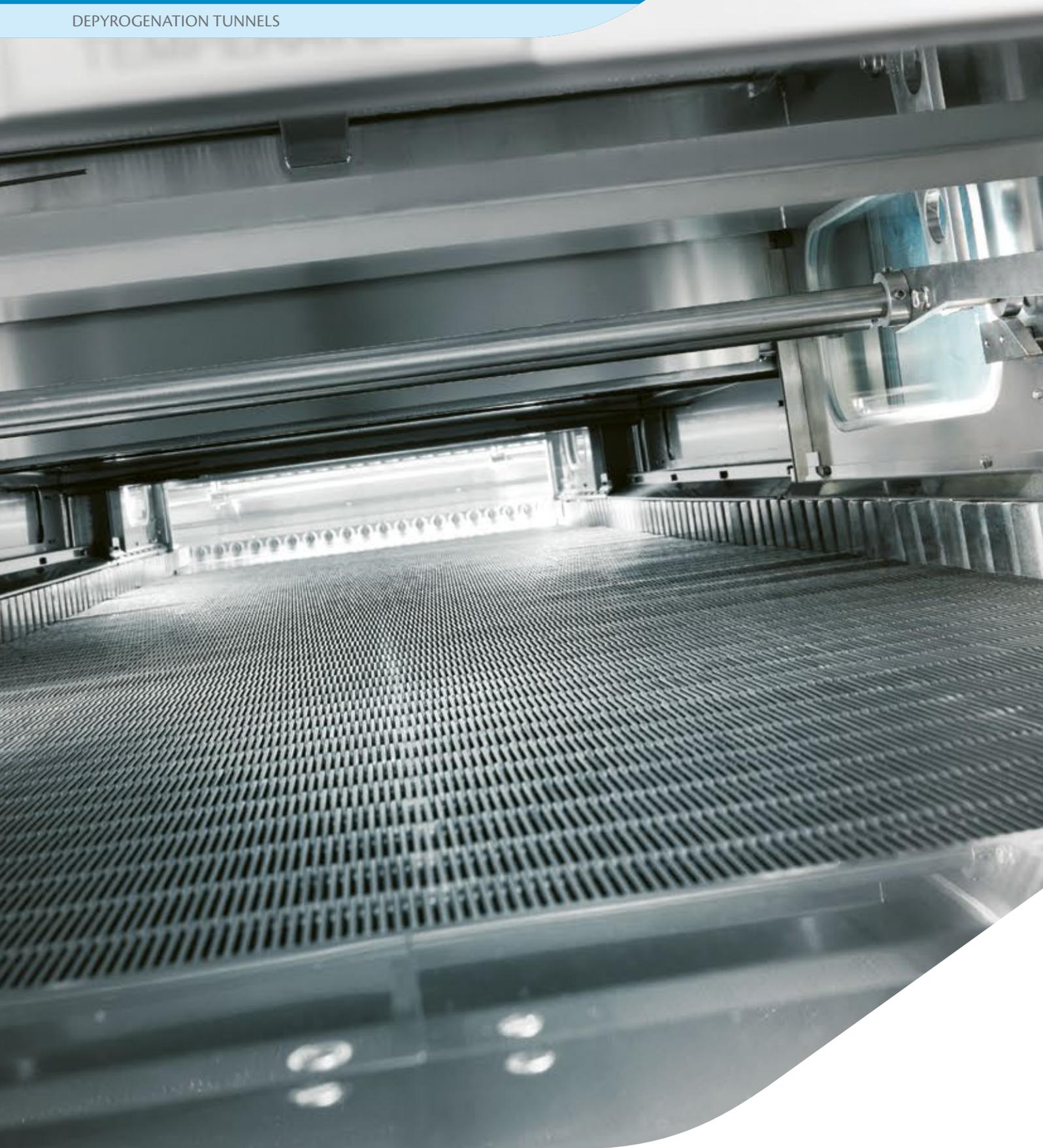


# BLUE GALAXY

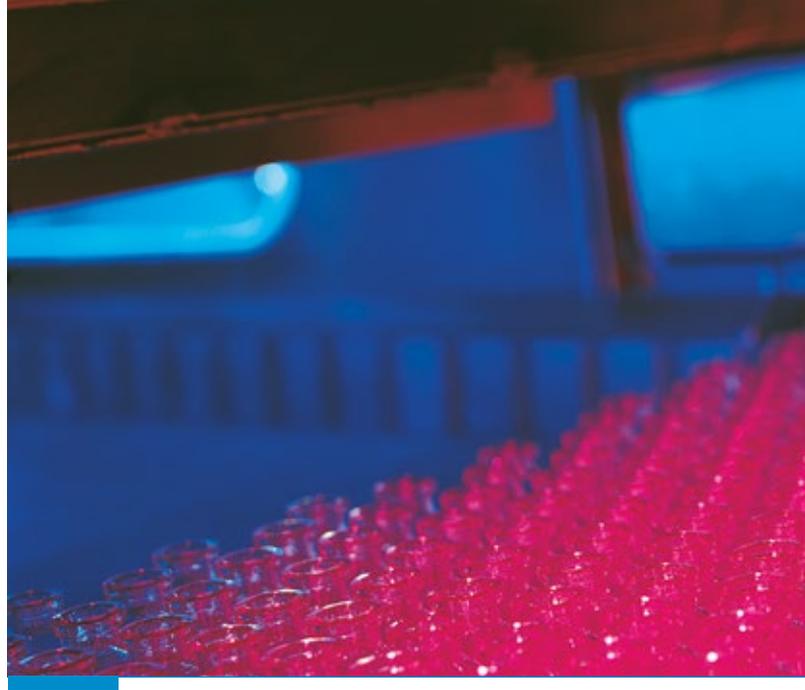
DEPYROGENATION TUNNELS



# DEPYROGENATING TUNNEL

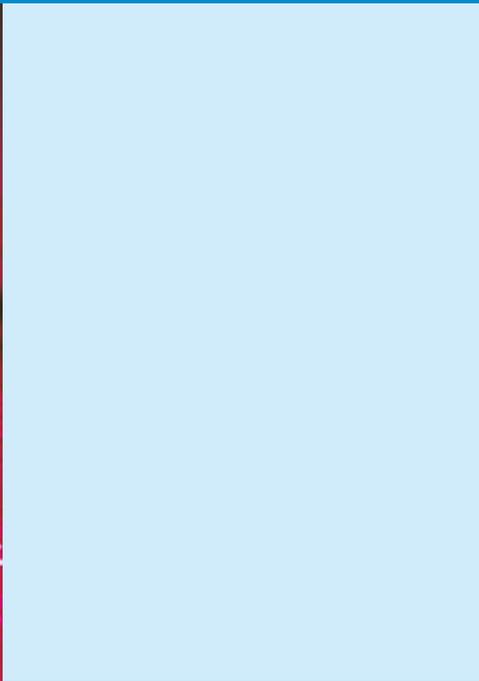
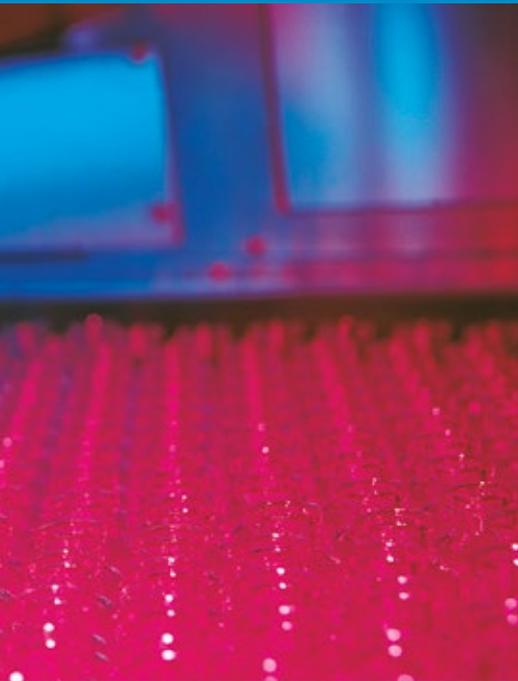
The IMA LIFE laminar flow depyrogenating tunnels of the BLUE GALAXY series are the result of years of research and experience in the field of sterilization and depyrogenation.

The tunnels are suitable for being included in continuous production lines, which require a sterilization and depyrogenation process by dry heat for glass containers such as vials, ampoules, carpoules, etc. The heating of containers is made by using hot air, treated with pre-filters and absolute filters HEPA or ULPA, which protect the container during the complete preheating, sterilizing-depyrogenizing and cooling process; along the entire length of the tunnel the air quality is ISO5 as per ISO 14644. The machine, designed and built according to cGMP standards, uses solutions at the forefront of technology and therefore is able to guarantee the repeatability and the absolute control of the process, and the easy use.



