

# GRUPPO ERBOZETA

Food Supplements

Medical Devices

Since 1987

[www.erbozeta.com](http://www.erbozeta.com)

gruppo  erbozeta

HEADQUARTERS



LIQUID MIXING MACHINES



INCOMING RAW MATERIAL LABORATORY





- Cutting edge formulations
- Innovative raw materials
- Advanced technology
- Production under pharmaceutical standards
- Professional team

All this is ERBOZETA quality



# COMPANY HISTORY



**1987**

Our Start

**1995**

Manufacturing

**2000**

A Growing Reputation

**2005**

New investments

**2009**

New manufacturing site

**ERBOZETA S.p.A** was **established** in 1987 in the Republic of San Marino as a commercial company with the passion towards natural health products, especially food supplements.

It appeared necessary to internalize production to be able to guarantee the best quality: the only way was to manage internally the production starting with solid forms such as capsules and tablets, and liquid forms such as syrups and drops.

In the beginning of the 2000's, ERBOZETA started growing its reputation and expanded in the whole territory of Italy, adding new products to its portfolio and building a team of Medical representatives visiting doctors all over the country.

The necessity of increasing its production capacity was fundamental to maintain the growth of the company therefore investments were made in order to improve the machinery.

The portfolio was significantly enlarged and ERBOZETA started selling first products abroad. In 2008, the subsidiary company **PHMALUCE S.r.l** was founded.

2009 marked a new beginning for **ERBOZETA** a major investment was made to build a new state of-the-art production facility of 2500 m<sup>2</sup> in compliance with the highest pharmaceutical standards. The site was designed with Clean Rooms and Climatic Rooms, monitoring constantly **TEMPERATURE, HUMIDITY** and **PRESSURE**, with an area exclusively dedicated to the manufacturing of probiotics, under specific conditions. Not only the manufacturing itself was re-designed, but also Erbozeta decided to acquire new innovative machines such as fluid bed granulator and Long Life single-dose bottles.

The group started expanding its presence in foreign countries. In 2013, the subsidiary company **LOGUS PHARMA S.r.l** was founded.





## 2014 International Expansion

ERBOZETA has observed a remarkable expansion into foreign markets, with a presence in more than **40 countries in the world**, increasing accordingly its production capacity and warehouse space to 2500 m<sup>2</sup>, adding also new pharmaceutical forms.

In 2014, the European branch in Vienna was established, **Erbozeta Austria GmbH**. ERBOZETA started with the first productions of Medical Devices class I such as nasal sprays, and throat sprays.

Due to a strong expansion in Asian markets, the Asian branch was established in Hong Kong, **Erbozeta Asia LTD**

## 2017 Certification focus

After investing significantly into machinery innovation and quality of its manufacturing site, the necessity was to add other official recognitions such as certifications.

Not only the company was approved by several foreign Ministries of Health, such as Libya, Iraq, USA, Kazakhstan but also with certifications recognized at an international level. Indeed in 2017, ERBOZETA obtained the **ISO 13485 certification**, followed by LOGUS PHARMA in 2018 and PHARMALUCE in 2019.

## 2019 Continuous growth

In 2019, due to an expansion in Central America, ERBOZETA decided to add a new commercial branch, **Erbozeta Iberica LDA**.

In addition, ERBOZETA made major investments in the machinery and manufacturing site: new blistering machine, new mixing tanks to increase productivity, with ALU/ALU blisters, high performing solid stick machine.

Our medical devices have been certified by renowned accredited certifying bodies.

