# EW 1

## Automated endoscope reprocessor (AER)

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**Steelco EW 1 has been developed to be compliant with the standard UNI EN ISO 15883-4 and UNI EN ISO 14937.**

EW 1 is an automatic device for the reprocessing of one (1) flexible endoscope or up to two (2) video-broncho/cystoscopes or up to four (4) single-channel fiber broncho/cystoscopes of the major brands.

It also allows the reprocessing of rigid endoscopes with dedicated washing carts.

EW 1 has been validated for low temperature high level disinfection and liquid sterilization processes and it can perform the thermal self-disinfection, as recommended by the standard UNI EN ISO 15883-4.

Highest flexibility is granted by the compact design, which assures low cycle costs reducing consumption of water, chemicals and energy.

### *Models*

The AER is available as **single door** or **double door** pass through versions.

EW 1 is also available in a *Rack* configuration having two units installed one on top of the other in a unique frame structure, in order to exploit small spaces and enable the asynchronous treatment of two endoscopes.

The *Rack* configuration is available both with single and double door.

### *Specifications*

**Single unit dimensions**

External dimensions
Single door: 600 mm x 630 mm x 945 mm
Double door: 710 mm x 570 mm x 1206 mm

Washing chamber
415 mm x 480 mm x 375 mm

Loading height
Single door: 683 mm
Double door: 950 mm

Door passage
415 mm x 260 mm

**Rack configuration dimensions**

External dimensions
Single door: 750 mm x 690 mm x 1643 mm
Double door: 860 mm x 570 mm x 1663 mm

Washing chamber
415 mm x 480 mm x 375 mm

Loading height
Single door – lower chamber – 712 mm
Single door – upper chamber – 1322 mm
Double door – lower chamber – 720 mm
Double door – upper chamber – 1350 mm

Door passage
415 mm x 260 mm



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**Water consumption**

6 liters per chamber fill

**Sound level**

< 60 dB

## *Certifications*

EW 1 is classified class IIb, according to rule 15 of Annex IX, 93/42/EEC Medical Device Directive.

EW 1 is compliant with the standard EN ISO 15883 parts 1, 4 and 5.

EW 1 is compliant with the standard EN ISO 14937.

## *Construction*

**Exterior**

- Main frame made of stainless steel AISI 304 (DIN 1.4301).
- Panels made of AISI 304 MS2 finish.

**Hinged Door**

- Stainless steel frame hinged door.
- The glass door grants total visual monitoring of the process and it is realized with a double HST (High Shock Tested) tempered glass.
- Interlocked doors in case of double door version.

**Washing Chamber**

- Constructed using AISI 316L BA Ra < 30µin (Ra < 0.8µm).
- Designed and constructed with smooth edges and corners to allow the total chamber draining at the end of the cycle and to avoid areas where dirt can accumulate and allow bacterial growth.

**Components**

- Manufactured using stainless steel and other materials which are resistant against the effects of aggressive detergents.

**Insulation**

- High performance melamine insulation guards for thermal and acoustic insulation.

## *Standard features*

**Loading/unloading doors**

- Door locking system during cycle execution to guarantee operator safety and to prevent any interference with the washing cycle.
- The double door model is equipped with an automatic interlock system to keep the dirty/ clean areas separate.
- Open doors also work as a stand for the washing cart during loading and/or unloading operations and as an anti-dripping surface, thus helping keep the floor dry, clean and safe.

**Endoscope loading and connection to the AER**

Steelco EW 1 is equipped with a removable washing cart made of stainless steel, with guiding rails to ease its pull-out and allow the ergonomic load of one big size flexible endoscope. Such washing cart can be similarly pulled out from the opposite side in double door versions at the end of the cycle.

**Washing system**

- Washing circuits with two (2) dedicated pumps:
  - For the washing arms placed on the top and on the bottom of the washing chamber. They are set to grant an efficient dynamic washing flow which allows a thorough endoscope cleaning.
  - For the basket connection and endoscope channels.
- Spray arms, made of AISI 316L stainless steel, which can be easily disassembled for cleaning and maintenance operations.
- The drain system grants the complete emptying of the washing chamber and the hydraulic circuit.

**Water connections and filtration**

- Two (2) water line connections available for softened cold/mixed and demineralized water.
- Water line is equipped with two (2) flowmeters for the control and validation of water quantity introduced in the chamber.
- Water filtration system through a sequence of two filters (one 0.45 µm and one 0.1 µm filter).
- The dual stage water filtration system not only ensures the presence of a microbiologically adequate final rinse water, but it also filters and ensures the high quality of all the water used in the disinfection phase.
- Filters are automatically decontaminated during the thermal self-disinfection.



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**Channels treatment and monitoring**

- The channels treatment is guaranteed by a dedicated pump, a flow sensor and a pressure transducer for the water circulation control.
- Endoscope channels flow and pressure are monitored during the whole cycle.
- Automatic stop of the cycle in case of alarm and automatic rinse (single or double) to remove chemical product residuals, when needed.

**Channels purging/drying system**

- Endoscope channels are purged through 0.2 µm filtered compressed air (built-in air compressor).
- Alternatively, the machine can also be directly connected to external medical grade quality compressed air (air compressor not available).
- An additional setup for the connection to external medical grade quality compressed air is available as an option. In this case, built-in air compressor and connection for external compressed air are both available, but the default functioning will be with built-in air compressor.
- A forced heated air-drying system is available as an option for the elimination of residual humidity inside the washing chamber and on the external surfaces of the endoscope.

**Leakage test**

- The leak test verifies the instruments suitability to be treated into the AER preventing possible problems before they can cause damages.
- Leak test check is active during the whole cycle with automatic cycle stop in case of anomalies.

**Washing chamber heating elements**

- 2.5 kW electrical heating element in the sump of the washing chamber
- Two (2) independent temperature probes (PT 1000) in the washing chamber
- Additional PT1000 probe to check the inlet water temperature and the temperature during the heating phase.

**Chemical dosing system**

**The correct dosing quantity is essential for trust-worthy disinfection results.**

- Three (3) automatic membrane dosing pumps precisely add liquid chemical agents.
- Volumetric control of the dosed chemicals by double, high-accuracy flowmeters to control and validate the disinfectant and detergent quantity.

**Chemical storage**

**The endoscope washer EW 1 allows the storage of chemical tanks inside its frame.**

- Capacity of up to four (4) tanks equipped with protective caps to avoid any vapors emission.
- Collection tank in case of chemical leakages.
- The feeding system is equipped with low level sensors.

**Drain pump**

## *Control System*

The control system allows the definition and the memorization of customized programs dedicated to the treatment of each single instrument according to the chemical products used.

- Three (3) electrical boards: one (1) master and two (2) slaves.
- Standard pre-memorized programs certified by microbiological hygienic reports carried out by certified laboratories.
- All different programs can be selected from the control panel. Cycle start is possible only after the operator recognition.

**System control panel**

- Soft touch control system on glass panel.
- A 3,5" graphic color LCD display constantly informs the operator about the machine status: cycle phase, time left, chamber temperature, chemical and water quantities. The system registers all the sensible parameters to print and archive them.
- At the end of the cycle, the system highlights the correct instruments reprocessing.
- Acoustic and visual alarms provide quality control for each wash cycle.
- Printer connection to monitor and validate the washing cycles.
- USB port on frontal panel for cycle data, machine parameters and washing programs download. It also allows easy firmware update.
- Optional Ethernet RJ 45 connection via gateway for supervisor SW connection.

## *Process traceability*

The identification of each single endoscope ensures that the cycle control information is closely related to the single instrument, thus granting its complete traceability.

**EW 1 prints a final report for each cycle with:**

- AER serial number identification
- ID of the instruments
- ID of the operator

It also reports all the process parameters as:

- Cycle time



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- Water consumption
- Chemical products dosing
- Phase details
- Events

At the end, the cycle status is pointed out (pass/fail).

**Built-in printer**

Built-in printer for validating washing phases with detailed information

## *Reprocessing cycles*

**EW 1 is compatible and has been validated for low temperature high level disinfection (35°C) and liquid sterilization processes.**

By using Steelco chemical products, EW 1 grants instruments maximum safety conditions as well as **efficient results proven by microbiological tests** together with complete documentation.

**Validated high level disinfectant**

The validation has been performed by a certified European microbiological laboratory to attest the conformity to UNI EN ISO 15883-4.

**Validated liquid sterilant**

The validation has been performed by a certified European microbiological laboratory to attest the conformity to UNI EN ISO 14937.

**Self-disinfection cycles**

- The device performs the thermal self-disinfection cycle: 80°C/176°F washing phase as requested by the standard UNI EN ISO 15883-4.
- Completely automatic and programmable self-disinfection cycles.
- Self-disinfection of the hydraulic circuit and of the water filtration system.

## *Optional*

**Washing chamber forced warm air-drying system**

- A forced HEPA H14 filtered air drying system ensures the drying of the external surface of the endoscopes.
- 0.75 kW electric heating element.

**Extra heating elements**

4 kW heating element to be used where there is only cold water available (to reduce the total cycle time without the installation of boilers).

