



# COMPANY PROFILE

Cleaning | Isolation | Decontamination



**mw**t<sup>®</sup>  
TECNIPLAST GROUP



# ALL ABOUT PHARMA

WITH OVER 30 YEARS OF EXPERTISE IN TURN-KEY SOLUTIONS

**IWT offers a comprehensive range of cleaning, isolation, and decontamination solutions for the pharmaceutical, cell & gene, nutraceutical, cosmetic markets, and related industries.**

IWT specializes in the design, development, manufacture, and installation of outstanding cGMP pharma solutions. Our manufacturing base in Varese, just a few kilometers away from Milan Malpensa International Airport, spans over 20,000 square meters (215,000 square feet) of production areas, R&D, design studios, training, testing, and showroom facilities.

Our production departments are equipped with state-of-the-art laser cutters, orbital welders, and robots for processing stainless steel parts. The warehouse, fully automated in alignment with the most stringent cGMP traceability requirements, features comprehensive oversight and management of products and materials. IWT offers in-house advanced 3D design and simulation technologies, as well as software programming capabilities to ensure complete fulfillment of any user requirements specifications, in terms of quality and flexibility.

Our comprehensive range of cleaning solutions includes full cGMP product contact part washers, as well as high-pressure washing systems for bulk containers in cleaning-in-place applications or cabins for bulk parts and containers cleaning-out-of-place.

Multipurpose modular aseptic isolation technologies are at your disposal, ranging from sterility testing to component preparation, from fill-finish to Advanced Cell & Gene Therapies.

A decennial expertise in cold decontamination methods, decon chambers and airlock systems, ensures safe and efficient material transfer through physical barriers and differently classified areas.

Both our Isolation and Decontamination product ranges ensure complete compliance with cleanroom standards according to the new EU Annex 1 requirements.

You are always welcome to visit our facilities, to experience IWT Pharma's passion and commitment firsthand, and to witness the quality and efficiency in our daily operations.



IWT Headquarters in Casale Litta (Varese, Italy).  
We strive to protect our surroundings and keep  
our ecological footprint as small as possible.



WHO  
WE ARE

75 YEARS AND COUNTING

As part of the Tecniplast Group, our story began in 1949 when Carlo Bernardini, a visionary and courageous entrepreneur, founded Tecniplast.

This is a story of a family driven by passion, commitment and dedication, of quality and expertise 100% Made in Italy.

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A sound expertise built in over 30 years of activity, a team of dedicated, passionate and skilled experts, the attention to our customers' needs: these are the ingredients of our success.

Edoardo Bernardini - IWT Managing Director



# WHAT **WE DO** AND **FOCUS ON**

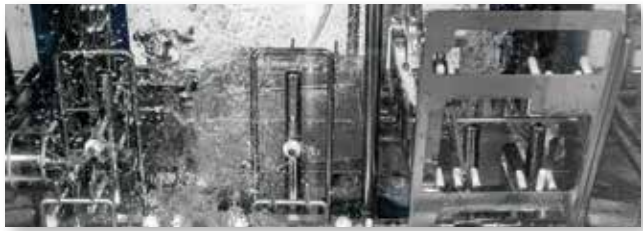
CLEANING, ISOLATION AND DECONTAMINATION SOLUTIONS FOR PHARMA, CELL & GENE, NUTRACEUTICALS AND COSMETIC MARKETS

IWT portfolio includes state-of-the-art full cGMP products contact part washers, designed to ensure thorough cleaning and sanitization of critical equipment components. Additionally, we specialize in high-pressure washing systems adept for various applications, from Cleaning-In-Place (CIP) procedures for bulk containers to dedicated cabins facilitating cleaning-out-of-place for bulk parts and containers.

Our aseptic isolation technologies are meticulously engineered to uphold the highest standards of sterility and contamination control, safeguarding the integrity of your processes and products. IWT offers cutting-edge decontamination VPHP (Vaporized Hydrogen Peroxide) pass-through chambers, ensuring the safe and efficient transfer of materials between differently classified areas.