THE EXCLUSIVE SYSTEM OF AIR BALANCING, PRESSURIZATION AND HEATING/ COOLING ALLOWS A PERFECT THERMIC TREATMENT OF GLASS CONTAINERS; THIS IS THE REASON WHY WE USE CONTROL AND ACCEPTANCE CRITERIA WHICH ARE SO STRICT TO MAKE IMA LIFE TUNNELS REMARKABLE IN THEIR FIELD.

THE WIDE RANGE OF MANUFACTURED TUNNELS GIVES THE POSSIBILITY OF SATISFYING ANY PRODUCTION NEED; IN THE SAME WAY THE HIGH TECHNOLOGY ALLOWS TO USE OUR TUNNELS FOR ANY KIND OF APPLICATION AND THAT'S WHY THEY CAN BE EASILY INTEGRATED IN LINES FOR TREATING VERY HIGH TOXIC PRODUCTS AND/OR IN LINES WITH ISOLATORS. THE TUNNEL CAN BE EQUIPPED WITH AN EXCLUSIVE PATENTED SYSTEM FOR STERILIZING. THE COOLING ZONE WITH HYDROGEN PEROXIDE IN VAPOUR PHASE OR WITH CONVENTIONAL DRY HEAT.



# DEPYROGENATING TUNNEL

THE TUNNEL CONVEYOR BELT HAS LATERAL FINS WHICH ARE FITTED DIRECTLY ON THE CHAIN AND WHICH THEREFORE MOVE AT THE SAME SPEED AS THE BELT, GUARANTEEING A COMPACT ROW OF CONTAINERS. BELT MOVEMENT AND TENSION ARE OBTAINED, RESPECTIVELY, BY MEANS OF A MOTOR WITH CONTINUOUS SPEED REGULATION AND A ROLLER WHICH COMPENSATES FOR ANY STRETCHING DUE TO HEAT.

HIGH TECHNOLOGY FOR THE SAFETY OF DEPYROGENATION PROCESSES.





THE SIMPLE SIDE ACCESS (NO UPPER ACCESS IS REQUIRED) ALLOWS AN EASY MAINTENANCE, SUCH AS FILTER REPLACEMENT, AND A VERY EASY ACCESS FOR SENSOR CALIBRATION.