**Barcode reader**

For the recognition of operators and instruments.

**Stand on wheels (only for single door machine)**

**SteelcoData Live software**

Dedicated software for the traceability of all the information of the endoscope washing cycles.

**SteelcoData ARES software**

Dedicated software for the monitoring of the whole endoscope reprocessing system including the use, the manual prewashing, the automatic reprocessing, the storage, the service and all the waiting times between any of these phases.

**Light inside the chamber**

And others, please verify with your local distributor/ agent.

## *Accessories*

- Complete range of connectors for endoscopes brands and models.
- Duodenoscope dedicated reprocessing support.
- Steelco Process Challenge Device (PCD) kit for the control of the cleaning efficacy.
- Trolleys for the transport and short time storage of contaminated and/or disinfected endoscopes and accessories.

## *Required utilities*

For any connection detail, please refer to installation drawing of the selected model/version.

**Demineralized and softened cold/mixed water**

**Drain connection**

**Electrical requirements**

- The total power of the machine in the standard configuration is 3,05 kW.
- 230V 50Hz
- Other electrical connections are available to match electrical requirements of installation site.



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# User manual

COMPACT WASHER-DISINFECTOR-STERILIZER FOR ENDOSCOPE EQUIPMENT

# EW 1

**Serial N°:**

CE 0051

Miele Group Member

**Via Balegante, 27**
**31039 Riese Pio X (TV)**
**ITALY**

**Manufacturer:**

**STEELCO S.p.A.**
Via Balegante, 27
31039 Riese Pio X (TV)
ITALY

# CONTENTS

**Thank you for purchasing this appliance.**

**The installation, maintenance and operating instructions given in the following pages have been prepared to ensure the long life and good performance of the appliance.**

**Following the instructions carefully.**

**The appliance was designed and constructed using the latest technological innovations available.**
**Please take good care of it.**

**Your satisfaction is our best reward.**

**WARNING:**
**NON OBSERVANCE, EVEN IN PART, OF THE RULES INDICATED IN THIS MANUAL WILL CAUSE THE PRODUCT GUARANTEE TO BECOME INVALID AND RELIEVES THE MANUFACTURER OF ANY RESPONSIBILITY.**

**THE MANUAL CONTAINS ALL THE OPTIONALS THE MACHINE CAN BE EQUIPPED WITH.**

# 1. GENERAL RULES

## 1.1 Limits of manufacturer's liabili

The manufacturer shall not be held liable for failures or problems which arise due to tampering and/or incorrect applications and/or improper use of the machine.
The purchaser must comply with all instructions set forth in the user's manual, and he must in particular:

- Always work within the allowable limits for the use of the machine;
- Always carry out constant and diligent maintenance;
- Allow use of the machine by persons with proper skills and abilities for their role and purpose who have been properly trained and instructed;
- Use only manufacturer original spare parts.

Any modifications, adaptation or the like which may be made to machines which are subsequently placed on the market do not oblige the manufacturer to intervene on previously supplied machines, nor to consider the machine and the related user's manual lacking and inadequate.

The installation, maintenance and operating instructions given in the following pages have been prepared to ensure the long life and outstanding performance of the appliance.

For some especially demanding programming or maintenance operations, this manual serves as a memorandum of the main operations to be carried out.
Education on these topics can be obtained by attending training course held by the manufacturer.

The instructions in this manual do not replace but rather are in addition to employer requirements to adhere to current legislation on standards of prevention and safety.

The machine is guaranteed for 15 months as from the time of shipment.

## 1.2 Manual validity, contents and conservation

This manual reflects the state of the art at the moment of manufacture and delivery of the appliance and is valid for its entire life cycle.
The manufacturer is at clients' disposal for further information or to receive suggestions for making the manual more compliant with the needs for which it was prepared.
The translation of the contents into the client's language has been carefully prepared.
In order to prevent possible accidents to persons or property due to in correct translation of the instructions, the client must:

- Not perform operations or manoeuvres with the machine if there are any doubts or uncertainties about the operation to be performed;
- Ask technical service for clarification of the instruction.
- If lost, ask for a new copy from the manufacturer.

It is important to keep this instruction manual with the machine for future reference.
If the machine is sold or transferred, the manual must be handed over to the new owners or user in order for them to become acquainted with its functioning and the relative warnings.

**Read the warnings carefully before installing and using the machine.**

**This is a translation of the Italian text, which prevails in case of doubts.**

## 1.3 Regulations

The purpose of the warnings is to safeguard the user in compliance with following Regulations and “Technical Product Standards”:

**EUROPE:**

- 2006/42/CE (Machine directive);
- 93/42/EEC and s.m.i (Medical Devices Directive);
- 2014/35/EU (Low Voltage Directive);
- 2014/30/EU (EMC - Electromagnetic compatibility directive);
- 2014/68/EU (PED Directive);
- EN 61010-1 (Safety);
- EN 61010-2-040 (Safety);
- 2011/65/EC (RoHS II);
- 2012/19/EC (WEEE);

**and recognized international standards:**

- IEC 61000 (Electromagnetic compatibility);
- IEC 61326-1 (Electromagnetic compatibility);
- ISO 14971 (Medical devices risk analysis);
- ISO 15883-1 (General requirements, terms, definitions and tests);
- ISO 15883-4 (Requirements and tests for medical washer and disinfectors that carry out the chemical disinfection of flexible endoscopes);
- ISO/TS 15883-5 (Soil test – A soil test method to prove the effectiveness of cleaning activities);
- IEC 60529 (IP Grade);
- UNI EN ISO 14937 (Sterilization of healthcare products).

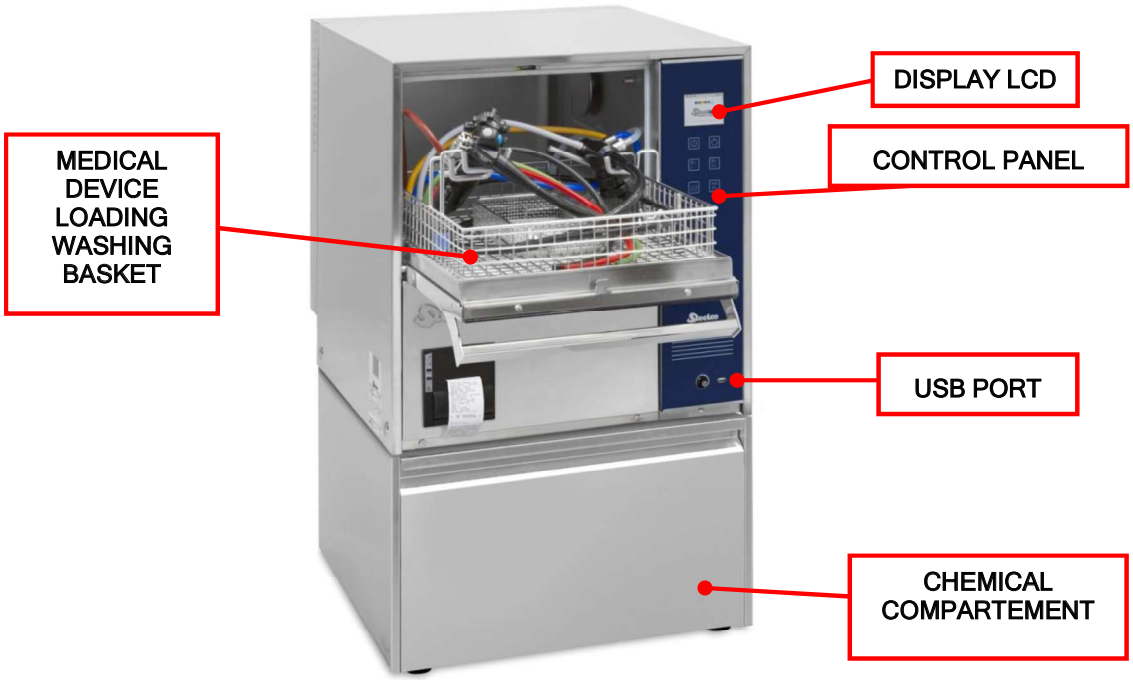
Steelco declares that this product, when it is equipped with a water steam version, is in accordance with PED 2014/68/UE directive art. 4 par. 3 and it has been designed and built in accordance with the correct building procedure.

# 2. SAFETY INFORMATION

Compliance with safety standards allow the operator to work productively and calmly, without the danger of harming himself or others.

Before starting work, the worker must be completely familiar with the functions and proper operation of the machine.
He must know the precise function of all command and control devices of the machine.

## 2.1 Machine components description




## 2.2 Intended use, improper use

**INTENDED USE:**

The use of this device is intended for washing, high level disinfection and/or sterilization of thermolabile endoscopes by using only chemical agents approved and validated by the device manufacturer.
This device is intended only and exclusively for the medical devices treatment.