**HIGH PRESSURE WASHERS**



**CONTACT PART WASHERS**



**IBC & CONTACT PART WASHERS**



**FLEXI, MODULAR AND TAILORED BASKETS**



**ASEPTIC ISOLATORS**



**DECON CHAMBER PASS THROUGH**

A large, industrial-grade machine with a glass front and multiple circular openings, labeled 'isocare' and 'iwt'. It appears to be a decontamination or isolation chamber.

*We are committed to delivering solutions that not only meet but exceed your specific requirements. Beyond our innovative technologies, we offer a comprehensive suite of related services, including calibration, qualification, and validation, ensuring the optimal performance and compliance of your systems. Partner with us to explore the most suitable and efficient solutions tailored to your exacting standards.*



# OUR **KNOW-HOW** AND **CAPABILITIES**

**SAFE, REPEATABLE AND RELIABLE RESULTS**

IWT systems are developed in compliance with the current international guidelines and standards, while the mandatory validation process ensures the unit exceeds the most challenging user's requirement specifications.

Proper engineering with a perfect blend of performance, timing and cost, combined with a comprehensive set of services, allow us to deliver safe, repeatable and reliable operations.

Welcome to our state-of-the-art Tech Centre, where innovation meets precision. Our test area boasts fully operational GMP washers, providing an unparalleled platform for conducting tailored cleaning tests on your distinct loads. Whether you're facing stubborn residues or seeking to optimize cleaning efficiency, our facility offers a bespoke solution. With the ability to adjust parameters such as coverage, temperatures, time, and chemical composition (type and concentration), our experts stand ready to collaborate with you. Together, we'll explore diverse setups to minimize time and consumptions while ensuring compliance with the most stringent validation parameters. Step into our Tech Centre, where challenges transform into opportunities for excellence.



## **COMPLIANCE**

Our mission is to deliver the finest equipment in one of the most highly regulated environments. Our absolute focus is to achieve regulatory compliance, validate both systems and processes, install quality in every engineering phase, and exceed all safety standards.

IWT equipment is developed following worldwide standards and guidelines (cGMP, GAMP5, FDA, ASME-BPE, ISPE Baseline...), including the new EU Annex 1 requirements.



## **VALIDATION**

Any validation final goal is to assure the tested equipment is built in full compliance with the users' requirement specifications.

At IWT we strongly believe that communication with our clients is the key for a successful partnership. Several protocols and documents are shared upfront in order to set clear and definitive project targets, which will constitute the bases for designing and manufacturing phases as well as benchmarks for all the commissioning activities.



## **ENGINEERING**

Multiple years of experience and several challenging projects managed for the the most prestigious pharma companies result in a solid knowledge and understading of the industry dynamics.

The IWT expertise means delivering optimal solutions for automatizing cleaning operations, for safety introduce variouos material through classified areas add for effectively protect your aseptic preparation and Q&A processes under isolators.



## **SERVICE**

All IWT systems are designed with safety in mind for either operators and process itself. A safe process ensures not only a clean and aspetic load exceeding the QA acceptance criteria but also prevents any possible cross contamination between product batches and any microbial growth during inoperative phases.

To do so, all the machines are designed with particular focus on the best practices in term of material and welds traceability and quality controls, design specifications and certificates. All the manufactured units feature premium quality non-propetary components and long lasting equipment selected among top global suppliers.

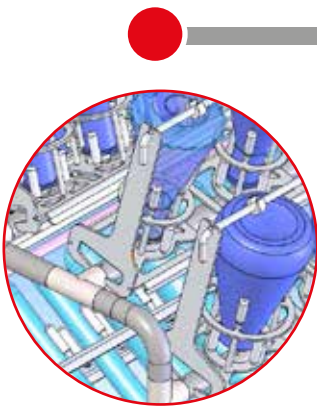


# 100% VERTICAL INTEGRATED APPROACH

INTEGRATION, TRACEABILITY AND EFFICIENCY

One single source supplier to meet all your needs with “Made in Italy” top quality enriched by flexibility and responsiveness along the whole designing and manufacturing processes.

