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*SECTION 0 - PREAMBLE*

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### 0.1. COMPANY DETAILS

<b>Company name</b>	ACQUA MINERALE DI CALIZZANO S.P.A.
<b>Field</b>	Mineral water and soft drinks
<b>Business activity</b>	Bottling mineral water and carbonated soft drinks.
<b>Starting date</b>	1962
<b>Tax ID number</b>	00112190095
<b>VAT number</b>	00112190095
<b>Category of the business activity (ISTAT code)</b>	15.98
<b>Chamber of Commerce registration number</b>	41165
<b>Court registration number</b>	3393 reg. – 4420 vol.
<b>Headquarters</b>	1
<b>Employees</b>	19

<b>Address</b>	Via Madonna delle Grazie		
<b>Post Code: 17057</b>	<b>Place Calizzano (SV)</b>	<b>tel. + 39 01979613</b>	<b>fax + 39 01979656</b>

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## ***0.2. DECLARATION OF RESPONSIBILITY***

The Company undertakes to follow a policy that ensures the hygienic safety of the products. The implementation of a Self-Control Program for the prevention of sanitary risks is the means by which the company implements this policy and complies with the law on safety and food hygiene quality.

The Company undertakes to ensure that the Self-Control Program is strictly implemented and documented. All the Company departments and employees involved in the maintenance activities and that guarantee the hygiene are required to comply with the requirements of this manual. The Self-Control Program is not considered a simply legal compliance, but it is a means to spread the culture of hygiene among all the workers of the company. And a continuous review and updating mechanism is provided, such as to produce a continuous improvement of the system effectiveness and efficiency.

The Self-Control Program is based on the HACCP (Hazard Analysis and Critical Control Points) principles as provided in Art. 3 of Italian Legislative Decree No. 155/97 and Italian Legislative Decree no. 852/04:

- a) analysis of the potential hazard/risk for food;
- b) identification of points where risk may occur for foods;
- c) decisions to be adopted with respect to the critical points identified, i.e. the points that can be dangerous for the product safety;
- d) identification and implementation of the critical points control and monitoring procedures;
- e) periodic review, and on the occasion of the change of each process and of the type of activity, of the risk analysis, of the critical points and of the control and monitoring procedures.

Calizzano, February 26, 2016

The HACCP Manager

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**0.3. ROLES AND RESPONSIBILITIES**

The HACCP Manager (R.A.) is identified as the head of the food industry, i.e. in the owner, or in a representative specifically appointed (as per Italian Legislative Decree no. 155/97 art.2).

His/Her main functions are:

- prepare and update the Self-Control Program and monitor the implementation of the requirements detailed in the above mentioned Program;
- make sure that all personnel involved in the system activities is properly trained and is aware of the role and of the consequences that may arise from the non-fulfilment of the requirements;
- organize and manage the personnel training and updating hygiene activities;
- make sure that on the occasion of change of tasks or of new hiring, the non-expert personnel is properly trained regarding hygiene;
- prepare and manage the monitoring systems of the people hygienic conditions;
- prepare each year and coordinate the meeting for the review of the Self-Control Program.

In addition, the HACCP Manager is the contact person for official control authorities and oversees the legislative update on products safety and hygiene.

<b>HACCP Manager</b>	Angelo Nan
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*SECTION 1 - FOREWORD*

	<b>SELF-CONTROL PROGRAM</b>	
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### ***1.1. PURPOSE AND SCOPE***

This manual describes and defines the Self-Control Program implemented by the Company for the prevention of risks to the consumer health, in compliance with the provisions of the Italian Legislative Decree no. 155/97 and subsequent Decree no. 852/2004

The implemented Self-Control Program is formalized in the requirements of this manual, in the operating procedures, in the instructions, and in the annexed forms.

The requirements of this Program shall apply to all stages of corporate activity.

The Company operates in the mineral water sector, in particular the activities are divided into the following steps:

- collection of the natural mineral waters
- preparation of the mixtures for the soft drinks
- bottling of mineral water and soft drinks
- storage of the packed products



# SELF-CONTROL PROGRAM

## 1.2. SUPPLIERS

The Company uses qualified suppliers according to the following criteria:

1. quality of incoming goods;
2. long-lasting relationship with the supplier.

In pursuing the consumer safety protection policy to ensure the hygiene and safety of the products distributed, the Company implements a goods acceptance program (raw materials for soft drinks, packaging materials) based on the request to the suppliers of the data sheets relating to the goods purchased.

In addition, inspection checks are performed on incoming supplies for:

- trucks/vehicles      hygienic condition
- goods                      corresponding to the purchase order  
   state of preservation

The results are shown on the sheet "A" "Acceptance of Raw Materials".