### 2.2.1 Application fields

The use of this device is intended only and exclusively for the treatment of medical devices, such as:

- Flexible endoscopes
- Rigid endoscopes

## 2.2.2 Validated cycles

The cycles of high chemical disinfection and sterilization have been validated by the following chemical products:

| HIGH-LEVEL DISINFECTION CYCLES | CHEMICALS |
|---|---|
| HYDROGEN PEROXIDE | SteelcoXide-DT (detergent) |
| | SteelcoXide-A (component A) |
| | SteelcoXide-B (component B) |
| PERACETIC ACID | Neodisher SC (detergent) |
| | Neodisher Septo PAC (paracetic acid) |
| GLUTARALDEHYDE | Neodisher SC |
| | Neodisher Septo GDA |

| STERILISATION CYCLES | CHEMICALS |
|---|---|
| HYDROGEN PEROXIDE | SteelcoXide-DT (detergent) |
| | SteelcoXide-A (component A) |
| | SteelcoXide-B (component B) |

The improper use of this device is any use other than that for which the machine is intended.

The device has been validated to achieve high-level disinfection and liquid sterilization.

| WARNING |
|---|
| **Any use other than the one intended is forbidden.** |
| Improper use of this unit may be hazardous to the operator and may seriously damage the machine itself. |
| If the appliance is used in a manner not specified by the manufacturer, protection of the appliance may be compromised. |

## 2.3 Important warnings and suggestions

For proper use of the machine, and in order to safeguard employed staff, carefully comply with the following general and specific standards.

**THE OPERATOR MUST:**

- **Carefully adhere to the provisions and instructions** provided by the employer, managers and supervisors for individual and group safety.
- **Use safety devices appropriately and with care**, as well as group and individual safety gear provided by the employer.
- **Immediately inform the employer,** the manager and the supervisor of deficiencies in the aforementioned devices and means, as well as any hazardous conditions which he may become aware of, taking action directly in urgent cases within their scope of responsibilities and abilities to eliminate or reduce the deficiencies or hazards.

**THE OPERATOR MUST NEVER:**

- **Remove or modify, without authorization, the safety devices**, nor those for signalling and measuring, nor the individual and group safety gear.
- **Undertake on his own initiative operations or manoeuvres which are not his responsibility which** may compromise safety.
- **Insert foreign objects into the electrical parts.**
  Do not insert foreign bodies into the covers of the electrical motors or into the moving parts of the machine.
- **Provide power to the machine by tampering with the main switch and the safety devices.**

## 2.4 Safety recommendations

- If the new machine seems damaged, contact the retailer before using it.
- Any modification of electrical and hydraulic systems necessary to install the machine must be carried out by qualified, authorised persons only.
- This machine must be operated by trained persons only.
- This machine has been designed for the reprocessing of flexible and rigid endoscopes and the thermal disinfection of washing chambers;
- Any use other than that for which the machine was intended is forbidden.
- The user is forbidden to carry out any work or repairs on the machine.
- Technical Assistance for this machine should be carried out by qualified and authorised operators only.
- The equipment should be installed by authorised persons only.
- The electrical safety of machine is only guaranteed if it is connected to an efficient earth system.
- Take great care when handling detergents and additives: avoid contact, wear gloves, goggles and mask and act in compliance with the safety recommendations indicated by the manufacturer of the chemical products.
- Do not inhale the fumes produced by chemical products.

**WARNING: The chemical products are an irritant for the eyes, in case of contact rinse thoroughly with plenty of water and consult a doctor.**
**If these products come into contact to the skin, rinse with plenty of water.**

- The water in the tank is not drinking water.
- Do not lean on the door and do not use it as a step.
- Do not install the equipment in rooms where there is the risk of explosion (ATEX).
- Do not expose the equipment to intense cold.
- Do not wash the machine using high-pressure jets of water.
- The machine reaches a temperature of 80°C during the self-disinfection: take great care to avoid burns.
- Disconnect the machine from the electrical supply before carrying out maintenance work.
- The acoustic pressure of the machine is < 60 dB(A).
- The operator has always to verify before starting of the cycle the presence of the filters water in the sump and their correct positioning.

### 2.4.1 Inlet water

**Physical Properties**

| | |
|---|---|
| Min. flow pressure | 200 kPa (2,0 bar g) |
| Max. pressure | 300 kPa (3,0 bar g) |
| Max. temperature | 35° C |
| Max. hardness | 7° f (70 ppm CaCO3) |
| Max. conductivity / Ph: | n.a. / 5…8 pH |

**Chemical Properties**

| | | | |
|---|---|---|---|
| Heavy metal ions | Iron | min 0 mg/l (ppm) | max 2 mg/l (ppm) |
| | Manganese | min 0 mg/l (ppm) | max 2* mg/l (ppm) |
| | Copper | min 0 mg/l (ppm) | max 2* mg/l (ppm) |
| | Total heavy metal ions | min 0 mg/l (ppm) | max 10 mg/l (ppm) |
| Halides | Chloride | min 0 mg/l (ppm) | max 50 mg/l (ppm) |
| Others ionic contaminants | Phosphates ($P_2O_5$) | min 0 mg/l (ppm) | max 0,2 mg/l (ppm) |
| | Nitrates ($N_i$) | min 0 mg/l (ppm) | max 20* mg/l (ppm) |
| | Silicates ($S_iO_2$) | min 0 mg/l (ppm) | max 2 mg/l (ppm) |

**Microbiological parameters**

| Parameter | Parametric Value |
|---|---|
| Escherichia coli | 0/100 ml |
| Enterococci | 0/100 ml |
| Pseudomonas aeruginosa | 0/250 ml |
| Colony count 22 °C | 100 CFU/ml |
| Colony count 37 °C | 20 CFU/ml |
| Bacterial endotoxins | max 0,25 EU/ml |

## 2.4.2 Rinse water

### Physical Properties

| | |
|---|---|
| Min. flow pressure | 200 kPa (2,0 bar g) |
| Max. pressure | 300 kPa (3,0 bar g) |
| Max. temperature | 35° C max |
| Max. hardness | 1,5° f (15 ppm CaCO3) |
| Max. conductivity / Ph: | 30 µS/cm / 5…8 pH |

### Chemical Properties

| | | | |
|---|---|---|---|
| Heavy metal ions | Iron | min 0 mg/l (ppm) | max 0,2 mg/l (ppm) |
| | Manganese | min 0 mg/l (ppm) | max 0,2* mg/l (ppm) |
| | Copper | min 0 mg/l (ppm) | max 0,2* mg/l (ppm) |
| | Total heavy metal ions | min 0 mg/l (ppm) | max 10 mg/l (ppm) |
| Halides | Chloride | min 0 mg/l (ppm) | max 10 mg/l (ppm) |
| Others ionic contaminants | Phosphates ($P_2O_5$) | min 0 mg/l (ppm) | max 0,2 mg/l (ppm) |
| | Nitrates ($N_i$) | min 0 mg/l (ppm) | max 20* mg/l (ppm) |
| | Silicates ($S_iO_2$) | min 0 mg/l (ppm) | max 0,2 mg/l (ppm) |

### Microbiological parameters

| Parameter | Parametric Value |
|---|---|
| Escherichia coli | 0/100 ml |
| Enterococci | 0/100 ml |
| Pseudomonas aeruginosa | 0/100 ml |
| Mycobacterium Sp. | 0/100 ml |
| Colony count | < 10 CFU/100 ml |
| Bacterial endotoxins | max 0,25 EU/ml |

## 2.5 Recommendations to ensure high quality performance

- The user must oversee the machine during the cycle.
- The injection tube for washing water must always be connected to the appropriated basket.
- When the machine is running do not interrupt the cycle since this jeopardises disinfection.
- Check periodically the correct disinfection with final rinse water checks.
- Use recommended detergents and chemical additives only.
- The use of other products may damage the machine.
- The use of opportune PPEs is compulsory, in order to avoid contact with infected material and to prevent contamination during the handling procedures of medical devices to be reprocessed.
- The chemical products recommended by the manufacturer are those that have been certified and validated by ISO 15883:4, 15883:5-TS and ISO 14937 standard.
- Check that type of chemical product is suitable for the specific washing program used.
- Comply with the instructions provided by the chemical product manufacturer.
- The machine was designed for use with water and chemical additives.
  Do not use organic or other types of solvent as this may result in the risk of explosion or the rapid deterioration of certain machine parts.
- Residues of solvents or chloric acid can irreparably damage the machine.
- Contact should be avoided.
- Repairs and servicing of this machine must be carried out by authorised persons only.
- Do never use soap powder.
- Do never use foaming detergent.
- Use original accessories only.
- Under no circumstances should the user attempt to carry out repairs.
- The machine is to be used only with the accessories provided by the manufacturer.
- Accessories which are not approved by the manufacturer may compromise the results achieved as well as user safety.
- Do never use chemical products based on chlorides (bleaches, sodium hypochlorite, hydrochloric acid and so on).
- These kinds of chemical detergents irreparably damage the machine and jeopardise the integrity of materials and objects treated.
- Check at every cycle the integrity of the connexions used to connect the endoscopes.
- Wet location.
- Mains supply voltage fluctuations: +/- 10%.
- Overvoltage category: II.
- Pollution degree: 2.
- IP:00.