- ▶ Technical Department with over 50 engineers, dedicated internal R&D division, software house, risk analysis, documentation, validation and commissioning experts
- ▶ Three highly automated metal workshops specialized in S/S. Precise craftsmanship for sheets, tubulars, piping and wires
- ▶ ASME-BPE certified welders and qualified operators for inspections
- ▶ Lean manufacturing techniques applied in the full supply chain to guarantee maximum accuracy, efficiency and cleanliness for the final assembled units
- ▶ Complete traceability of materials, documents and quality control across the whole production chain (ERP and ECM systems in place)
- ▶ QA department to oversee the manufacturing conformity and internal commissioning prior any factory acceptance activities
- ▶ In-house project management, customer care and service department to ensure smooth processes prior, during and after installations



1,300sqm (14,000ft²) offices with CAD and Solidwork stations



1,500sqm (16,000ft²) internal metal workshops and new GMP units assembly line 40,000sqm (43,000ft²)



Automated warehouses and bar coding system for total material traceability



Manual welding stations for certified operators



Automated orbital welding



State-of-the-art laser cutting and bending equipment



Quality inspections performed by certified operators



Lean Assembly stations for internal commissioning and FATs



# OUR VALUES

Sharing and promoting values that we consider important both in our private and professional lives represents the foundation and the framework of our guidelines for pursuing and offering excellence.



## PASSION AND INNOVATION

We proactively shape change, anticipating, leading, and spreading it, fueled by a passion for innovation, and relentlessly pursuing excellence.



## SOCIAL AND ENVIRONMENTAL RESPONSIBILITY

We give value to life by contributing day-by-day to leave a cleaner, safer, and socially sustainable world to future generations, ensuring that our actions prioritize the well-being of both people and the planet.

We foster agility and cooperation to jointly achieve ambitious goals with our clients. As a global company, we are attentive and responsive to the unique needs of every country and client, prioritizing close collaboration to ensure mutual success and sustainable growth.