## Today

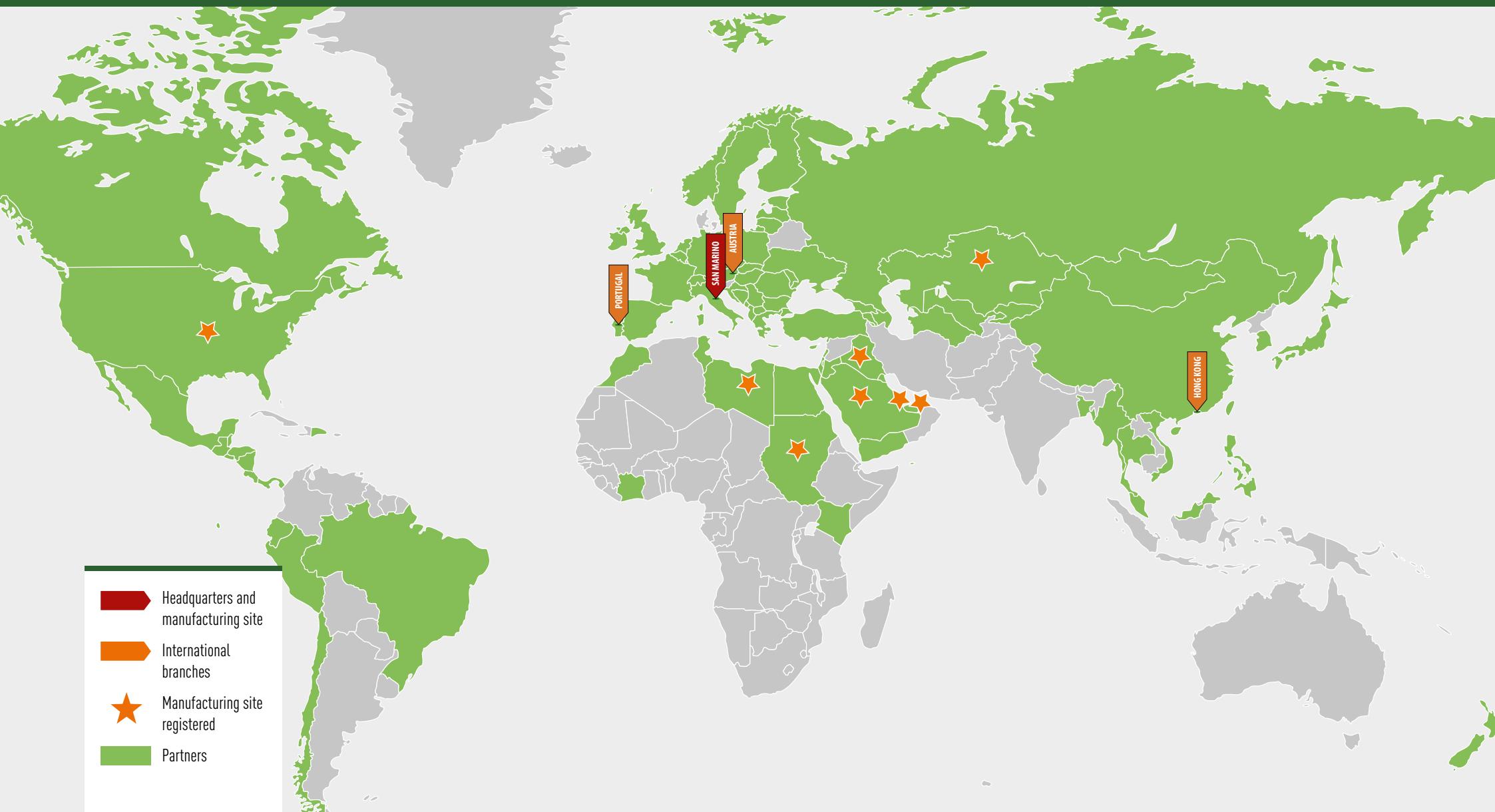
In the last years, Erbozeta has been more and more paying attention to environment protection and promoting a sustainable lifestyle thanks to some important actions:

- transition to green energy by installing solar panels on its roof, thus allowing to produce its own solar energy for the manufacturing site, warehouses and offices.
- sustain a plastic-free life in working hours, with the introduction of water purifying systems and water bottles in our offices.

**ERBOZETA GROUP** is an example of **INNOVATION, QUALITY and SAFETY**. It's now present in more than **70 countries in the world with a worldwide reputation**. Our product range covers more than **20 specialties**, with over **150 products**, including Food Supplements, Medical Devices, Food for Special Medical Purposes and Cosmetics.

With **206 employees**, and **250 national medical representatives** and **hundreds of international business partners**, ERBOZETA GROUP is planning on maintaining its growth by giving innovative response to the worldwide market needs.