**ATTENTION:**

**The taps of the water must be always turned off, as the safety and diagnosis system will be deactivated, in the following situations:**

- **If the machine is left unused;**
- **If the machine is disconnected from the electrical connection.**

**The Manufacturer cannot be held responsible for damage or injury caused by failure to observe the above rules.**

**The non-observance of these rules produces the total and prompt cancellation of the guarantee.**

## 2.6 Residual risks

The appliance includes a series of fixed guards to prevent access to hazardous internal parts or zones.
It is however considered that the **EW 1** includes some residual risks.
Hereunder for each phase or significant work intervention are useful measures to be taken:

| PHASE | BASKET LOADING |
|---|---|
| RISK | **Contusions and cuts to the upper limbs,** due to accidental contact with due to falling or striking against tools, objects and instruments, mainly while loading and handling the basket. |
| MEASURE | Assign staff that is instructed and equipped with work equipment (e.g. basket with protections, transport carts) and appropriate clothing and individual protection gear (e.g. shirts and protective gloves). |

| PHASE | OBTAINING DETERGENTS/CHEMICAL ADDITIVES |
|---|---|
| RISK | **Contact with body parts with chemical washing products.** |
| MEASURE | Assign staff that is instructed and equipped with appropriate clothing and individual protection gear.<br>Wear clothing, gloves, goggles and mask and act in compliance with the safety recommendations indicated by the manufacturer of the chemical products. |
| **FIRST AID MEASURE** | • **Immediately take off/remove clothing which has been contaminated or soaked by the product.**<br>• **If the substances come into contact with the skin, wash off affected skin areas immediately and rinse with water.** |
| RISK | **Inhalation of vapours of chemical wash products.** |
| MEASURE | Assign staff that is instructed and equipped with appropriate clothing and individual protection gear.<br>Comply with the safety instructions provided by the manufacturer of the chemical products and if there are none, wear a mask for the protection of the respiratory airways. |
| RISK | **Accidental release of chemical wash product** |
| MEASURE | Do not flush concentrate into drains, surface or ground waters.<br>Collect spillage with adsorbent material (e.g. sand, earth, vermiculite, diatomaceous earth).<br>Flush away minor amounts with plenty of water. |
|  | **IN CASE OF CONTACT WITH BODY OR RELEASE OF CHEMICAL PRODUCT LOOK ALWAYS AT THE SAFETY MEASURES INDICATED IN THE CHEMICAL TECHNICAL DATASHEET.** |

| PHASE | MAINTENANCE OF INTERNAL EQUIPMENT |
|---|---|
| RISK | **Burns of body parts by hot parts of the appliance.** |
| MEASURE | Allow maintenance to be performed only by trained personnel, equipped with appropriate clothing and individual protection gear.<br>Wear suitable clothing and protective gloves. |

| PHASE | EMISSION OF HAZARDOUS GAS |
|---|---|
| RISK | **Inhalation of vapours of hazardous gas.** |
| MEASURE | With a correct installation, concurring with the manufacturer prescription, using the authorized chemical product and concurring with the rules in force in your country, the machine doesn't generate hazardous gas.<br>However, the machine is supplied with vapours discharge, that have to be connected concurring with the instruction in chapter 3. |

## 2.7 Safety signals used

To inform personnel operating on the machines of obligations of behaviour and residual risks, adequate safety signals (as set forth by 92/58 EEC) are applied to the machine and near the workplace.

***GENERIC SAFETY SIGNALS:***
In particular, labels with signals of obligation, prohibition and danger contained in this manual and pertinent to this machine and most commonly used are:

**Electrical risk**

**Warning!**
**See annex documentation**


**Caution hot surface**

***INDIVIDUAL SAFETY WEAR:***
The evaluation of risks for the health and safety of workers carried out in the workplace and on any equipment used, as well as the evaluation of residual risks as indicated, allow the employer to evaluate the need to adopt the individual protection gear which is most suitable and appropriate to be provided to workers.
Considering the type of machine, it is felt that the individual protection gear should be provided to staff.

# 2.8 Training

Instructions for use of the machine will be provided by the **STEELCO INSTALLATION TECHNICIAN** during the start-up phase to **MACHINE OPERATORS** and **MAINTENANCE TECHNICIANS** for their areas of responsibility, which will be thus instructed and trained. Moreover, an appropriate course certificate is issued (see Annex A).
It will be the duty of the **EMPLOYER** to check that the degree of staff training is suitable for assigned duties.

## 2.8.1 Staff qualification

Depending on the difficulty of certain installation operations, and of the operation and maintenance of the system, professional profiles are identified as follows:

***Is*** ***INSTALLATION and REPAIR TE CHNICIAN:***

Specialized installation and maintenance staff capable of carrying out all machine positioning and installation operations, connection of various systems and machine start-up at the client's place of business, as well as all routine and special maintenance operations.
This operator is responsible for training staff for machine operation and for testing the machine.

***As*** ***RESPONSIBLE AUTHORITY FOR THE MACHINE IN THE WORKPLACE:***

Specialized staff assigned to the verification of safety devices and procedures for proper use of the machine in complete absence or hazards.

The *responsible authority* is personally responsible for training courses for staff assigned to machine operation and maintenance.
He must ensure that staff assigned to operation has acquired all information required for use and routine maintenance of the machine, registering attendance and documenting comprehension tests.

The *responsible authority must* have a perfect understanding of all command, control and safety devices of the machine.
He must inform all personnel assigned to machine operation and maintenance of the instructions concerning *safety standards*, the *actions to be avoided* and the *first aid interventions* connected with use of the machine and the chemical wash agents it contains.

The *responsible authority* must be aware of all correct procedures for carrying out in absolute absence of danger all operation and maintenance of the machine, as well as all procedures for disposal of any residual pollutants and manufacturing wastes.
He must always be present during extraordinary or routine maintenance and give his *approval to proceed* to staff assigned to operation or to personnel assigned to routine or special maintenance.

The *responsible authority* will be responsible for operation of all command, control and safety devices in the machines of the system.
He shall carry out scheduled verification of those devices in order to ensure their continued operation over time.

***Ac*** ***MACHINE OPERATOR:***

Skilled personnel assigned to machine operation.
The *machine operator must* be perfectly aware of all of the machine's command and control devices.

Only after approval by the *safety supervisor, the machine operator* must be capable of using the assigned commands to do the following:

- Commissioning and start-up of the machine;
- Loading and unloading of material to be washed in the baskets;
- Operation of the machine in the various possible working modes, such as the start of various programmed wash cycles.
- Programming and setting data from the operator panel, adjustment of single control devices during working phases, starting or resetting of work functions.
- In addition, the *machine operator* must, by making use of all required individual protection gear and following adequate safety measures, be capable of performing some routine maintenance such as cleaning inside the machine, cleaning clogged filters, and disposing of pollutant waste materials produced during working.

## 2.9 Indication of sound level

The value shown refers to the measurement obtained on a machine of the same type as that covered herein and measured with an instrument at a height of 1,5 m at a distance of 1 m from the machine.

**AVERAGE SOUND PRESSURE LEVEL: < 60 dB (A)**

## 2.10 Transport and storage

**Environment conditions:**

- Temperature range +5 ... +50 °C;
- Relative Humidity range 20…90% without condensation;
- Ventilation: Air exchange not required (required only if chemical tanks are installed).

## 2.11 Chemical products connections

The chemical product dosing system consists of two different systems: one for aggressive chemical products (neutralizing detergent etc.) and another for disinfectants (peracetic acid, hydrogen peroxide, aldehydes):

- Dosing pump for chemical products.

- Presence sensor chemical product.

- The system can be equipped with meter quantity of dispensed product.

Further dosing pumps and accessories can be ordered as optional.
Each pump is combined with a corresponding type of chemical, according with the references on the table below.

| PERACETIC | | |
|---|---|---|
| PAA | DISINFECTANT | YELLOW |
| SC | DETERGENT | BLUE |
| 3rd | CHEMICAL | BLACK |

| PEROXIDE | | |
|---|---|---|
| XIDE B | YELLOW | DISINFECTANT |
| XIDE A | RED | DISINFECTANT |
| DT | BLUE | DETERGENT |

**ATTENTION**

**In order to guarantee the right treatment of the objects, we suggest the use of specific products. In the case of necessity, ask for advises to the seller or the producer.**

## 2.11.1 Presence sensor of chemical product

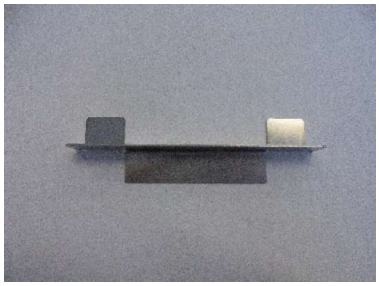
Each dosing pump is combined with a sensor that confirm the presence of chemical product inside the container. If the product is scarce, the electronic control system of the machine sends a message on video of lack of product.

## 2.11.2 Meter quantity of chemical product

Each individual pump is linked to two volumetric sensors in order to measure the quantity of chemical product dispensed. The dual PLC electronic control unit manages the value of the minimum quantity requested and, if necessary, it interrupts the cycle.