Glass bottles	Avir – O.I - Vetreria Cooperativa Piegarese
PET preforms	Pizzorni – Italtet - Resilux
Caps	Cds - Viroplastic
Carbon dioxide	Siad
Nitrogen	Siad
Soft drink products	Giotti – Bruscoli – Aromificio Salamina - Mastertaste

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### **1.3. DEFINITIONS**

#### **HACCP (Hazard Analysis and Critical Control Points)**

A system which identifies, evaluates, and controls hazards which are significant for food safety

#### **HACCP PLAN**

A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration

#### **HAZARD ANALYSIS**

Procedure which has the purpose of identifying the potential significant hazards, where the significance is given by the combination of two factors: the probability that the hazard will occur and the severity of the damage.

#### **HAZARD**

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

#### **RISK**

Likelihood or probability that a hazard occurs.

#### **SEVERITY**

Importance of the hazard (potential damage).

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**CRITICAL CONTROL POINT (CCP)**

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**CRITICAL LIMIT**

Boundary within which the critical point must be considered to be under control.

**CONTROL MEASURES**

Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**MONITORING**

A planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

**CORRECTIVE ACTION**

Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

**VERIFICATION**

The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan and/or the need to modify the HACCP plan.

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*SECTION 2  
DESCRIPTION OF THE PREMISES, THE EQUIPMENT  
AND THE MACHINERY*

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## **2.1. COLLECTION AREA**

The mineral aquifer used is characterized by the following areas:

- *Collection area*

Area around the source within which all the activities different from the utilization of hydro-mineral resources are forbidden.

This area is defined by a natural rock protection and closed with steel doors.

- *Close protection area*

Area around the collection area in which a higher pollution could dangerously affect the quality of the water.

All the works, activities, staging, installations, soil and subsoil modifications that can pollute mineral water are forbidden in this area.

## **2.2. PREMISES**

Premises are designed so that they can be easily cleanable and ensure a rational flow of production to avoid possible product contaminations.

The floor and the walls are made of a nonabsorbent and easily cleanable material.

The floors are equipped with grids and gutters so that they can allow the natural outflow of the liquid.

The surface in which the activity is carried out is divided in the following rooms:

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1. Bottling room - glass bottles
  - Area of bottle reception and washing
  - Area of packaging (1L bottles)
  - Area of packaging (0.5L bottles)
  
2. Room of PET bottle preparation
  - Area of "preforms" storage
  - Area of blowing
  
3. Bottling room - PET bottles
  
4. Storage room of raw materials for syrup
  
5. Mixing room
  
6. Pasteurization room
  
7. Packaging materials warehouse
  
8. Finished products warehouse

### **2.3. EQUIPMENT AND SYSTEMS**

All the equipment and systems which are in direct contact with the mineral water can be easily emptied, cleaned, disinfected and made of a material that does not modify the original product features (stainless steel).

#### List of equipment and systems

- Stainless steel decanting tanks
- Collection tanks
- Packaging machine for (0.5L) glass bottles
- Packaging machine for (1L) glass bottles
- Packaging machine for PET bottles
- 2 decraters
- 2 craters
- 2 glass bottles washers
- Preforms blowing machine
- Mixers
- Pasteurizer
- CO<sub>2</sub> reservoir
- Scales
- Nitrogen reservoir
- UV system

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#### ***2.4. MAINTENANCE OF THE EQUIPMENT***

The ordinary maintenance is done by the internal staff of the Company and consists of a periodic inspection of the proper machinery functioning.

The extraordinary maintenance is entrusted to external specialized staff that act in response to anomalies found in the machinery and equipment.



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*SECTION 3 – CORPORATE HYGIENE*

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### **3.1. PLAN OF SANITATION**

The aim of the plan of sanitation is to control the bacterial count and to eliminate the pathogenic micro-organisms that are a possible reason of the consumer diseases.

Sanitizing is the set of cleansing and disinfection procedures.

The key operations that are done sequentially on surfaces, machinery and tools are the following:

- rinse
- cleansing
- rinse
- disinfection
- rinse

1. The *rinse* removes the dirt and cleaning and/or disinfectant substances and must be done before the cleansing, before the disinfection and at the end of the sanitation.
2. The *cleansing* through water and cleaning substances removes the dirt and processing residues. It precedes the possible disinfection because an excess of dirt neutralizes the disinfectant action, allowing the microbes to survive.
3. The *disinfection* reduces the bacterial count and completely removes pathogens that are a possible reason of the consumer diseases.

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The effectiveness of the plan of sanitation is assessed through inspections and analytical tests (see Section 8 paragraph 8.5.).

The Company identifies someone who is responsible for the sanitation whose tasks are:

- define the process of sanitation of the plants, structures and machinery
- provide training to the operators involved in the sanitation operations
- verify the correct application of sanitation processes
- check the hygiene conditions after the sanitation and the good condition of maintenance of the structures and the plants.