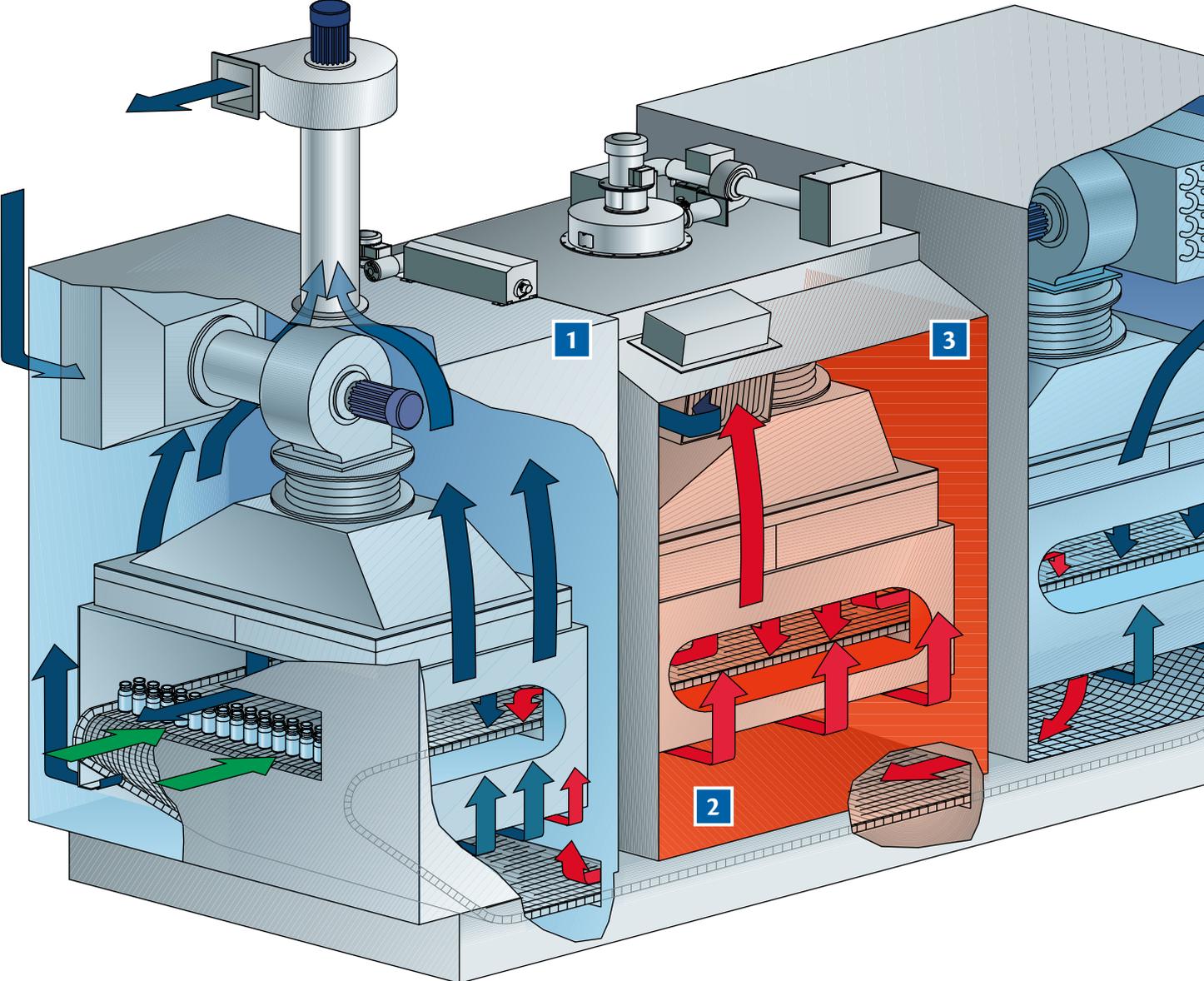


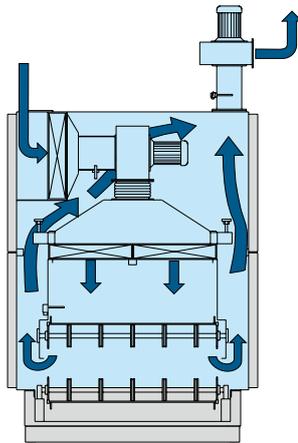
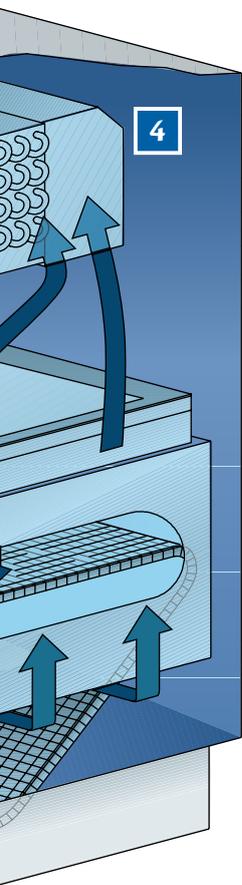
THE UNLOADING PROCEDURE, CAN BE COMPLETELY AUTOMATIC. WITHOUT OPERATOR AND/OR TOOLS INTERVENTION.

The tunnel, constructed in AISI 304, consists of three laminar flow zones: infeed zone, heating zone, cooling zone. The clean containers are arranged and automatically conveyed by the washer onto the tunnel conveyor belt at the infeed zone; large vials or bottles are loaded in off-set position to optimize the loading.



# AIR FLOW AND BALANCEMENT SYSTEM





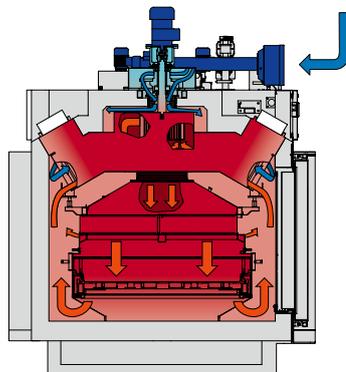
## 1 INFEEED ZONE

The laminar flow at the infeed zone is generated by a centrifugal fan that sucks the air from the environment surrounding the tunnel or from the air conditioning system. The air passes through a prefilter and is then sent to the absolute filters. After having passed through the vials, it is sucked from under the belt by the exhaust fan and then is expelled.

In order to enter the chamber, as in all the three zones, simply open the side sealed doors: filters may then be easily changed.

## 2

The belt remains inside the tunnel at the infeed and outfeed zones and is always protected by the vertical laminar flow. When returning, the belt passes outside the heating chamber through a closed and sealed channel that links the infeed zone to the outfeed one, at the same time balancing the pressure differences between these two chambers (principle of communicating vessels).

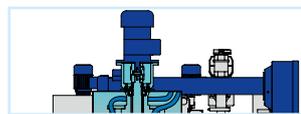


## 3 HOT ZONE

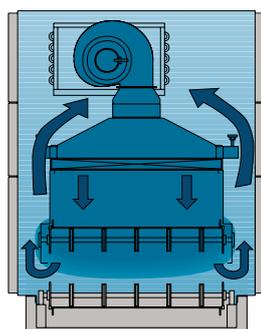
The laminar flow (high-temperature air) used in this zone is recycled in closed circuit to reduce energy consumption.

Laminar flow is generated by a centrifugal fan connected to the intake hood by means of a st.st. expansion joint so as to avoid the transmission of vibrations.

Air is sucked uniformly from two sides of the chamber in order to obtain high temperature distribution precision. The chamber is connected to the two adjacent chambers with two st.st. expansion joints.



