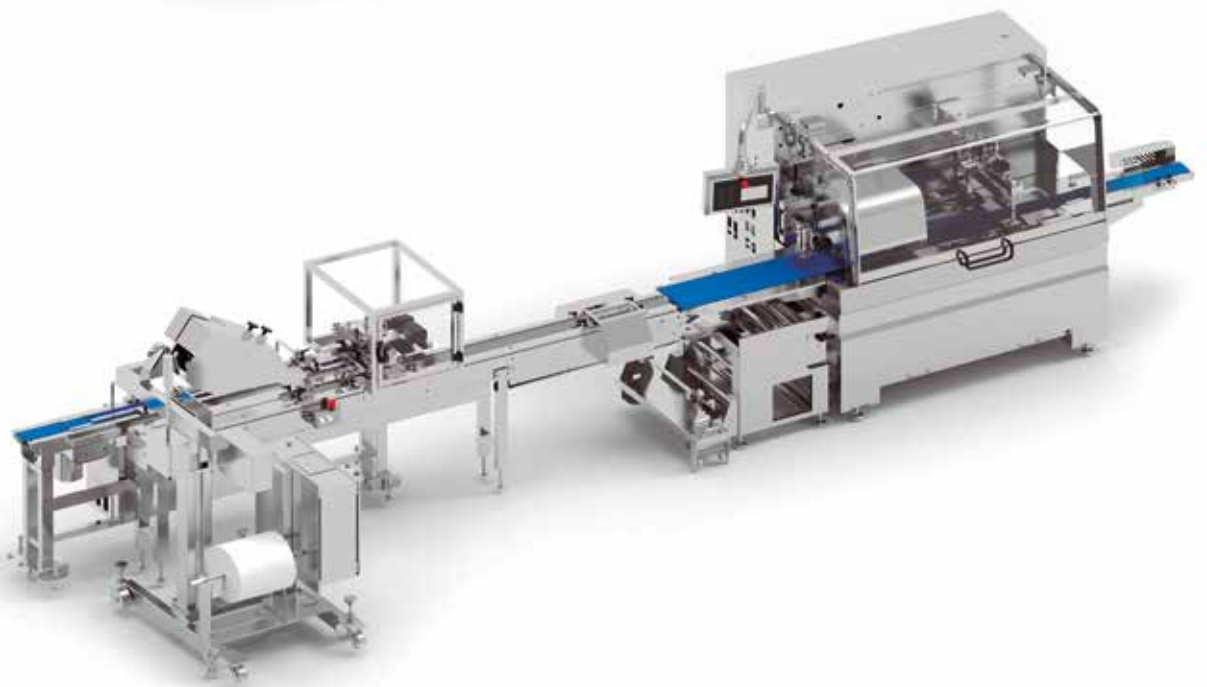
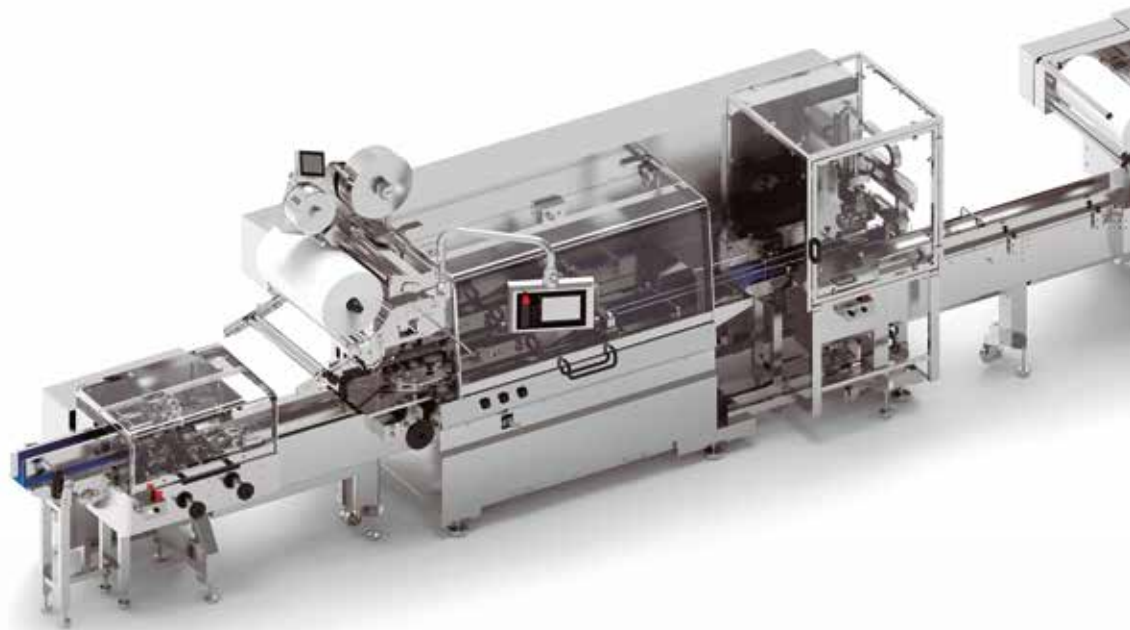
## SYRINGES

High-speed automatic packaging line for syringes.

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## LINES AND TURNKEY SOLUTIONS

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Primary and secondary packaging line for Petri dishes.



## PETRI DISHES



## DIAGNOSTIC KIT

Automatic diagnostics kit packaging line with desiccant dispenser.

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## LINES AND TURNKEY SOLUTIONS

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Catheter packaging line with vision inspection system and reject cobot at the end of the line.



## CATHETERS



GLOBAL PACKAGING



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