## 2.11.3 Container block

**Each container must be locked by the special bracket to ensure the correct data reading.**



## 2.11.34 Replacement of chemical product container

To replace the chemical product container perform the following procedure:

- Take the new product container.

- Open the chemical compartment.

- Replace the chemical product container removing the level sensor from the empty tank and put into the new one.

- Close the topper of the chemical product container and place it in the area for the storage of chemical substances.

- Close the chemical compartment.

| | ATTENTION |
|---|---|
|  | **The used chemical product can be dangerous if touched or inhaled. Before the use, read carefully the safety information supplied by the manufacturer of the chemical product and the label on the package.** |
| | **During the operations of replacement of chemical product container, use the appropriate tools for individual protection (chemical protective gloves, face masks for breathing, etc.).** |
| | **The access to the technical compartment, where are located the chemical product containers, is permitted only with keys and to the authorized personal.** |
| | **If the chemical tank is in the vacuum or overpressure condition (tank deformation) use the PPE before doing every operation.** |

If the machine gave an alarm for chemical lack (Error 17-Error 18), after the replacement of the canister, the machine automatically proposes a special cycle for the circuit filling and for the chamber rinsing.
This cycle called **CHEMICAL LOAD** has to be started imperatively after this alarm: it will be not possible to select other cycles until the machine have filled the detergent circuit.
At the end of this cycle the machine will return on stand-by status waiting for a new command.

**NB:** the chemical loading cycle will not be saved on the historical and will not be printed.

## 2.12 Ambient ventilation requirements

During the normal operation, the machine warms up itself dispersing heat and hot air increasing the humidity value; in the drying phase, these events increase. Therefore, in order to guarantee a comfortable environment with good temperature and humidity for the operator, it is necessary to prepare an air conditioning or air circulation system capable to balance the emissions reported in the installation plan.
The machines with drying system are equipped with an exhaust which can be connected to an external extraction system.
As for machines designed to use Glutaraldehyde, connect the exhaust air connection to an external air evacuation system or put the machine under an extraction hood.

# 2.13 Table of symbols

**Symbols installed on the machine:**

| | |
|---|---|
|  | Electrical risk |
|  | Warning - hot surface |
|  | Manufacturer |
|  | Manufacturing date |
|  | Attention! See the enclosed documentation for important warnings, such as warnings and precautions. |
|  | See instruction for use |
|  | Protective conductor terminal |
|  | EC Mark |
|  | WEEE waste disposal |
| MD | Medical device indication |
| REF | It indicates the catalogue number of manufacturer. |
| REP | Authorized Local Representative. |

# 3. USING THE MACHINE

## 3.1 Checks

Check the quantity of chemical additives present and replace if necessary, as described below:

- Obtain appropriate individual protection gear (gloves for protection from chemical substances, breathing protection masks, goggles etc.) and the new detergent container.
- Turn off the machine by pressing the OFF button.
- Follow the instruction on section 2.11.3.

**ATTENTION:**
**The chemical product which is used may be hazardous if touched or inhaled.**
**Prior to use, carefully read the safety information provided by the detergent supplier and the label applied to the package.**

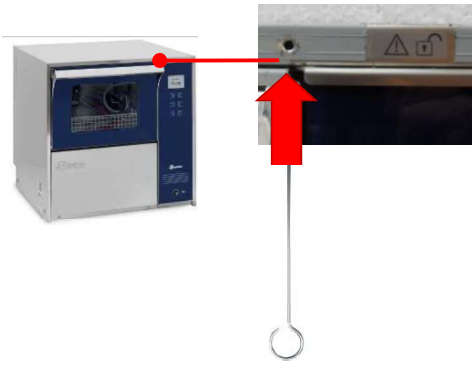
## 3.2 Opening and closing the door

- The machine is fitted with an electric door lock to prevent it being opened when the machine is running.
- To open the door during a wash cycle, interrupt the cycle and remember that:
  1. The items inside the machine may be very hot (**ONLY DURING THE SELF-DISINFECTION**).
  2. The objects inside the machine could be contaminated
  3. The entire wash cycle must be repeated.

### 3.2.1 Door unlocking

In case of power fail or malfunctioning of door lock, it is possible to unlock and open the door by follow the procedure:

1. Identify the hole between the door and the cover panel (see the picture).
2. Insert the dedicated instrument.
3. Keep pushing the dedicated instrument. In this moment the door is unlocked and it is possible to open it.
   To close the door, keep pushing the dedicate instrument as described on point 3.



| | ATTENTION |
|---|---|
| | **After performing the procedure described previously, remember that:**<br>• **The items inside the machine could be very hot and contaminated.**<br>• **The entire treatment cycle must be repeat.**<br>• **Material contaminated with peri acetic acid could be present inside the machine.** |

## 3.3 Switching on

Turn on the machine following the procedure:

- Press the ON-OFF switch as shown below:

- The control panel starts automatically.
- Check that no alarm messages are present. In negative case remove it.

## 3.4 Preparation of the endoscopes

In order to be correctly reprocessed inside the EW 1 system, the endoscopes must undergo pre-cleaning and manual washing procedures.
Follow the current applicable National Guideline instructions as well as any internal protocols in force.
Some of the main currently available Guidelines are specified below:

| COUNTRY | | GUIDELINES |
|---|---|---|
|  | **EUROPE** | *ESGE±ESGENA guideline: Cleaning and disinfection in gastrointestinal endoscopy Update 2008.* |
|  | **ITALY** | *ANOTE-ANIGEA - Linee guida Pulizia e disinfezione in endoscopia - Update 2011* |
|  | **FRANCE** | *Guide de Bonne Pratique de désinfection des dispositifs médicaux - obligatoire depuis le 14 juin 1998.*<br>*Conseil Supérieur d'Hygiène Publique de France, section prophylaxie des maladies transmissibles.*<br>*Comité Technique Nationale des Infections Nosocomiales.* |
|  | **IRELAND** | *PART 4: RECOMMENDED PRACTICES FOR ENDOSCOPY UNITS*<br>*Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices - Review date August 2008.* |
|  | **GERMANY** | *Recommendation of the Commission for Hospital Hygiene and Infection Pr evention at the Robert Koch Institute (RKI).*<br>*Hygiene Requirements for Reprocessing Flexible Endoscopes and Additional Endoscopic Instrumentation - Published in the Federal Health Gazette in April 2002.* |
|  | **GREAT BRITAIN** | *National Endoscopy Programme - Decontamination Standards for Flexible Endoscopes - Updated March 2009.* |
|  | **UNITED STATES** | *SGNA Society of Gastroenterology Nurses and Associates, Inc.*<br>*Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes - Revised in 2012.* |

### 3.4.1 Check of endoscope instrument connectors

Connectors for the endoscope instruments supplied with the EW 1 machine must be checked daily by machine users and periodically by technicians in charge of maintenance.
The use of not original Steelco connectors or worn connectors can damage the endoscope instruments, activate machine alarms (ex. “channels disconnected”, “channel partially clogged” etc.) and most of all does not guarantee a correct disinfection process, endangering both patients’ and sanitary personnel’s wealth.

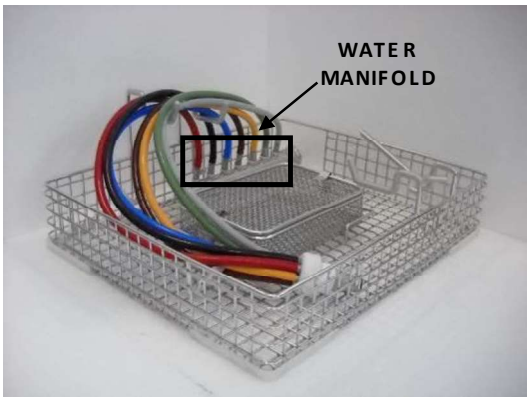
# 3.5 Thermal-disinfection cycle in conformity with EN ISO 15883:4

The Endoscope washer-disinfector must perform a daily thermal self-disinfection (regardless the chemical products used).
It is recommended to run the thermal self-disinfection program daily, to minimize contamination risk. This cycle can be performed automatically at a defined time: in case the endoscope washer-disinfector is not used during the weekend, make sure that the automatic self-disinfection is conducted.
If the endoscope washer-disinfector is not used for more than 24 hours, before restarting the operation:
1. Run 2 thermal self-disinfection processes.
2. Control the shelf life of the reprocessing chemicals and replace if expired.
3. Run 1 reprocessing program without endoscopes.

**MACHINE WITH ONE DOOR**

- Connect the CPC connections of the basket water manifold.