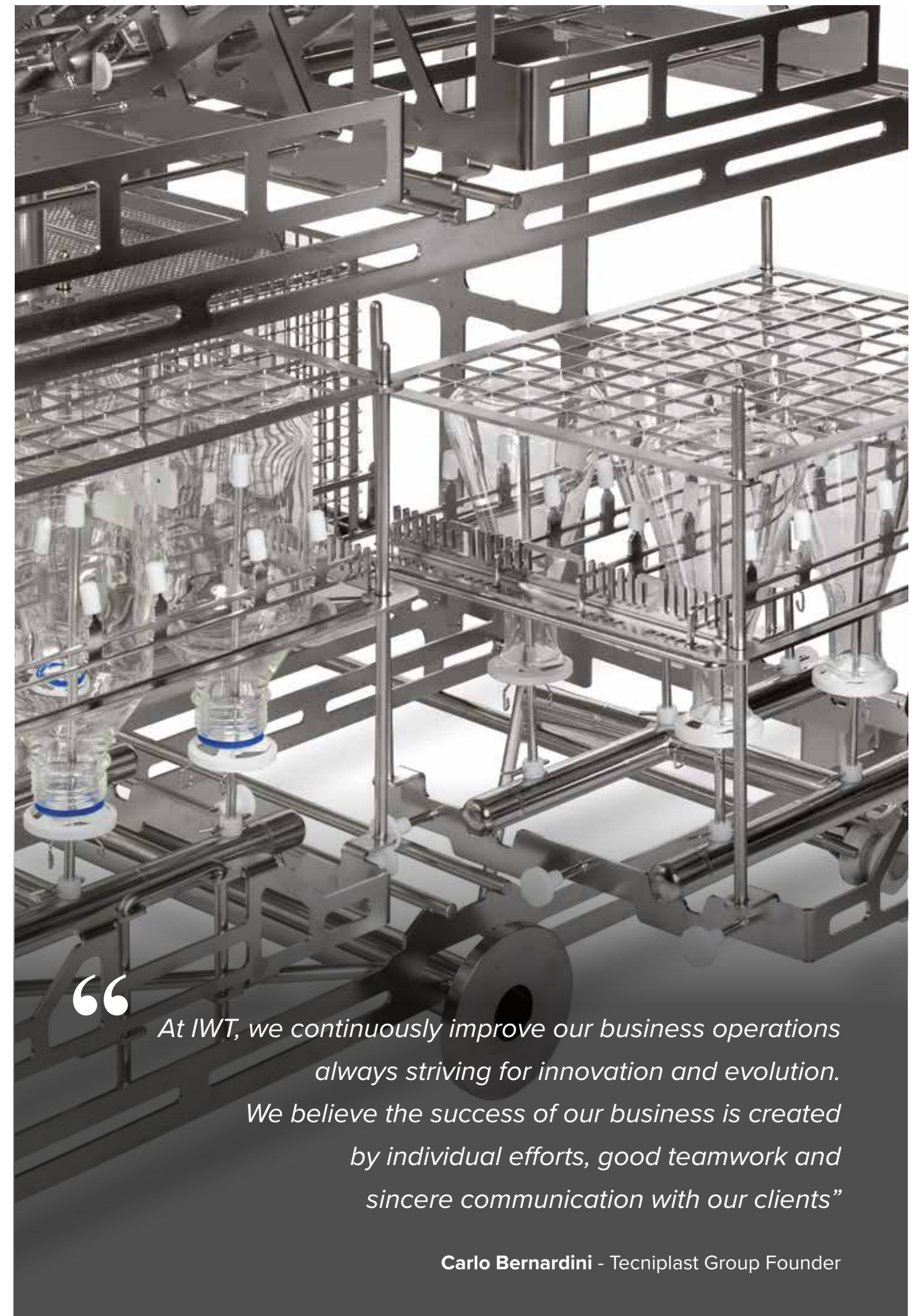
## COMPETENCE AND EXPERIENCE

We put our experience at the service of customers, who reside at the center of our world. Drawing upon a solid foundation of knowledge in processes and technologies, we attentively listen to our clients' needs, striving to deliver results that consistently exceed expectations.



## ENDURING ACCOUNTABILITY

We deserve trust through endless sincere communication, indisputable accountability and mutual respect among individuals in every interaction.



“*At IWT, we continuously improve our business operations always striving for innovation and evolution. We believe the success of our business is created by individual efforts, good teamwork and sincere communication with our clients”*