# OUR PRESENCE IN THE WORLD



# CERTIFICATIONS



Company with **UNI CEI EN ISO 13485**  
certified quality system for Medical Devices



## FOOD SAFETY SYSTEM CERTIFICATION 22000 FSSC 22000

Certification scheme for food safety management systems consisting of the following elements:

ISO 22000:2018

ISO TS 22002-1:2009

Additional FSSC 22000 requirements V5.1



## HACCP CERTIFICATE

Erbozeta S.p.A. company works in strict compliance with the good manufacturing practices for food supplements

# MANUFACTURING SITE FOREIGN REGISTRATION CERTIFICATES



US FDA Manufacturing Site  
Registration Certificate



Kazakhstan Manufacturing Site  
Registration Certificate



Qatar Manufacturing Site  
Registration Certificate



United Arab Emirates  
Manufacturing  
Site Registration Certificate

Iraq Manufacturing Site  
Registration Certificate



Libya Manufacturing Site  
Registration Certificate



# OWN PRODUCTS

## Research & Development and Marketing

Our Research and Development Department is paying special attention to innovation, researching always the latest scientific evidences on active ingredients, new packaging solution, new technologies and cutting-edge machinery for the development of advanced and high quality products.

Every year we develop **more than 400 projects** for numerous partners. All ingredients and contents are chosen based on clinical studies and scientific literature to support the formula.

We are also continuously collaborating with the most famous doctors in Italy to perform **Clinical Studies** on our products in order to demonstrate their safety and efficiency.

Moreover, we regularly organize **Scientific Conferences** to spread the knowledge of internationally renowned speakers in the field of phytotherapy.



## Food Supplement Specialties

**Andrology**

**Cardiology**

**Dermatology**

**Dietetics**

**Phlebology**

**Gastroenterology**

**Geriatrics**

**Gynecology**

**Immunostimulators**

**Neurology**

**Ophthalmology**

**Dentistry**

**Oncology**

**Orthopedics**

**Physiatrics**

**Rheumatology**

**Sports medicine**

**Otolaryngology**

**Pneumology**

**Pediatrics**

**Probiotics**

**Mineral salts**

**Urology**

## Medical Devices CE

Quality Management System of Erbozeta is in compliance with the standard EN ISO 13485. Erbozeta has strong skills in the production of medical devices (class IIa, IIb), all certified by accredited notified bodies.

The advanced technologies we have, combined with professional skills and strong expertise in the field, allow us to offer a wide range of medical devices, in various forms (bottles, oral and nasal sprays, vaginal ovules and douches, aerosols, eye drops, cream) , which cover numerous therapeutic areas.



PRODUCT	Sterile drops	Sterile Vials	Creams	Vaginal suppositories	Vaginal douches	Nasal sprays	Throat sprays	Syrups
Specialties	Ophthalmology	Otorhinolaryngology and Aerosol therapy	Dermatology	Gynecology	Gynecology	Otolaryngology	Otolaryngology	Otolaryngology