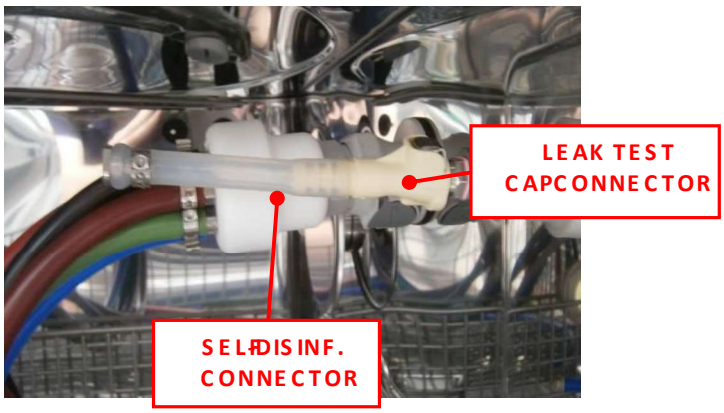
Connection with tubes for auto-disinfection (code 671511)




Basket

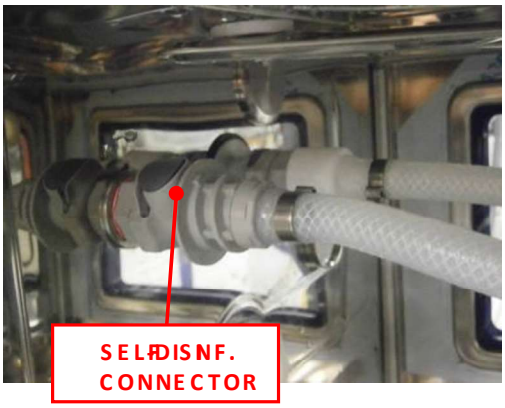
- Put the basket inside the machine and connect the connection with tubes for auto-disinfection to the relative connector. Then close the leak test inlet by means of the appropriate cap connector as shown in the illustration.

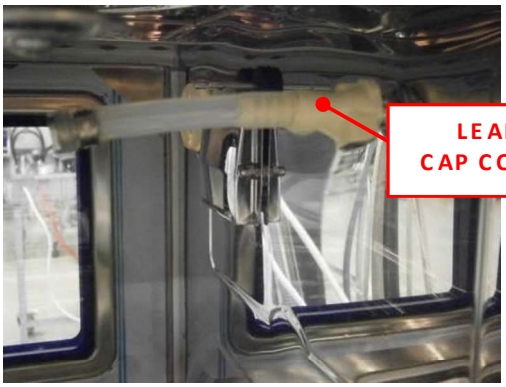
- The yellow tube must be connected to the basket and the opposite side must be free in order to drain the basket water manifold.



## MACHINE WITH TWO DOORS

- Connect the connection for auto-disinfection inside the washing chamber.



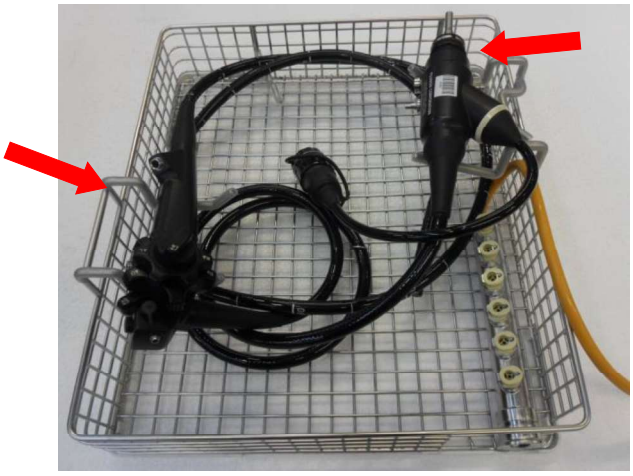




- Close the leak test inlet by means of the appropriate cap connector as shown in the illustration.

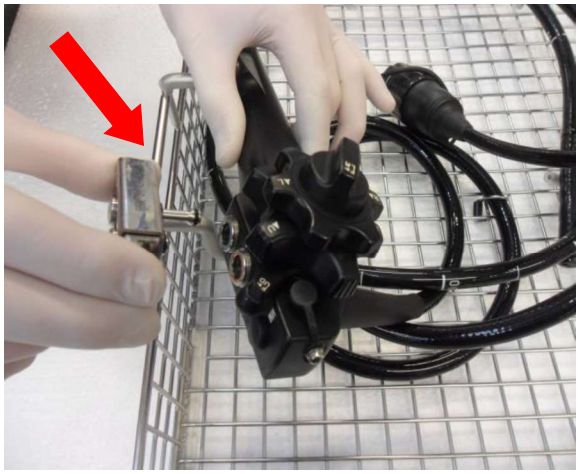
## 3.6 Load preparation

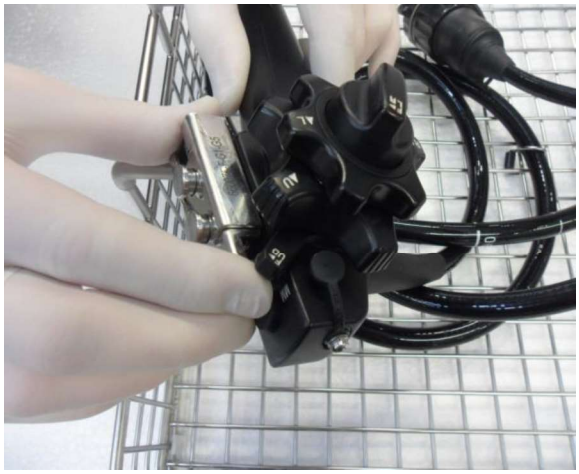
Once the thermal disinfection cycle has finished, remove the sanitation and leak test connectors and proceed with the loading of the endoscope into the basket by carrying out the following procedure:

**PUT THE ENDOSCOPE CAREFULLY INTO THE BASKET USING THE APPROPRIATE SUPPORTS (SEE PHOTO);**



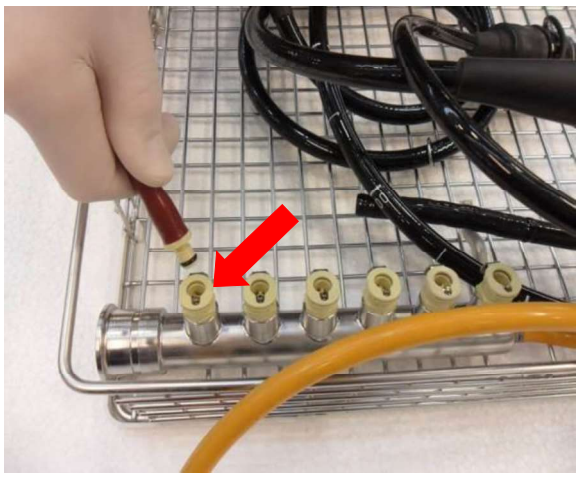
**INSERT THE CHANNEL SEPARATOR, ACCORDING TO THE ENDOSCOPE TYPE (SEE PHOTO);**

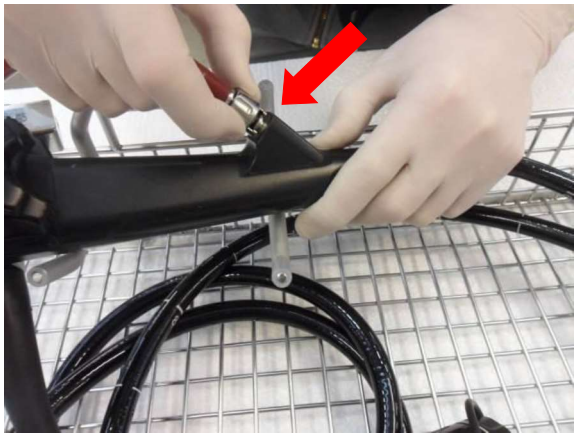




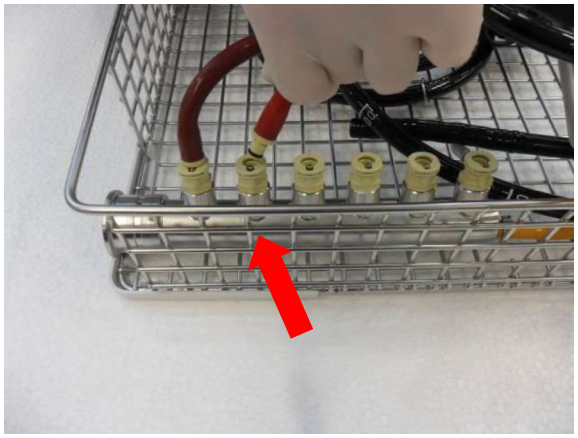
**COUPLE THE CONNECTION PIPES TO BE USED FOR CONNECTION TO THE ENDOSCOPE WHICH ARE DIFFERENT DEPENDING ON THEIR BRAND AND MODEL (SEE PHOTO);**

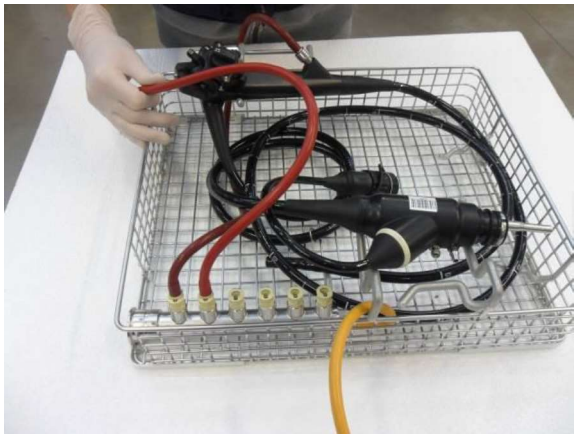
**EXEMPLE OF BIOPSY CHANNEL CONNECTION;**