<b>Person in charge for Sanitation</b>	Lorenzo Pesce
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### **3.2. SANITATION PROGRAM**

Surface	Product	Operating procedure	Operating frequency
Floors, plants		Removal of glass residues and labels	
Floors (glass dept.)	Soda Water	floor cleaning machine	Daily
Floors (PET dept.)	Water	Manual	Daily
Reservoirs, tanks, mixers, pipes in contact with soft drinks	Soda Water	Application for direct contact, rinse with water	At every change of soft drink

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Surface	Product	Operating procedure	Operating frequency
Glass bottles	Soda Water Dispersol 0.025% Deflok 4% on the liquid soda	Washing with hot water Immersion in soda baths at decreasing concentrations for 25' at a temperature of about 85°C Rinse with water	Before every use
PET bottles	Sanitizer OXONIL N Water	Pressure spray in the bottles head down with double treatment	Before every use
Pipes in contact with the mineral water	Sanitizer HERLISIL 846	Application in recycling by pumping	Every 6 months
External parts of plants and conveyor belts	Disinfectant cleaner with lubricating action LUBE ECO BT	Direct application, rinse with water	At the end of processing
Plastic crates for glass bottles	Hot water	Pressure spray	Before every use

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*SECTION 4 - PROTECTION FROM WEEDS*

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#### **4.1. GENERAL**

The defence against the infestation takes place by installing appropriate barriers to hinder the entry and the development of weeds as insects, mites, rodents, birds and to prepare a fighting program through the use of chemical, mechanical, physical means in order to suppress the weeds.

The company implements a fighting program against rodents through the use of rodents baits positioned in the highest risk points inside the premises. The monitoring of these baits is done by the internal staff every 15 days and the results are registered in the sheet C. The attached documents are the following:

1. planimetry of the premises with an indication of the points where the baits are placed
2. technical data sheet of the products used

The company identifies someone who is responsible for the disinfestation whose tasks are:

- prepare and manage the infestation monitoring system
- control the physical barriers against the infestation inside and outside the premises
- provides training to operators involved in monitoring and disinfestation operations.

<b>Person in charge</b>	Lorenzo Pesce
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*SECTION 5 - FOOD WASTE*



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### ***5.1. STORAGE AND DISPOSAL***

The processing residues are represented by fragments of glass, plastic, packaging and labels. These wastes are collected in some containers placed inside the plant from which they are removed with regularity in relation to the workload and at least once a day.

Glass and plastic are then collected in large containers placed outside the building from which they are taken periodically and disposed, after the filling in of the waste register, by specialized companies.

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*SECTION 6 – WATER SUPPLY*

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For the sanitation of the premises, machinery and equipment of the syrup room mineral water is used..

The water used is then drinking pursuant to the Italian Presidential Decree no. 236 dated May 24, 1988 concerning the characteristics of waters intended for human consumption.

For the management of the environments and the equipment, UV treated well water is used.

Periodically the microbiological characteristics verification is carried out by searching parameters laid down in the C3 type control of the Italian Presidential Decree above mentioned.

The bottling and the conveyor lines for PET and glass bottles are sanitized with the use of HERLISIL 846 and rinsed with UV treated well water and subsequently with mineral water.

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*SECTION 7 – PERSONNEL*

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### ***7.1. HYGIENE REQUIREMENT FOR THE PERSONNEL***

As provided by the laws in force (Italian Presidential Decree DPR 327/80), personnel working in the plant is in possession of the food safety inspection register to be valid for one year. The schedule of due dates of the validity of each employee is followed by HACCP manager.

A personal metal cabinet is assigned to each employee. This cabinet has two compartments to hold separate street clothes from work uniform.

Changing rooms and toilets for the staff are equipped with the facilities and the products necessary to ensure the hygiene of the hands and the forearms. In particular there are sinks with a dispenser of antibacterial liquid soap and a hot air dryer

During the work the staff wears a uniform made up:

- \* Suits (for men)
- \* Overall (for women)
- \* Non-slip footwear
- \* Personal protective equipment (gloves, headphones, goggles)

### ***7.2. TRAINING***

All the personnel is well informed about the hygienic-sanitary laws and on the risks associated with the work process and it is properly trained to perform the duties in compliance with the requirements of hygienic provisions.

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*SECTION 8 – SELF-CONTROL PROGRAM*

	<b>SELF-CONTROL PROGRAM</b>	
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The study is performed using the principles of the HACCP method as provided by Italian Legislative Decree No. 155/97 and the steps are the following:

- 1. DESCRIPTION OF THE PRODUCTS*
- 2. DESCRIPTION OF THE ACTIVITY STEPS*
- 3. DEVELOPMENT OF THE FLOW CHART*
- 4. FILLING IN OF THE CHECKLIST*
- 5. CHECK*
- 6. REVIEW OF THE HACCP*
- 7. DOCUMENTS*

	<b>SELF-CONTROL PROGRAM</b>	
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**8.1. DESCRIPTION OF THE PRODUCTS**