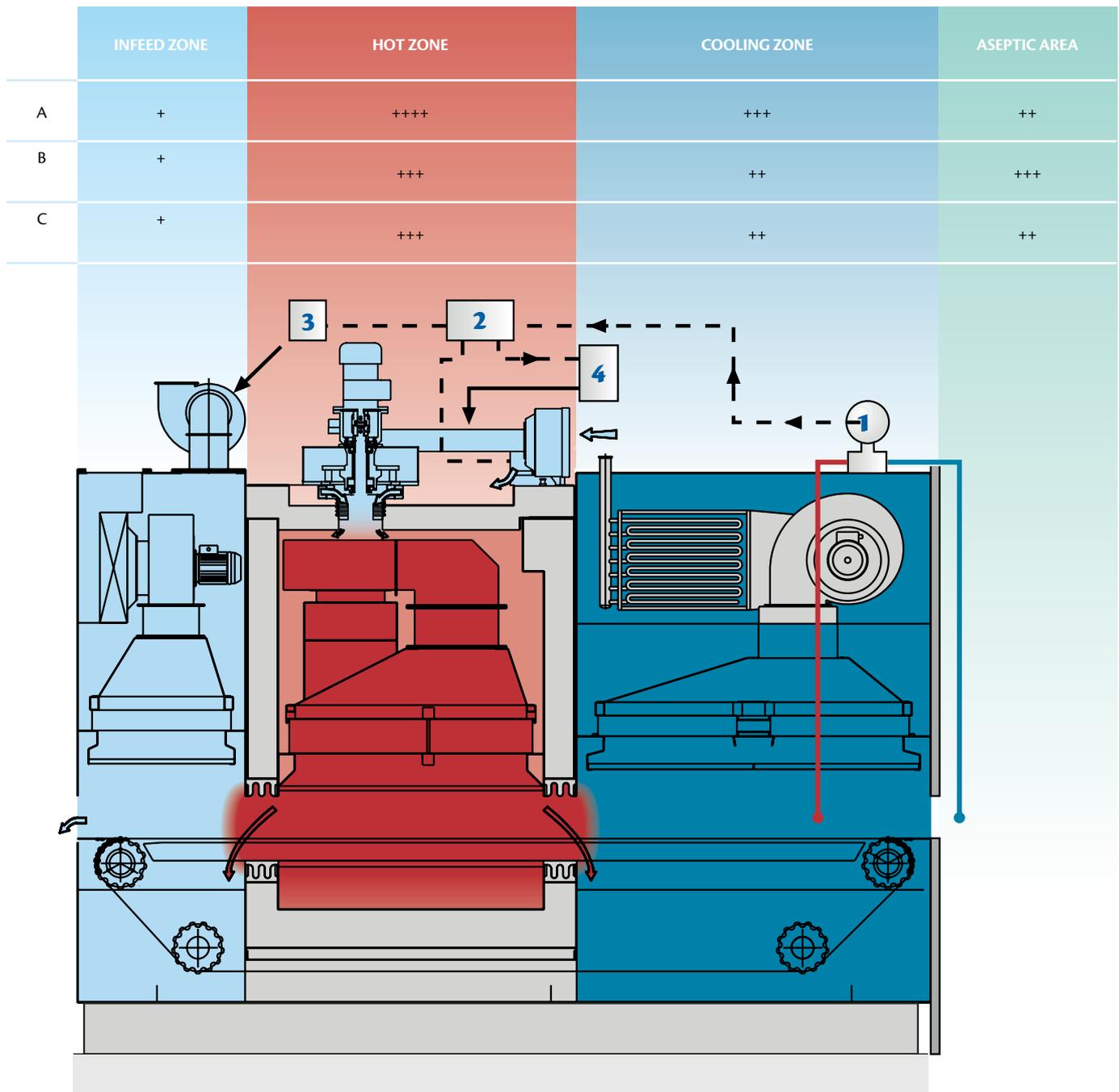
A special air make-up system keeps the tunnel hot zone in overpressure compared to the other areas, and it guarantees also the correct exhaust air exchange. This system prevents thermic glass shocks.



## 4 COOLING ZONE

In the cooling chamber the laminar flow is recycled in closed circuit to improve cooling efficiency by exchanging air/water heat (cooling battery) and to maintain a constant value of the pressure without risking the cooling zone going underpressure. As all the three zones, it is equipped with ports for integrity test and particles counting.

# AIR FLOW AND BALANCEMENT SYSTEM

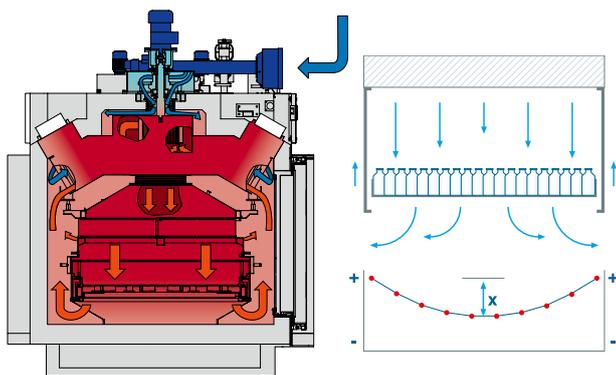


With the principle of communicating vessels, assisted by the make-up of the hot zone (over-pressure of the heating chamber), the tunnel allows operation with a pressure difference between the sterile chamber and the tunnel area of 50 pascals (variations of +/- 15% of such a value are absorbed and balanced automatically without altering the operating parameters).

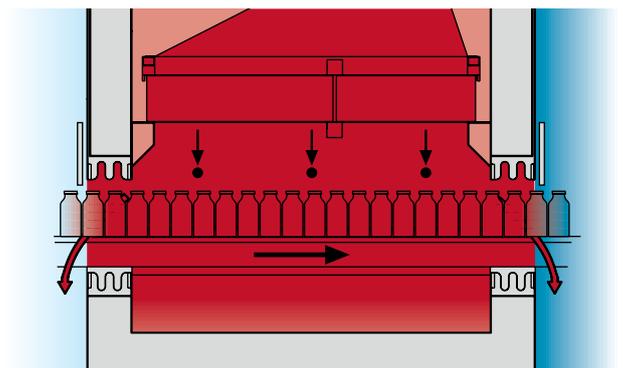
When the pressure transmitter (1) detects a variation, in comparison with the set point, the PLC (2) automatically increases/decreases the exhaust air quantity by means of the frequency variator (3) while the make-up air quantity is kept constant by means of the frequency variator (4). With this system it is possible, to work with the cooling zone in overpressure, compared to the sterile zone (case A), in underpressure, compared to the sterile zone (case B), or at the same pressure as the sterile zone (case C), avoiding any cold air flow entering into the sterilizing area.