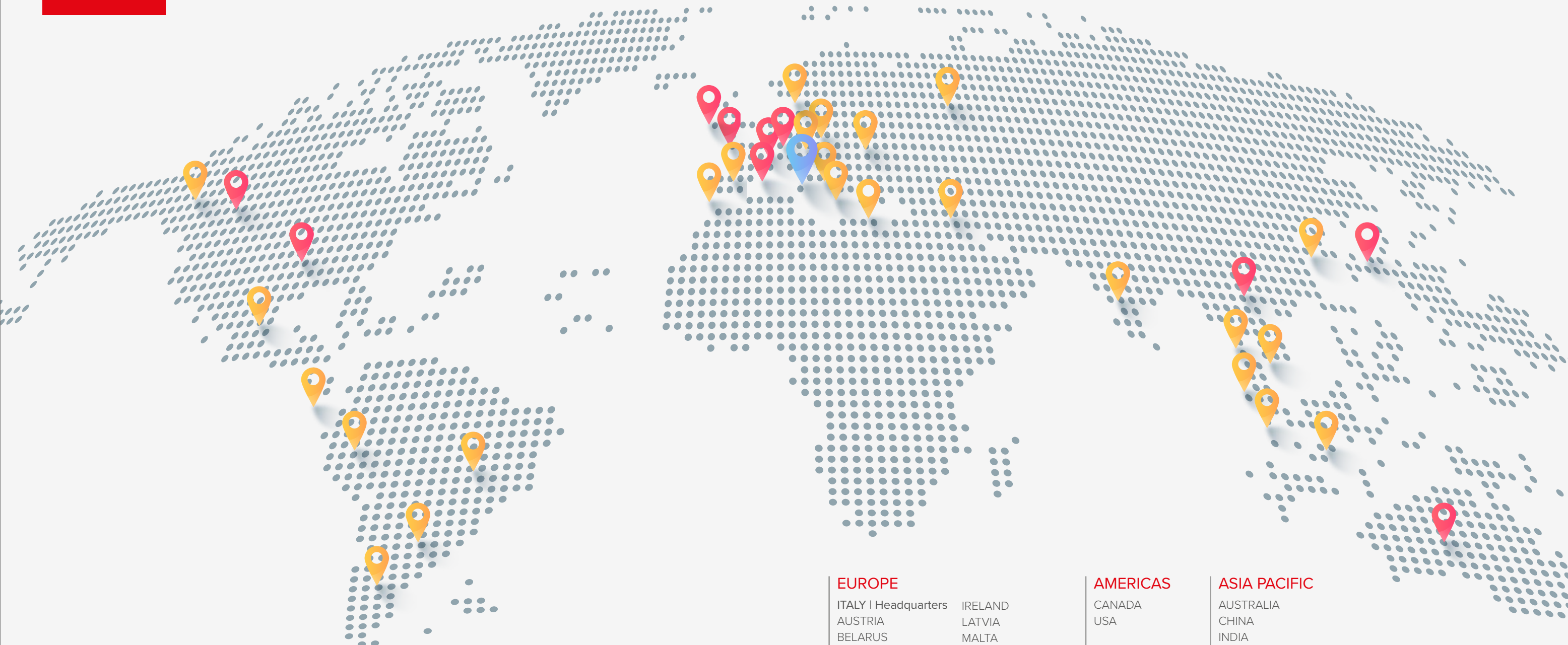
**Carlo Bernardini** - Tecniplast Group Founder





# WE OPERATE LOCALLY. WORLDWIDE.


Being a global company, as part of the Tecniplast Group, means we are well aware of the challenges the world is facing.

Our worldwide network of Subsidiaries, Dealers and Agents allows us to understand different cultures, languages and needs, thus perfectly responding to regional expectations.



**IWT Headquarters and production site**

**Group Subsidiaries and commercial offices**

**Dealers/Agents**

EUROPE		AMERICAS	ASIA PACIFIC
ITALY   Headquarters	IRELAND	CANADA	AUSTRALIA
AUSTRIA	LATVIA	USA	CHINA
BELARUS	MALTA		INDIA
BELGIUM	POLAND	ARGENTINE	INDONESIA
CROATIA	PORTUGAL	BRAZIL	JAPAN
CZECH REPUBLIC	RUSSIA	CHILE	MALAYSIA
DENMARK	SLOVAKIA	COLOMBIA	SINGAPORE
ESTONIA	SPAIN	MEXICO	SOUTH KOREA
FRANCE	SWITZERLAND	URUGUAY	THAILANDIA
GERMANY	THE NETHERLANDS		VIETNAM
GREECE	UKRAINE		
HUNGARY	UK		

**50+**  
Countries

**325M**  
annual Group turnover

**400+**  
installations

**1,500+**  
employees worldwide





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**iwt**  
TECNIPLAST GROUP

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IWT reserves the right to change or modify product and/or specifications without notice or obligation.