<i>PRODUCT</i>	<i>INGREDIENTS</i>	<i>PACKAGING</i>
Natural mineral water		Glass bottles, 0.25L Glass bottles, 0.50L Glass bottles, 1L Glass bottles, 0.75L PET bottles, 0.50L PET bottles, 1.5L and 1L
Sparkling natural mineral water	Natural mineral water CO <sub>2</sub>	Glass bottles, 0.25L Glass bottles, 0.50L Glass bottles, 1L Glass bottles, 0.75L PET bottles, 0.50L PET bottles, 1.5L and 1L



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Sparkling or still soft drinks	Natural mineral water CO <sub>2</sub> (if sparkling beverage) Granulated sugar Concentrated juices Food additives Flavourings	Glass bottles, 1L PET bottles, 1.5L and 1L PET bottles, 0.50L
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## **8.2. DESCRIPTION OF THE ACTIVITY STEPS**

### Collection

From the springs, the mineral water is collected in stainless steel pipes and transported to the decanting tanks from which it is conveyed to the collection tanks located inside the plant.

### Preparation of the glass bottle

The glass bottles are returned empty by the carriers in plastic crates. Upon the entry into plant, the crates are emptied by special decrater and sent by conveyor belts to the washing machine.

The bottles are transported on conveyor belts in a special washing machine from which they are cleaned and disinfected.

During the transport to the filling machine, the bottles pass through an electronic inspection unit which through a system of photocells, cameras and sensors is able to highlight the possible presence of foreign bodies, to verify the integrity of the bottle and the possible presence of residual liquid inside. Then they are checked by the operators

### Preparation of the plastic bottle

The plastic bottles are purchased as a "preform" (pre-mould) that when used are heated in their molds and blown with filtered air.

Any deformed bottles are automatically rejected by the blowing machine.

The normal bottles are immediately sent to filling machine.

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### Preparation of the soft drinks

The ingredients of various soft drinks (sugar, concentrated juice, flavouring additives, mineral water) are metered and mixed into the mixer.

The mixture is then filtered and transferred to the pasteurizer.

### Packaging

The natural mineral water from the collecting tank is conveyed to the filling machine and bottled.

Carbon dioxide gas taken from a special storage tank has been dissolved in the mineral water and soft drinks before being bottled.

Then the bottles are immediately closed with a crown cap, labelled and transported to the case packer where they are placed in plastic crates.

PET bottles are closed with a screw cap, labelled and transported to the bundling machine where they are wrapped in packs of 12 pieces, using a shrink plastic film.

### Storage

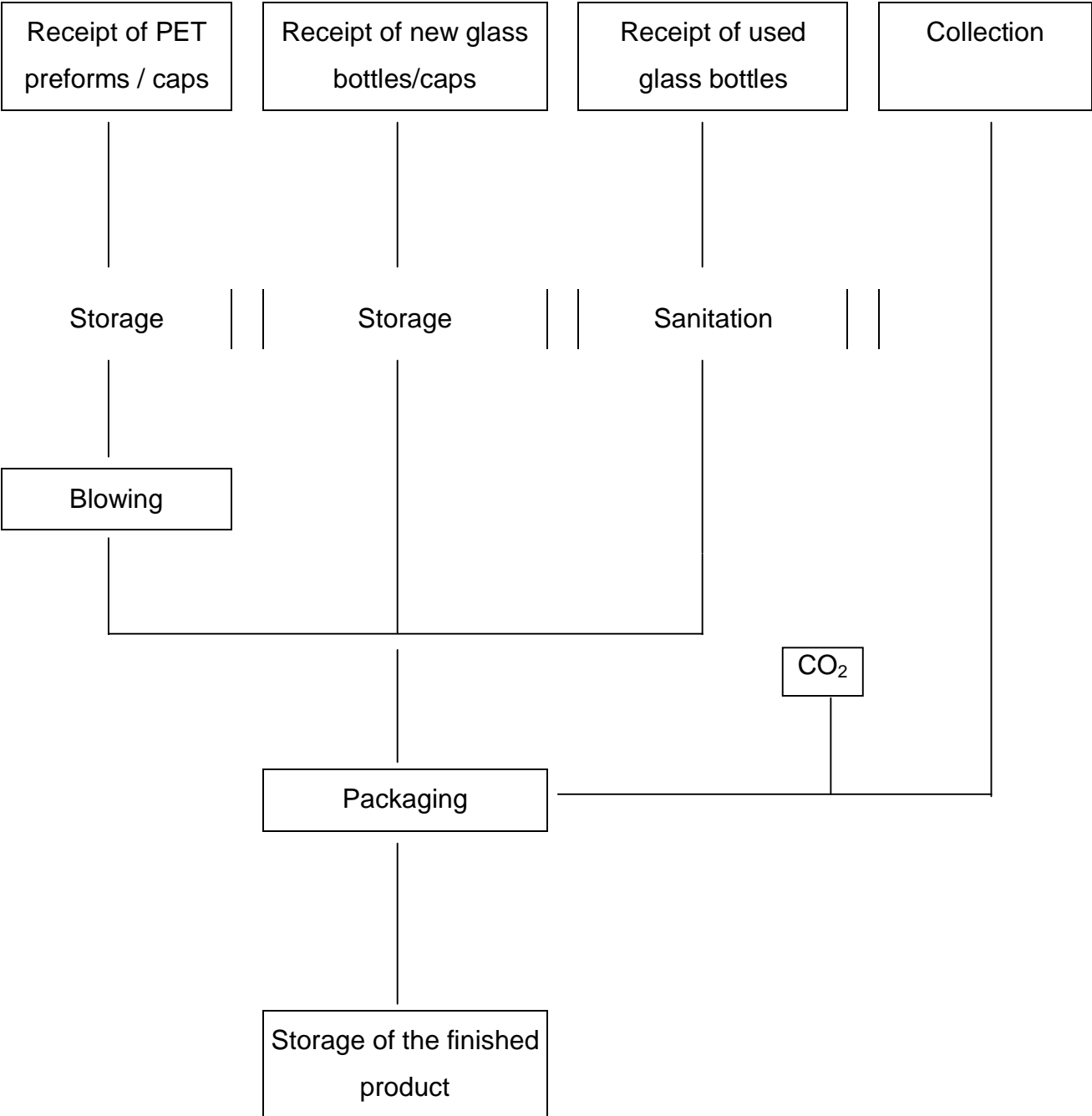
The crates and the plastic bottles already packaged are placed on the pallets in the warehouse.