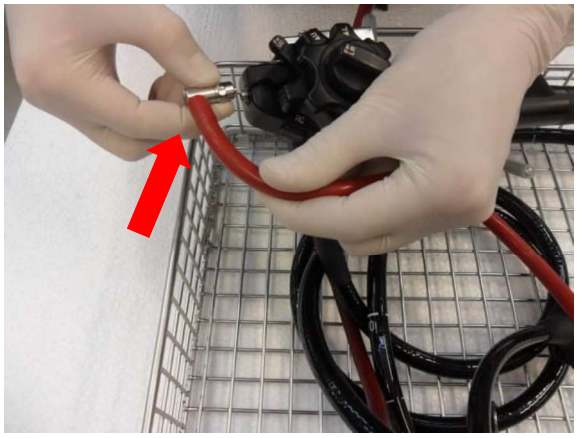


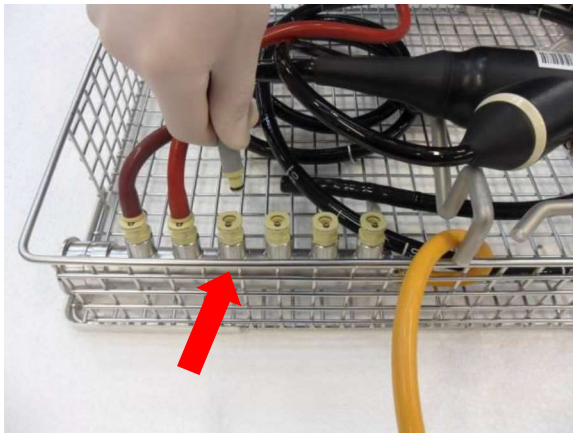
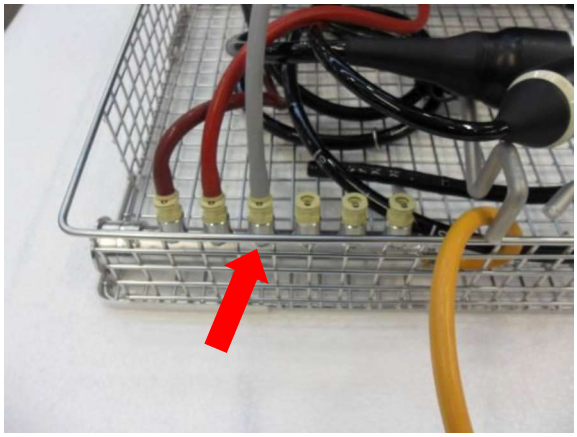
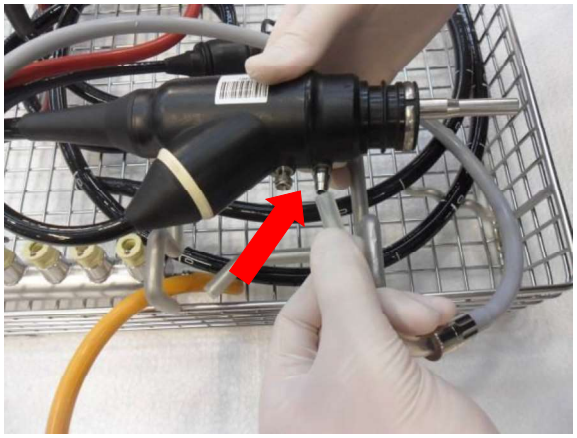


EXEMPLE OF "WATER JET" CONNECTION

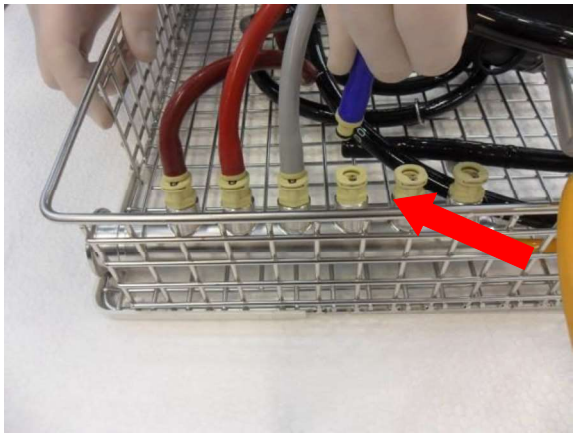


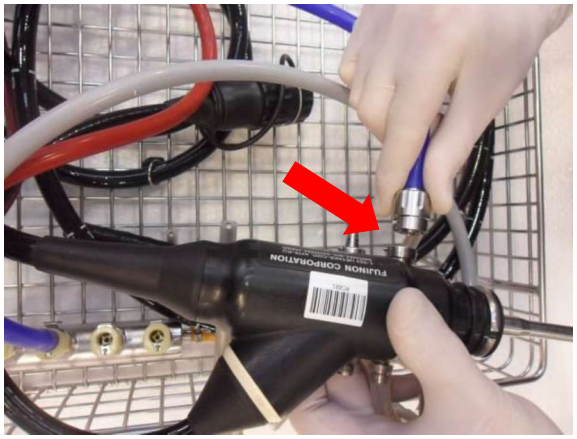





**EXAMPLE OF A WATER CONNECTON POINT;**

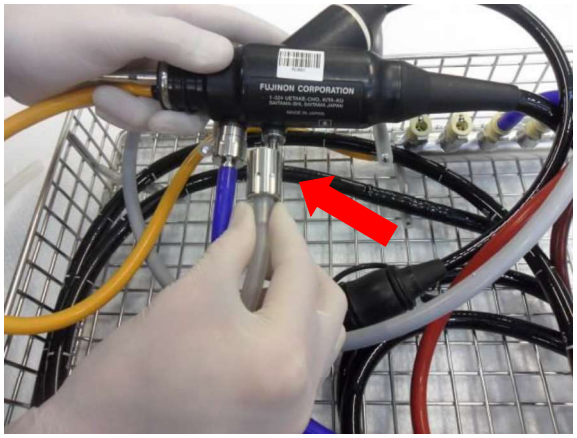


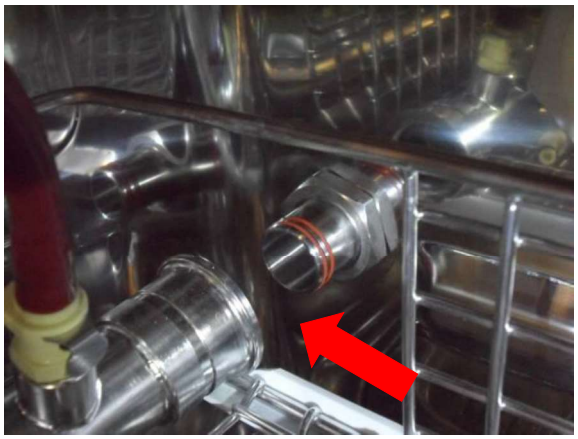


**EXAMPLE OF AN AIR CONNECTION POINT**

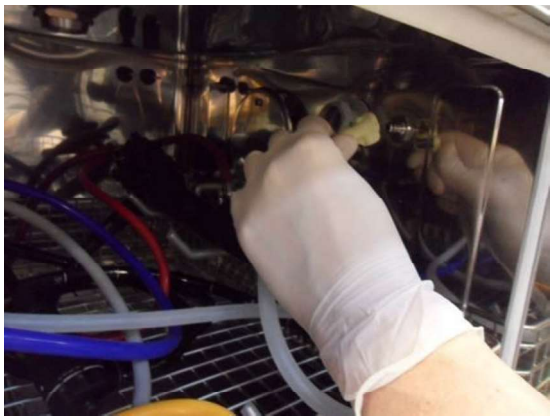
**EXAMPLE OF A LEAK TEST CONECTION POINT**




**PUT THE BASKET INTO THE MACHINE, MAKING SURE THAT IT FITS INTO THE APPROPRIATE COUPLING;**



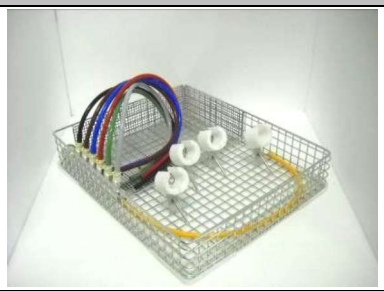
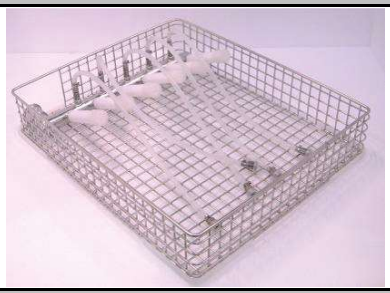
**CONNECT THE CPC QUICK DISCONNECT LEAK TEST COUPLING TO THE MACHINE;**