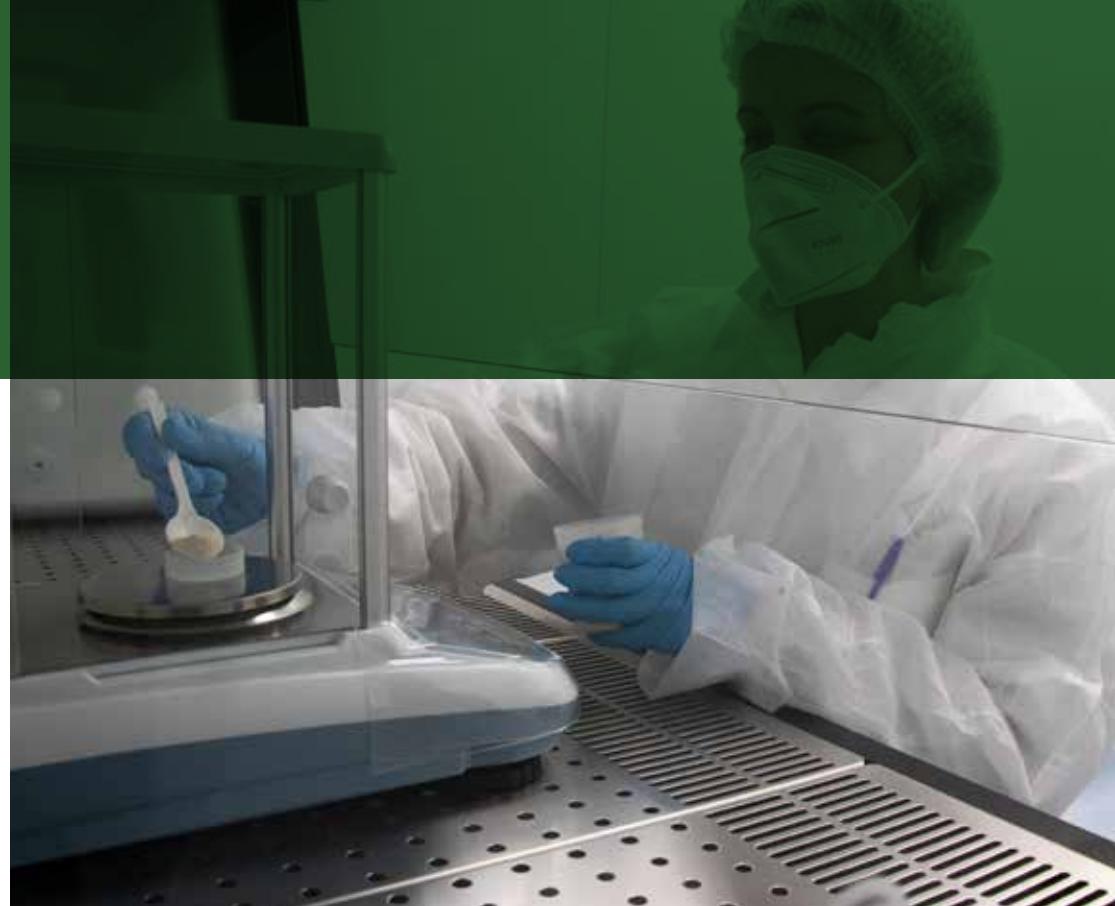
# CONTRACT MANUFACTURING

## Full service

ERBOZETA is a full service contract manufacturer that offers high quality products, tailored to each client's specific need, characterized by the compliance with quality standards at every stage of the production cycle. Using the latest equipment and combining our expertise with the skills and knowledge of our dedicated scientific, technical and quality control departments, we are able to follow the customer step by step in the development of new projects.

The full service offered for contract manufacturing contains:

- **Definition of the formula, including the selection of active ingredients and excipients**
- **Definition of the suitable pharmaceutical dosage forms**
- **Definition of the packaging with large flexibility**
- **Stability study in climatic chamber under various conditions: at 40°C (accelerated stability study), 25°C (long-term zone II) and 30°C (long-term zone IVB)**
- **Assistance in the preparation of the dossier for registration**
- **Manufacturing of the finished product**
- **Analysis made by external laboratory: microbiological, heavy metals, allergens, assay of active ingredients**
- **Assistance in logistics for transportation**



# MANUFACTURING SITE

## High quality standards

Quality is the main focus of ERBOZETA, from the raw material to the finished product.



## RAW MATERIALS

Our internal **quality control laboratory** is dedicated to certify the quality of all incoming raw materials performing various tests as **identification of raw materials** with NIR (Near Infrared), measurement of **water activity**, humidity, density, refractive index, pH, and control of organoleptic characteristics.

## 4500 m<sup>2</sup> of MANUFACTURING SITE

Our manufacturing processes take place in **ISO 8 clean rooms** under **controlled temperature, pressure and humidity 24/7**, thanks to a advanced air filtration system (high efficiency HEPA filters). There are 38 standard ISO 8 clean rooms dedicated to the manufacturing of our pharmaceutical forms.



# DOSAGE FORMS AND PRODUCTION POSSIBILITIES

## SOLID FORMS

### CAPSULES AND TABLETS

- tablets with or without coating in various sizes
- chewable tablets in various sizes
- gelatin capsules in various sizes
- vegetable capsules in various sizes



### PVC/PVDC BLISTERS ALU/ALU BLISTERS DOUBLE BLISTER



Possibility of  
**GRANULATION**  
with fluid bed

## SOLID FORMS

### **PILL BOTTLES**

in various sizes



### **POWDERS IN SACHETS**

in various sizes



### **POWDERS OROSOLUBLE STICKS**

in various sizes



# DOSAGE FORMS AND PRODUCTION POSSIBILITIES

## LIQUID FORMS

### SYRUPS

Possibility of packing into:  
**100ml, 120ml, 150ml, 200ml, 500ml**  
With **dosage cap**  
With **syringe**



### DROPS

Possibility of packing into:  
**6ml, 10ml, 15ml, 20ml, 30ml, 50ml**  
With **internal dropper**  
With **overturning dropper**



### BI-PHASE SINGLE-DOSE BOTTLES

With reservoir cap  
Possibility of packing into: **6ml, 10ml, 12ml, 15ml, 20ml**  
With boxes of: 5/7/10/12/20 bottles

The packaging solution grants the highest **stability and preservation** of the solid active principles present in the cap. Thanks to a **multilayer material** sealing the cap, ingredients present in the cap are perfectly isolated from the liquid phase.