The storage of the product is carried out according to the "first in, first out" logic in such a way that the older packaging are distributed before thus guaranteeing a correct stocks rotation.

# SELF-CONTROL PROGRAM

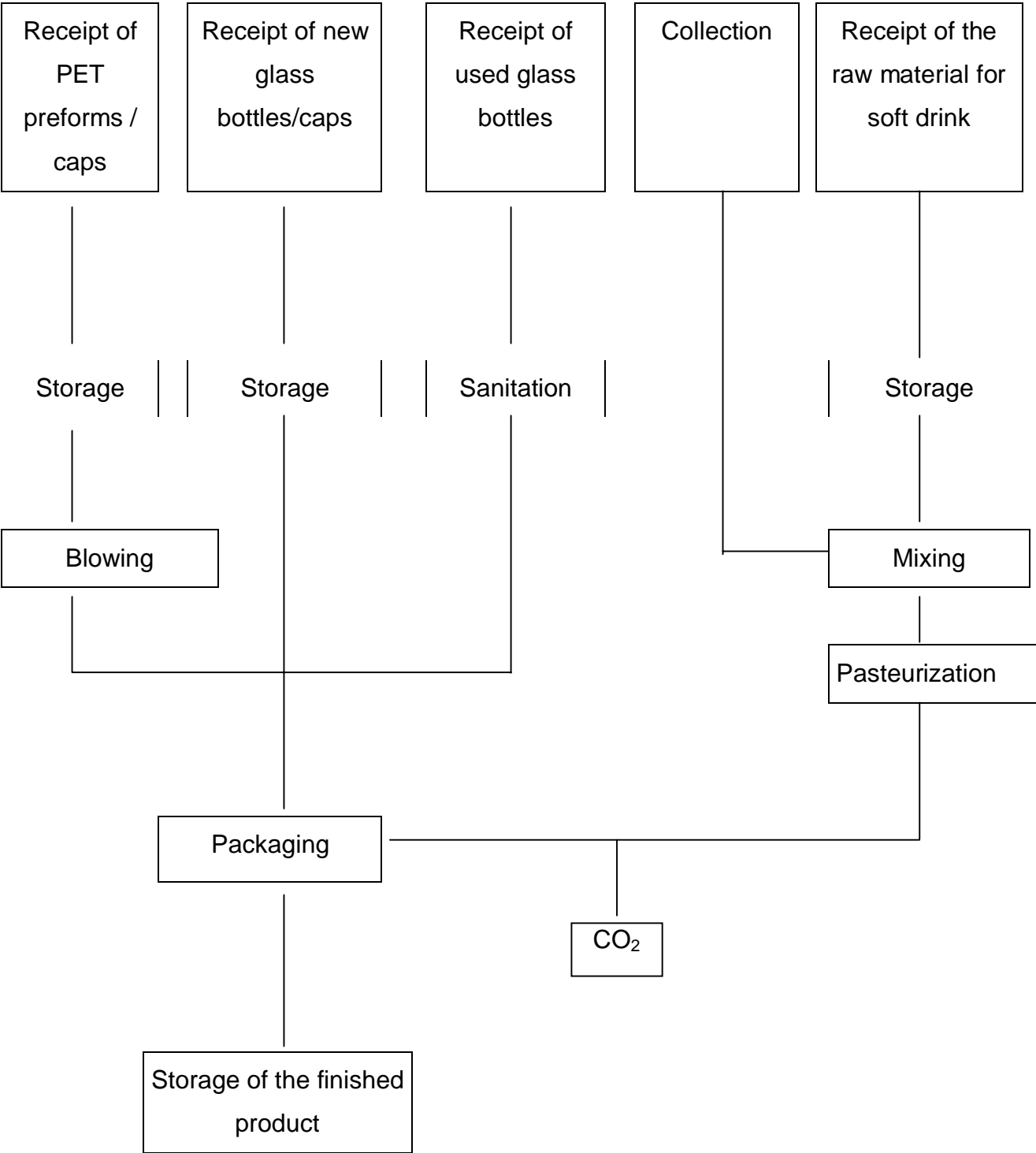
## 8.3. DEVELOPMENT OF THE FLOW CHART

### NATURAL MINERAL WATER



# SELF-CONTROL PROGRAM

CARBONATED SOFT DRINKS (if no carbonated, CO2 is not added)