THE AIR RECYCLING FROM BOTH SIDES OF BELT, ALLOWS TO HAVE THE STERILE PART IN OVERPRESSURE IF COMPARED TO THE NON-STERILE AREA, ALSO AVOIDING UNFILTERED AIR →TO BY-PASS THE FILTERS. IN THE DEPYROGENATION ZONE, THIS SYSTEM ALLOWS THE ASSEMBLING OF FILTERS WITHOUT GASKETS.

AN OPPOSITE AND CONSTANT BY-PASS ALLOWS THE RECYCLING OF THE AIR COMING FROM THE PERIMETER OF FILTERS, GUARANTEEING PARTICLES RETENTION, AS PER STD. RECOMMENDATIONS.



The particular execution of the aerodynamic system in the hot zone, allows - by recycling the air from both sides of the belt - the best distribution of air that, helped by the make-up system, guarantees a perfect uniformity of temperatures inside the vials, therefore minimizing the differences even with large volume bottles.

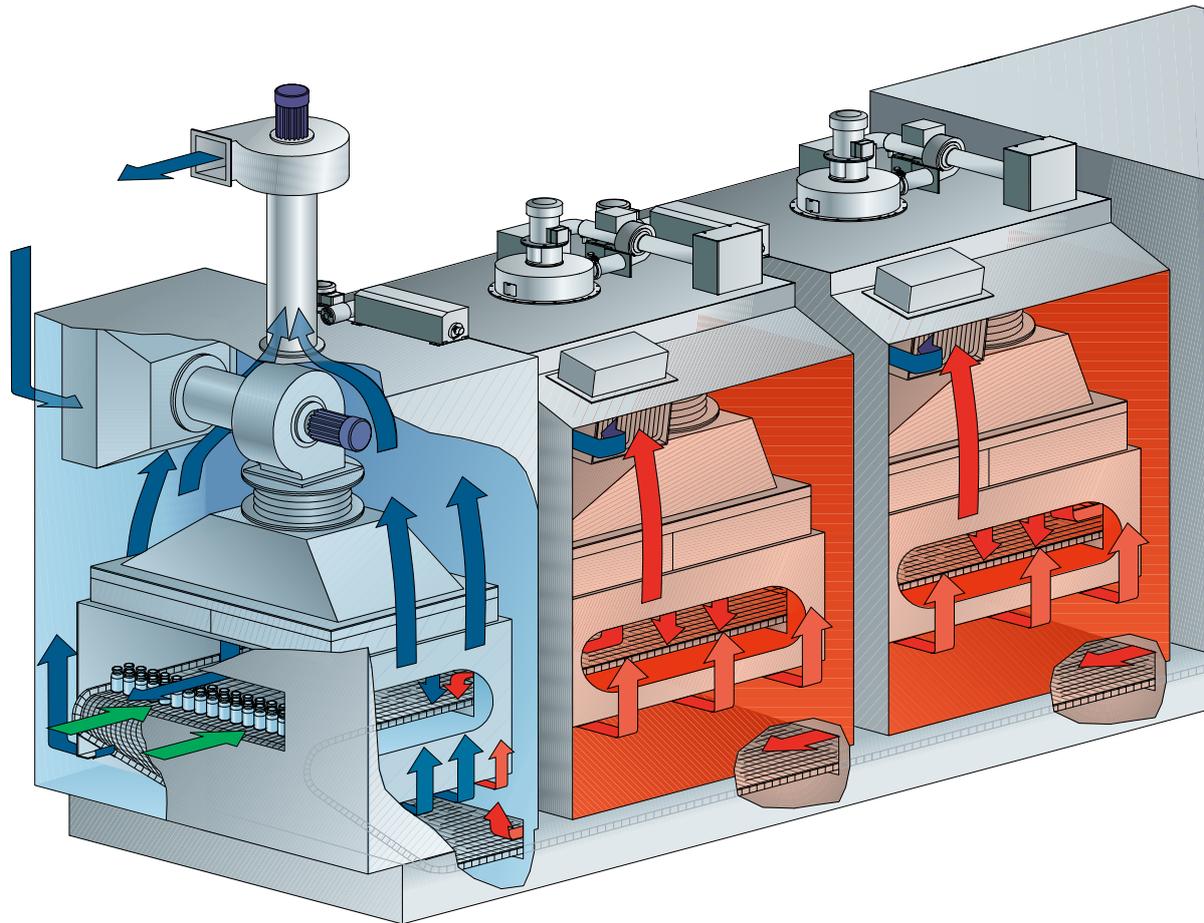


The hot zone, in overpressure if compared to the adjacent areas, guarantees the repeatability of depyrogenating time and temperature.

Being guaranteed the absence of cold air flows coming from the adjacent rooms, the exposure time and temperature will be guaranteed even in presence of pressure oscillation between sterile room and tunnel area.

# MODULAR SYSTEM

THE TUNNELS CAN BE BUILT WITH MODULAR SYSTEM TO SATISFY AND MEET THE MOST DIFFERENT PRODUCTION AND PROCESS NECESSITIES.