PRESS, SHAKE  
and DRINK

EASY AND PRACTICAL

A safe choice for  
stability challenges

IDEAL FOR PROBIOTICS  
AND MULTIVITAMINS

MIXERS FOR LIQUID PREPARATIONS



BOTTLE FILLING MACHINES - 3000 PIECES/ HOUR



## LIQUID FORMS

### ORAL SPRAY

With various cannula



### NASAL SPRAY

With various cannula



### SINGLE-DOSE BOTTLES

with various cap colors



### LIQUID STICKS

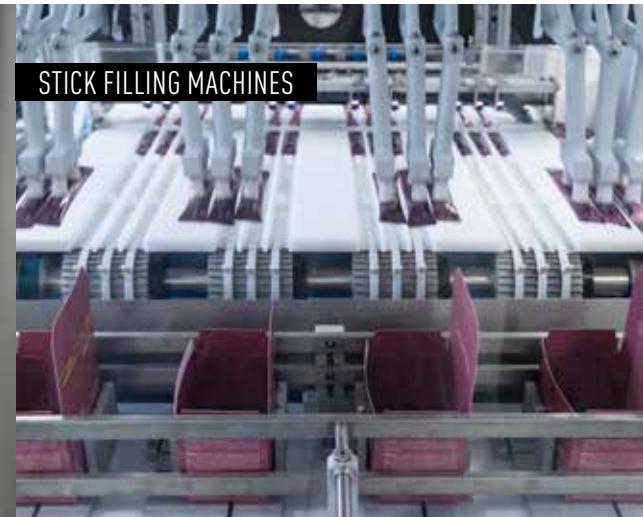
Up to 15 ml



LONG LIFE FILLING MACHINES - 50 MILLION CAPS PER YEAR



STICK FILLING MACHINES



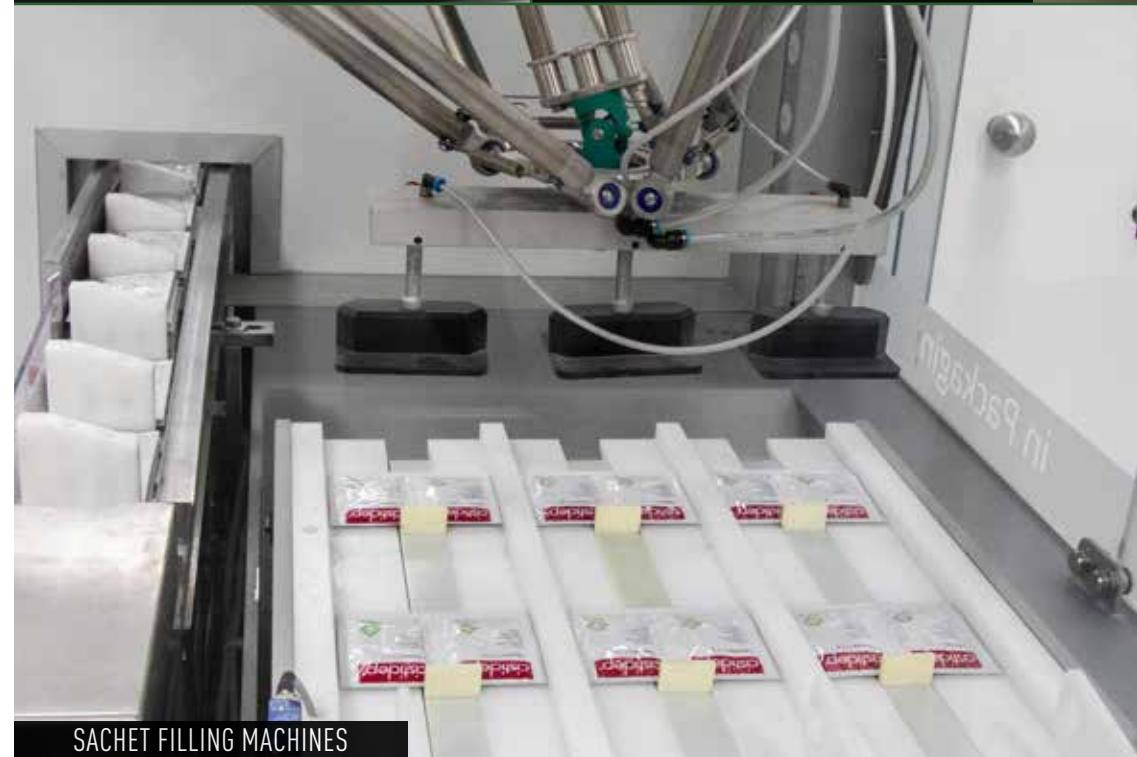
# PROBIOTICS AREA

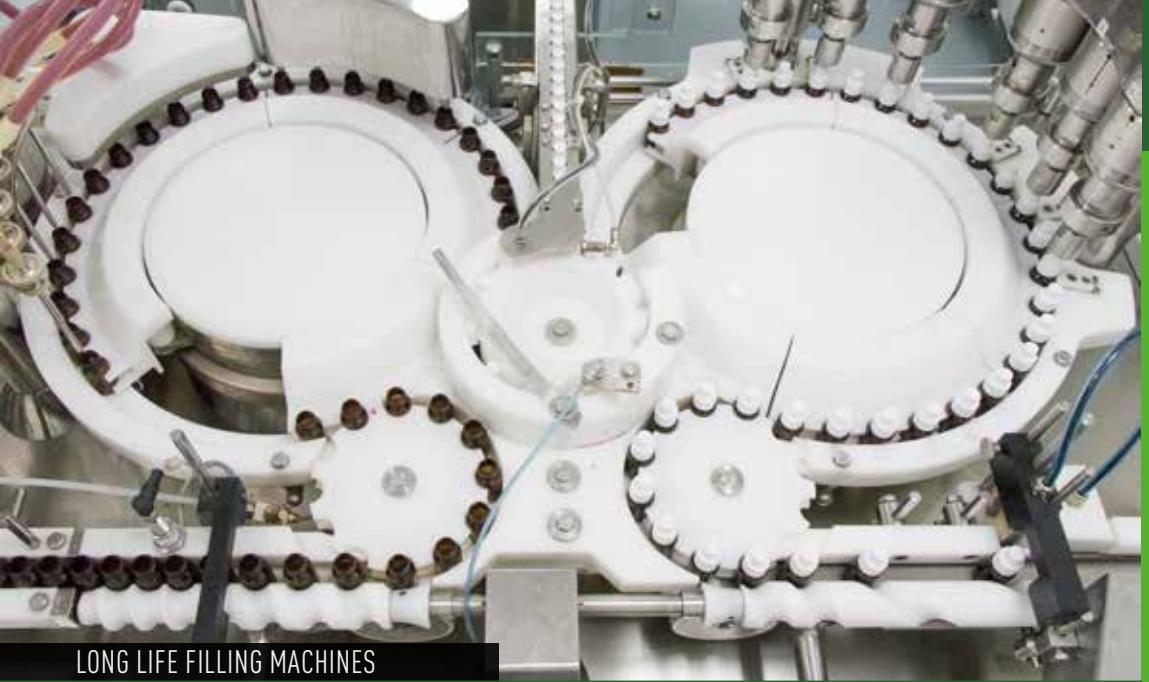
Production of probiotics in clean rooms of pharmaceutical standard under controlled temperature and humidity.

Storage of raw material and finished products in separate controlled temperature cooling room between 0°C and 8°C.



**GELATIN CAPSULES AND VEGETABLE CAPSULES  
POWDERS IN SACHETS  
POWDERS IN OROSOLUBLE STICKS  
BI-PHASE SINGLE-DOSE BOTTLES**





## MODIFIED ATMOSPHERE (NITROGEN)

Production is made in a **modified atmosphere (Nitrogen)**; by eliminating oxygen from the operculum/stick filling area, we decrease the oxygen inside the product thus minimizing oxidation and increasing the stability of the probiotic strains.



# ERBOZETA GROUP

Commercial brands



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Erbozeta branches  
in the world



gruppo  erbozeta



EZ02.01.18

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Vienna

**Erbozeta Iberica LDA**  
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**Erbozeta Asia LTD**  
Hong Kong



COMPANY PROFILE  
**DOWNLOAD**

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