	<b>SELF-CONTROL PROGRAM</b>	
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#### ***8.4. FILLING IN OF THE CHECKLIST***

For each stage of the flow chart have been

1. identified the physical, chemical and microbiological hazards;
2. established the critical control points (CCP) through the decision tree here attached;
3. set out the preventive measures, the monitoring and the corrective actions.

The above is shown on the following checklist.

## SELF-CONTROL PROGRAM

STEP	CCP	HAZARD	PREVENTIVE MEASURES	MONITORING	CORRECTIVE ACTIONS
<b>COLLECTION</b>	CCP	Contamination by chemical, physical and microbiological agents	Works that ensure a safe collection  Check of the activities taking place within the safety perimeter	Visual check  Periodic bacteriological analysis.	Temporary interruption of the use  Strengthening of the spring protection  Removal of the contamination causes
<b>STORAGE IN TANKS</b>		Contamination by chemical and microbiological agents	Correct sanitization procedures	Visual check  Periodic bacteriological analysis.	Emptying and sanitizing
<b>RECEIPT OF NEW GLASS BOTTLES, PET PREFORMS, CAPS AND RAW MATERIALS FOR SOFT DRINKS</b>		Unsuitable products and/or products not correspond to the specific request  Products in poor hygienic conditions	Procedure for the supplier referencing	Visual check (sheet A)	Reject the supply
<b>STORAGE OF NEW GLASS BOTTLES, PET PREFORMS AND CAPS</b>		Contamination and/or alteration of the bottles characteristics/closing devices	Correct storage procedures  Storage facilities hygiene	Visual check	Product disposal  Restoring of the best conditions  Change of the storage procedure  Staff training

## SELF-CONTROL PROGRAM

STEP	CCP	HAZARD	PREVENTIVE MEASURES	MONITORING	CORRECTIVE ACTIONS
<b>CLEANING GLASS BOTTLES</b>	CCP	Bottle not properly sanitized Chemical contamination by products residues used during washing Presence of foreign bodies	Appropriate sanitation procedures	Check via electronic inspection the proper cleaning of the bottles Visual check	Repeat the sanitizing procedures
<b>PREPARATION OF PET BOTTLES</b>		Contamination by foreign bodies Unsuitable bottles	Hygiene of the equipment Correct working procedures	Visual check	Products not used Change of the processing parameters
<b>RECEIPT OF RAW MATERIALS FOR DRINKS</b>		Raw materials of poor quality and/or does not correspond to specific requests	Supplier qualification	Visual check of the supplies	Return the goods
<b>SYRUP PREPARATION</b>		Biological, physical and chemical, contamination	Hygiene of the premises or of the equipment	Visual check	Restoring of the best conditions Staff training



## SELF-CONTROL PROGRAM

STEP	CCP	HAZARD	PREVENTIVE MEASURES	MONITORING	CORRECTIVE ACTIONS
<b>PASTEURIZATION</b>		Survival of microbes	Compliance with the pasteurisation times/temperatures	Time/temperature recording	Extension of the pasteurization times
<b>PACKAGING</b>	CCP	Contamination by chemical, physical and microbiological agents	Use of suitable systems, bottles and closing devices Proper sanitation procedures of the systems and the bottles	Visual check	Product disposal Restoring of the best conditions
<b>STORAGE OF THE PACKAGED PRODUCTS</b>		Alteration of organoleptic properties (smell, taste, appearance) due to the external causes	Storage rooms suitable Correct storage procedures (rotation of stocks)	Visual check	Removal of non-compliant lots Change of the storage procedure

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### **8.5. CHECK**

The purpose is to verify the correct, complete and documented implementation of the plan.

This activity provides:

1. Checks of documentation

2. Inspections/Audits of sanitation and disinfection. The persons in charge of the monitoring carried out, with an agreed frequency, checks of the general hygiene status of the premises, filling their monitoring sheets (sheets B and C).

3. Analytical tests

The following analytical tests are planned:

- verification of the effectiveness of the sanitation equipment and the plants through the direct application to the surfaces of pads suitable for the determination of total bacterial count.
- verification of the effectiveness of the system for the bottle sanitization by means of rinsing with physiological solution which then is analyzed for the determination of the total bacterial count at 30°C.
- verification of the microbiological characteristics of the water used in sanitizing procedures.
- chemical and microbiological tests on mineral water at source and the packaging and on beverage.