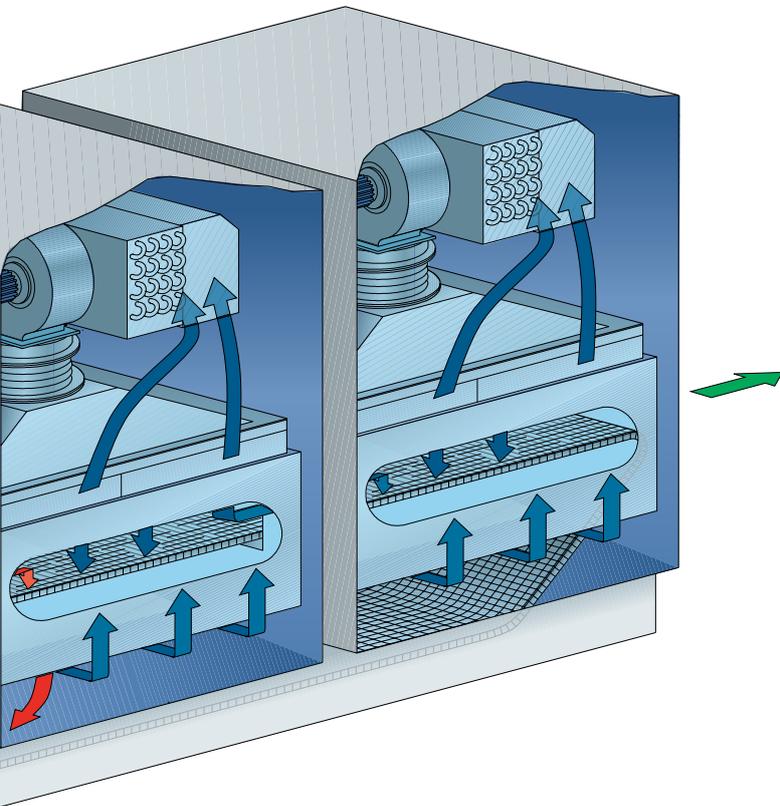


THE CONTROL AND AUTOMATION SYSTEM OF THE TUNNEL CAN BE REALIZED WITH DIFFERENT PLC OR PC TYPES, ACCORDING TO THE NECESSITY OF CUSTOMIZATION OR PROCESSING.

ALL INSTRUMENTS ARE EASILY ADJUSTABLE AND CALIBRATABLE: THIS CONSIDERED ALONGSIDE WITH DESIGN AND MANUFACTURING PRECISION, MAKES

BLUE GALAXY AN IDEAL TUNNEL FOR PRODUCTION REQUIREMENTS IN ACCORDANCE WITH ALL REGULATORY REQUIREMENTS.

TUNNEL CONTROL AND AUTOMATION, WHICH CAN ALSO BE EXTENDED TO THE OTHER MACHINES IN THE LINE, CAN BE 21CFR11 COMPLIANT OR CAN BE WITH A SCADA SYSTEM.



**The tunnel in its standard configuration is equipped with many control systems such as:**

- Anemometers for checking the air speed
- Differential manometers for checking the obstruction level of filters
- Air flow measuring system inside the hot area
- Automatic adjustment of the air speed based on the density (temperature)
- Automatic balancing
- Calibration systems on the installed sensors
- HMI with different password levels
- Connections for all calibration operations
- Weekly clock for automatic start
- Speed, thermoregulation adjustments directly from HMI
- Over-kill function during loading and unloading

**Other options are available such as:**

- Automatic gates
- Hermetic gates at inlet and outlet
- Total automatic unloading systems
- Water cooling units in closed circuit.



# COOLING ZONE STERILIZATION WITH...

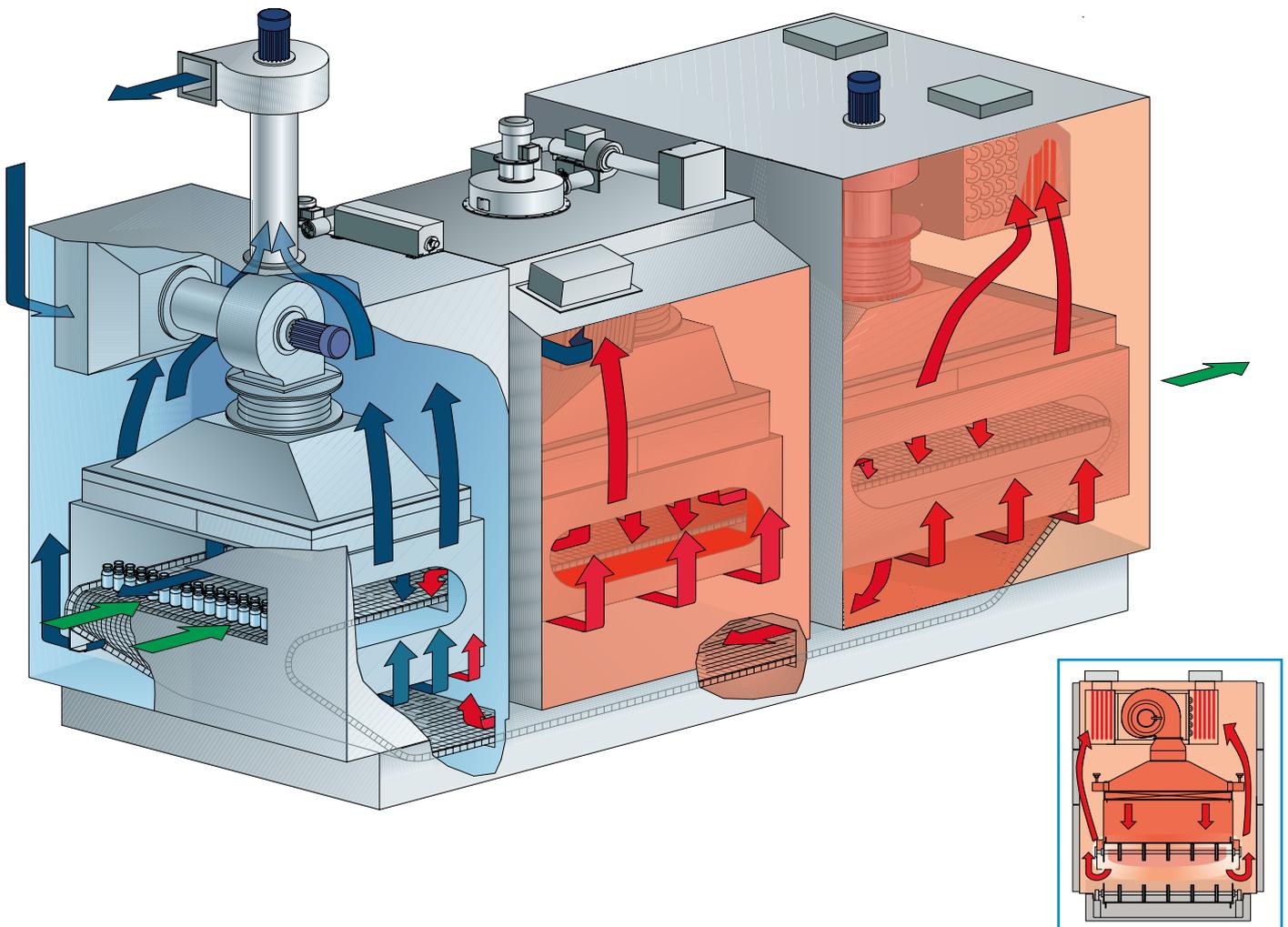
## ... DRY-HEAT

The cooling zone can be sterilized with dry heat. Double electrical heaters are installed in the return ducts with all electrical connections outside the heated area.