The frequency and the sampling parameters are attached here.

The certificates of the tests carried out are filed in the Self-Control Log.

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### **8.6. REVIEW OF THE PROGRAM**

The Company will prepare a review of the Program and of all modes of prevention and control introduced on an annual basis.

In addition, the Program reviews are foreseen in case of changes to the production processes and/or structures.

### **8.7. DOCUMENTS**

The documents consist of the monitoring records. Such records are collected in the Self-Control Log.

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*SECTION 9 - REFERENCE STANDARDS*

	<b>SELF-CONTROL PROGRAM</b>	
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The reference standard for the definition and implementation of Self-Control Program described in this manual is as follows:

- Italian Legislative Decree no. 155 dated May 26, 1997 - "Implementation of the Directive 96/43/EEC and Directive 96/3/EEC on the hygiene of foodstuffs".
- Regulation (EC) No. 852/2004.

In preparing this Program, some existing vertical standards for the mineral water sector have been taken into account:

- Italian Legislative Decree no. 105 dated January 25, 1992 "Implementation of the Directive 80/777/EEC on the exploitation and marketing of natural mineral waters".

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*SECTION 10 - ANNEXES*

	<b>SELF-CONTROL PROGRAM</b>	
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This section contains the following annexes:

- Decision Tree;
- Analysis Schedule;
- Planimetry of the Premises;
- Safety Data Sheet of the Pest Control (Rat Control) Products.





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*SECTION 12- TRACEABILITY OF THE PRODUCTS AND  
THE RAW MATERIALS*

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*SECTION 13 - DESCRIPTION OF THE ANALYSES*

## SELF-CONTROL PROGRAM

Whenever a check is made on Water from the springs or from the chain of production, a 3000 ml sample collected in sterile glass bottles is used. The storage temperature of each sample before the beginning of the analysis must be between 3° and 5°C (4°C ± 1°C).

Bacteriological analyses are normally carried out within 12h of collection.

In the case of analyses carried out in of the trade samples preserved in a warehouse, the date of production and the date of analysis is shown on the analysis sheet in order to verify the performance of cfu/ml bacterial counts over time inside of the respective containers.

The parameters and the methods used are those described in Italian Legislative Decree 176 dated November 8, 2011 (such as Implementation of the Directive 2009/54/EC) and in the Italian Decree dated February 10, 2015 (Italian Official Journal Rep.It. S.G. no. 50 dated February 3, 2015). The methods of analysis are set out below.

### **DETERMINATION OF THE TOTAL BACTERIAL COUNT (TBC) (UNI EN ISO 6222)**

For each sample are carried out, each time in duplicate, with the aseptic technique on 4 plates of Tryptic Soy Agar (or alternatively on Plate Count Agar) with 0.5ml undiluted water.

Two of the plates are successively incubated in a thermostated oven at 37°C ± 1°C for 24h ± 2h and the other two at 20°C ± 1°C for 72h ± 2h.

At the end of the incubation period, on each pair of plates the counts are performed and the results are registered on a sheet verifying that for the spring waters the limits of 5 cfu/ml at 37°C and 20 cfu/ml at 20°C are not exceeded.

For samples taken from the bottling machine, maintained at 4°C ± 1°C and examined within 12h, the limits which is considered not to be exceeded will be of 20cfu/ml at 37°C/24h and 100cfu/ml/20°C/72h respectively.

For the samples ready for the commercialization and taken to the routine bacteriological test it was decided not to set limits, such as envisaged by the current laws (Italian Legislative Decree no. 176 Art.9/5a and Directive 2009/54/EC Art.5/3).

In fact, since during this phase .... "the saprophytic microbial count of the mineral water may show large and unavoidable variations due to several factors such as the chemical composition of the water, the duration and the temperature of the storage, the type of the container, etc., it is not possible to establish strict limits for such parameters, while taking into account that, in principle, the highest values reach levels of 10E4 cfu/ml for the water without the addition of CO<sub>2</sub> and of 10E3 cfu/ml for the waters with the addition of CO<sub>2</sub>" (MINISAN circ. no. 17 dated September 13, 1991)

The values obtained from the analyses of the TBC on the samples examined are still regularly recorded on the Sheet R as merely indicative on further study to be carry out on the production controls.

## SELF-CONTROL PROGRAM

### DETECTION of COLIFORMS and E.Coli (UNI EN ISO 9308-1)

For the detection of total Coliforms using the MF method, **two** aliquots of each sample are filtered through 0,45u membrane filters.

The two membrane filters are then placed respectively on plates of **Tergitol 7 lactose Agar (AT7)** which are subsequently incubated at  $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$  in a thermostated oven for  $24\text{h} \pm 2\text{h}$ .

If on the Agar AT7 plates, yellow colonies are present, these are picked up and are seeded in tubes of Brilliant Green Bile Lactose Broth containing Durham tubes for the collection of metabolic gases.

These tubes are incubated for  $48\text{h} \pm 2\text{h}$  in a thermostated oven at  $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ .

From the positive tubes, seeding is carried out on MacConkey Agar plates.

For the detection of Fecal Coliforms and Escherichia coli using the MF method, **two** aliquots of each sample are filtered through 0,45u membrane filters.

The two membrane filters are then placed respectively on plates of **Tergitol 7 lactose Agar added with Triphenyl tetrazolium chloride (AT7+TTC)** which are subsequently incubated at  $44^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  in a thermostated oven for  $24\text{h} \pm 2\text{h}$ .

If on the Agar AT7+ TTC plates, yellow or yellow-red colonies are present, these are picked up and are seeded in tubes of Brilliant Green Bile Lactose Broth containing Durham tubes for the collection of metabolic gases .

These tubes are incubated for  $48\text{h} \pm 2\text{h}$  in a thermostated oven at  $44^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ .

From the positive tubes, seeding is carried out on MacConkey Agar plates,

From all the positive cultures isolated from the MacConkey Agar plates biochemical confirmation tests are performed (H<sub>2</sub>S, Indole, ornithine, and lysine decarboxylase, fermentation and use of carbohydrates, etc.) on ROCHE or API 20 systems for Enterobacteriaceae.

### DETECTION of FECAL STREPTOCOCCUS (UNI EN ISO 7899-2)

For the detection of the Fecal Streptococci (or Enterococci) using the MF method, **two** aliquots of each sample are filtered through 0,45u membrane filters. The two membrane filters are then placed respectively on plates of **Slanetz Streptococcus Agar (KF)** which are subsequently incubated at  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  in a thermostated oven.

In of the KFstreptococcus agar plates suspicious red colonies are present, these are picked up and are seeded on Bile Esculin Agar-Azide plates. These plates are incubated for  $44\text{h} \pm 4\text{h}$  in a thermostated oven at  $44^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ .

The negative black colonies grown on Bile Esculin Agar-Azide are confirmed as positive for Fecal Streptococcus.

### DETECTION of SULPHITE-REDUCING CLOSTRIDIA (UNI EN ISO 26461-2)

50 ml of each sample are heated to  $80^{\circ}\text{C}$  for 10 minutes.

Once cooled, the samples are filtered on 0.45u Millipore membrane filters.

The membranes are then collected and placed on SPS Agar plates and covered with SPS Agar melted and cooled to  $44^{\circ}\text{C}$ .

Once solidified, the SPS plates are incubated at  $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$  for  $24\text{h} \pm 1\text{h}$  in anaerobic jar.

	<b>SELF-CONTROL PROGRAM</b>	
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The alleged identification of *Clostridium perfringens* or its spores is determined by the development of black colonies.

These colonies are picked and seeded in tubes of thioglycollate broth previously heated to 100°C for 10 minutes and rapidly cooled. The tubes are then incubated at 37°C±1°C for 24h±1h.

After the incubation time, subcultures are performed in nutrient agar slant and in tubes with Litmus Milk covered with 2ml of sterile vaseline.

Both subcultures performed at 37°C/24h are used: the first one (anaerobic) to verify the Catalase-negative, the second one to check the acidification of the milk and the formation of fragmented clot.

**DETECTION of STAPHYLOCOCCUS AUREUS (UNI EN ISO 6888)**

The detection is carried out on a 250ml aliquot of the sample filtered on 0.45u Millipore membrane and subsequent incubated on Baird Parker Agar in thermostated oven at 37°C ± 1°C for 24h ± 1h.

Suspect colonies appear black with a halo, they must be subcultured in Brain Heart Infusion Broth and submitted to the rabbit plasma Coagulase test for confirmation.

**DETECTION of PSEUDOMONAS AERUGINOSA (UNI EN ISO 16266)**

Even this detection is carried out on 250 ml of the sample filtered on 0.45u Millipore membrane, and subsequent positioning of the membrane on Cetrimide Agar and incubation in the thermostatic oven at 37°C ± 1°C for 48h ± 2h.

The green-bluish and/or UVR fluorescent colonies are transferred through a Nutrient Agar slant and after incubated at 42°C ± 0.5°C for 48h ± 2h.

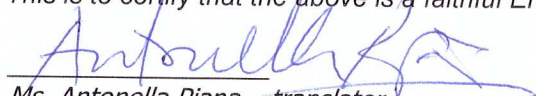
From the colonies grown therein, the Dimethyl-p-phenylenediamine oxidase test is made. If positive, the appropriate differential biochemical tests on API 20NE for Pseudomonas are performed.

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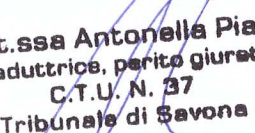
**TO WHOM IT MAY CONCERN**

*This is to certify that the above is a faithful English translation of Italian text.*



*Ms. Antonella Piana – translator*

*Sworn Translator No. 37 – Court of Law in Savona – Italy*



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