Before the sterilization cycle the cooling system is drained to avoid water pressurization or additive's coating if present. The cycle guarantees that all points reach at least 170° C or more- temperature and time adjustable.

The system guarantees 6 log of spore reduction.

The chamber is insulated to avoid external surface temperature...





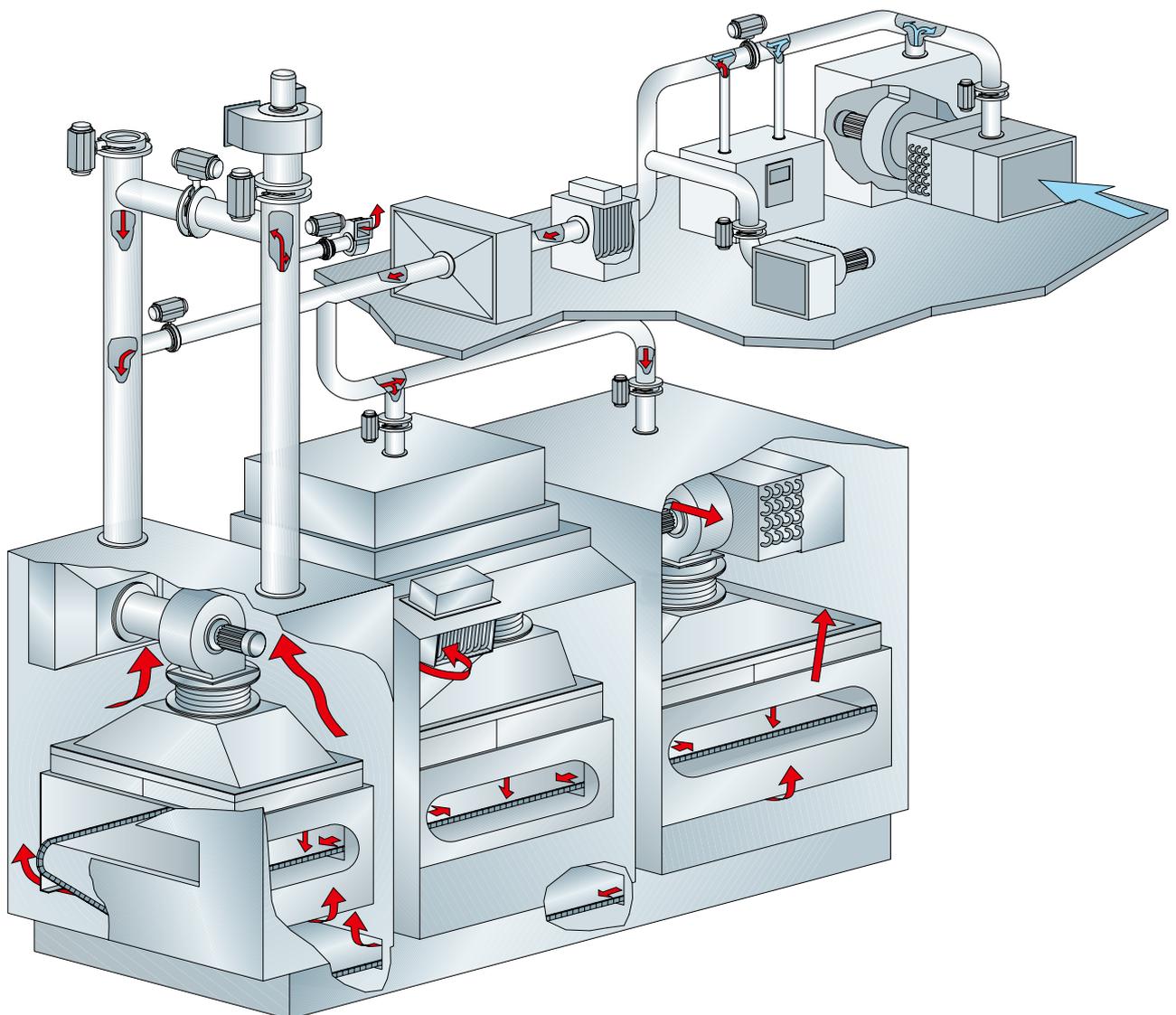
### ... HYDROGEN PEROXIDE IN VAPOUR PHASE

Equipping the tunnel with this exclusive patent sterilization system, it is possible not only to have an aseptic cooling zone, but also all tunnel's internal surfaces sterilization.

This system allows to sterilize the tunnel at the same time of the isolator sterilization or during the room gasification. The simple and efficient design permits a very optimal gas distribution within all the tree zones of the tunnel. The particularly cycles guarantee a very high hydrogen peroxide concentration and easy and fast aeration.

When isolator or room are sterilized at the same time, the gas can move from the isolator or room inside the tunnel sterilizing all transfer area.

The cycle guarantees 6 log of spore reduction.



THE STERILIZING TUNNELS, AS ALL OTHER MACHINES MANUFACTURED BY IMA LIFE, ARE SUPPORTED BY A TEAM OF SKILLED TECHNICIANS, WHO USING OUR COMPANY INSTRUMENTS AND LABORATORIES, CAN HELP CUSTOMERS DURING VALIDATION ACTIVITY.



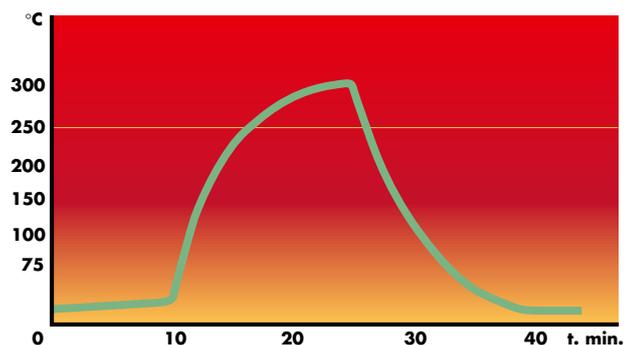
## GLASS TEMPERATURE PROFILE

Tunnels dimensions are conceived in order to guarantee to the treated glass a thermic cycle performing an endotoxin reduction of at least 3 log. As far as the calculation of the equivalent time is concerned (FT or FH or FENDO) we have adopted the most restrictive parameters. As per indications of Worldwide Pharmacopoeias we consider the glass to be depyrogenized only starting from 250°C, so this value has been considered as the Reference Temperature (Trif 250°). As far as the D value is concerned, time necessary for the reference temperature to get 1 log. endotoxins reduction, is considered 5'; therefore we can guarantee an Equivalent Time of at least 30 minutes at 250°C. As the depyrogenation is achieved at lower temperatures than the ones reached by glass, we use a temperature value (Z) of 46,4°C. This value is equal to the temperature value that, being added to the Trif value, reduces the D value of 90%.

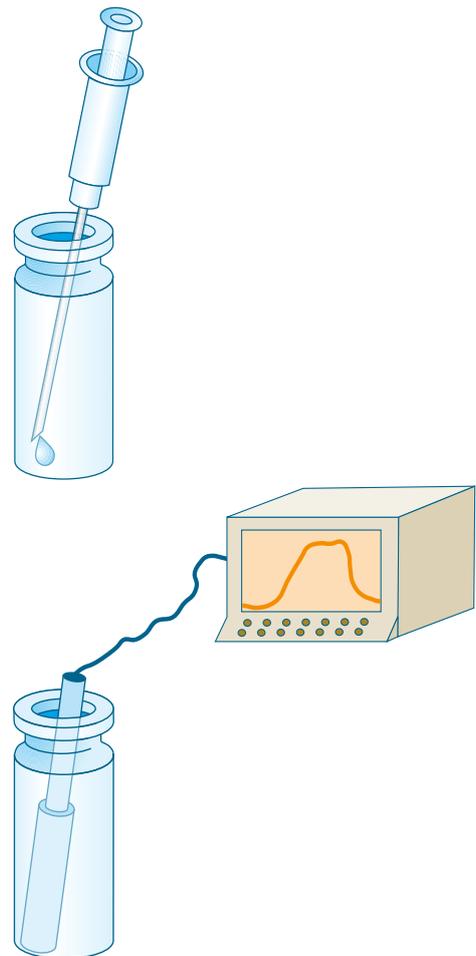
Applying the formula mentioned hereafter to a temperature curve, it is possible to get the equivalent times.

Any dimensioning with different parameters can be achieved by simply requesting to our technical departments thermic cycle simulations.

$$FT = \sum \Delta T \cdot 10^{(T - \text{Trif}) / Z}$$

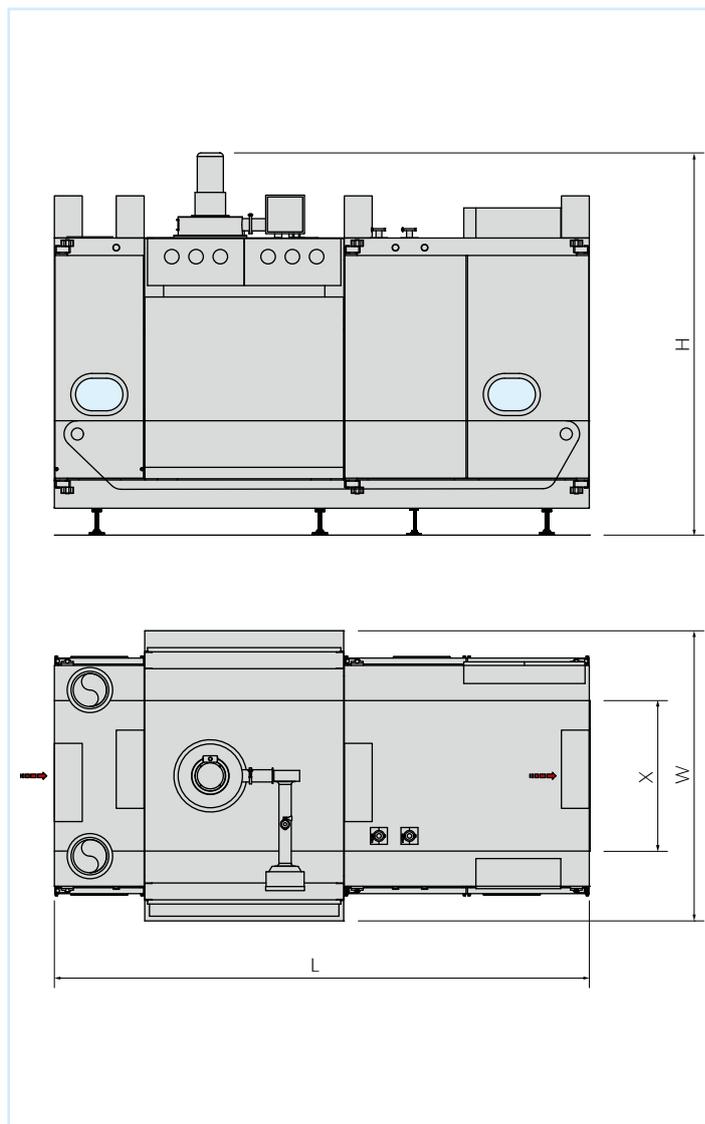


Typical profile of temperature distribution inside vials



Temperature profiles will be checked with a probe inside the vials, where the endotoxins are inoculated (coldest point) in order to have data to be compared to the results as the LAL test.

# BLUE GALAXY TECHNICAL DATA



The dimensions mentioned hereafter together with machine models are indicative and can be changed according to customer necessities.

## BLUE GALAXY SERIES

MODEL	550 FL	870 FL	870 FLS	1250 FL	1250 FLS	1250 2FLS	1250 3FLS
X (mm)	550	870	870	1250	1250	1250	1250
W (mm)	1705	2025	2025	2410	2410	2410	2410
L (mm)	2980	2980	3810	4410	7025	8245	9940
H (mm)	2980	2980	3075	3175	3175	3175	3175
Upon request Reduced height (mm)	2700	2700	2760	2760	2760	2760	2760
Power (kW)	39	50	60	70	145	149	214

## DRY-HEAT VERSION (APPLICABLE ON ALL A.M. MODELS)

MODEL	550 FL	870 FL	870 FLS	1250 FL	1250 FLS	1250 2FLS	1250 3FLS
Power (kW)	63	74	90	110	225	229	334
L (mm)	+ 70 mm						
Reduced H (mm)	NOT AVAILABLE						

The above mentioned heights are referred to a vial working flow height of 950 mm.

As far the production capacities of the different vials sizes are concerned, ask for thermic cycles simulation.

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