**CLOSE THE DOOR AND START THE DISINFECTION CYCLE.**

| | **ATTENTION** |
|---|---|
| | • **If the endoscope has less than 7 channels, keep free the CPC connections of the basket water manifold.**<br>• **During the wash the yellow tube must always be connected.**<br>• **Verify that all channels are properly connected before starting the cycle and at the end, before unloading the endoscope from the basket.** |

Below are shown some example of basket's type available for the machine:

| AVAILABLE ONLY FOR MACHINE WITH ONE DOOR | |
|---|---|
| **C566 - Flexible endoscopes** | |
|  | Maximum load for each cycle is 1 flexible endoscope. |
| **C569 - Video bronchoscopes** | |
|  | Maximum load for each cycle is 2 video bronchoscopes or 3 fibrescopes. |
| **C570 - Rigid endoscopes** | |
|  | Maximum load for each cycle is 10 rigid endoscopes. |
| **C575 - Flexible endoscopes without support** | |
|  | Maximum load for each cycle is 1 flexible endoscope. |

| | **ATTENTION** |
|---|---|
| | • **Do never emptying any solid waste into the machine (excrement etc.). This will block the outlet system with pump and destroy the machine.**<br>• **The treatment cycle has to be activated only if the basket is present into the machine or if it is used a basket equipped with an injection system.**<br>• **Non observance, even in part, of the rule here indicated, can cause dangerous leakage of water from the door.** |

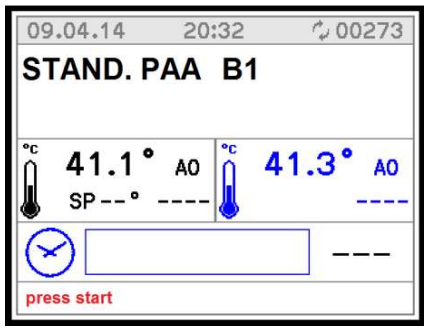
## 3.7 Start the washing cycle

To start the washing cycle follow the procedure:

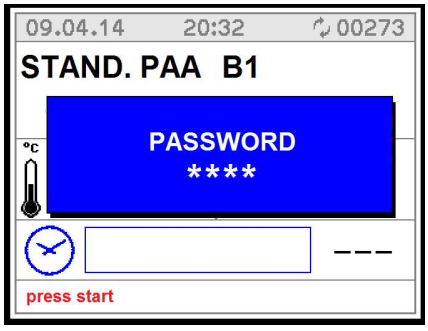
| | |
|---|---|
|  | **ATTENTION**<br>**Before starting a cycle the operators and instruments lists must be uploaded.** |

**WITH KEYBOARD**

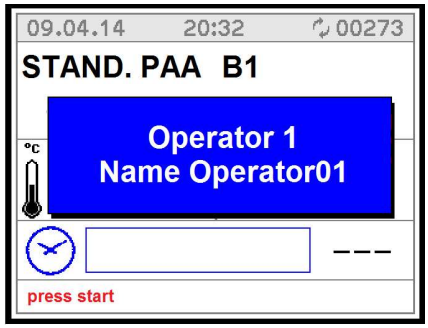
- Select the washing cycle and press **START**  button.



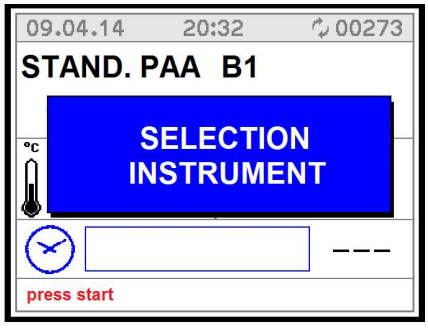

- The system requires the operator code (if it is activate). Enter the operator code (if the parameter P1.02=1).




- Confirm by pressing **START**  button.

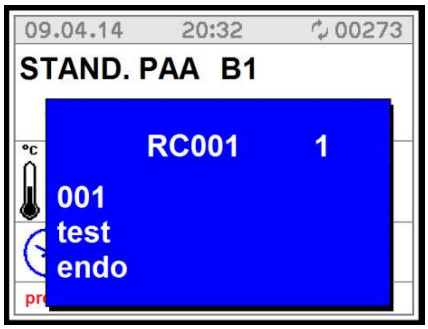



- The system requires the instrument code to be treated. Scroll the instrument list by using **P1**  and **P2**  buttons.

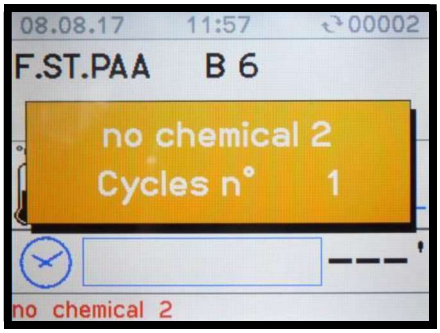


- Select the instrument or instruments by pressing PRG P+. Scrolling the instruments list, the LED PRG P+ button lights up only on the selected instruments.

  Press **START** button to start the washing cycle.

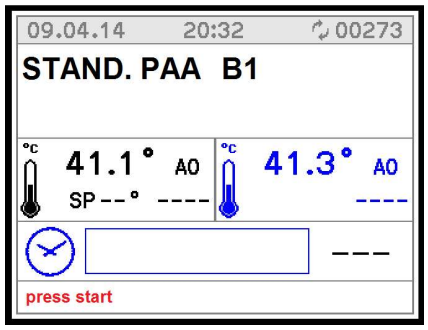


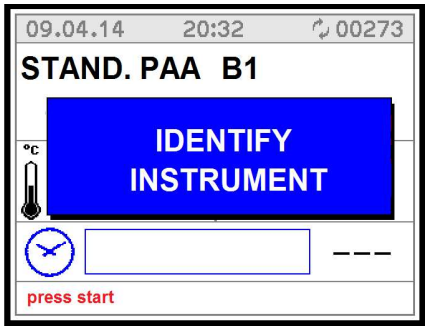

- If the chemical product is about to finish a pop-up appears as well as the number of cycles remaining.
  While the pop-up is still on the display, press the **START** button.



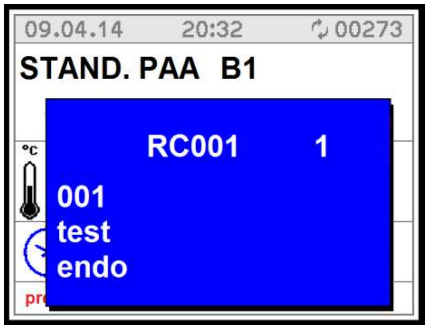

## WITH BARCODE (Optional)

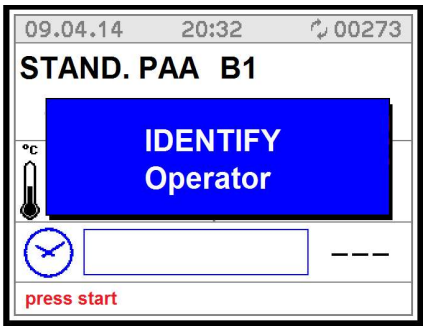
- Select the washing cycle and press **START** button.



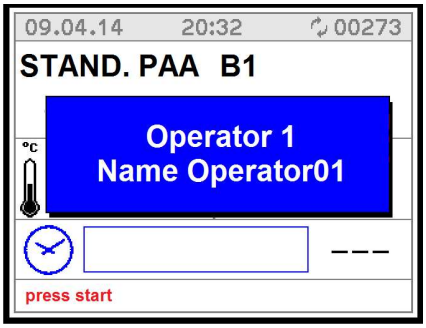



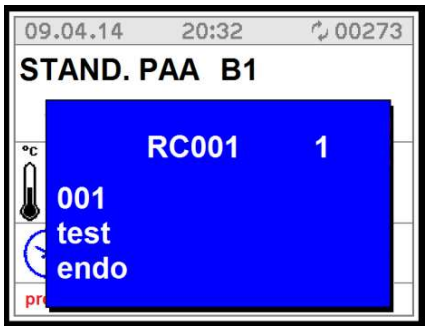

- Select the instruments by reading the instrument codes using the barcode reader. After completing this procedure, press the **START** button.





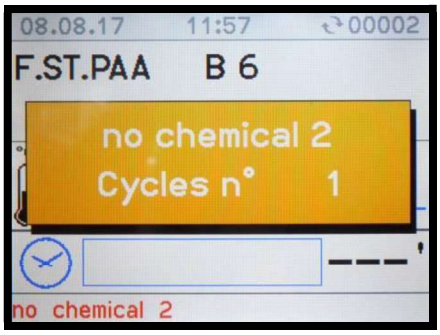

- Enter the operator code using the barcode reader and confirm this information by pressing the **START** button.




- The system shows the previously-entered data.

  Press the **START** button to start the washing cycle.




- If the chemical product is about to finish a pop-up appears as well as the number of cycles remaining.
  While the pop-up is still on the display, press the **START** button.

### 3.7.1 Endoscope requirements

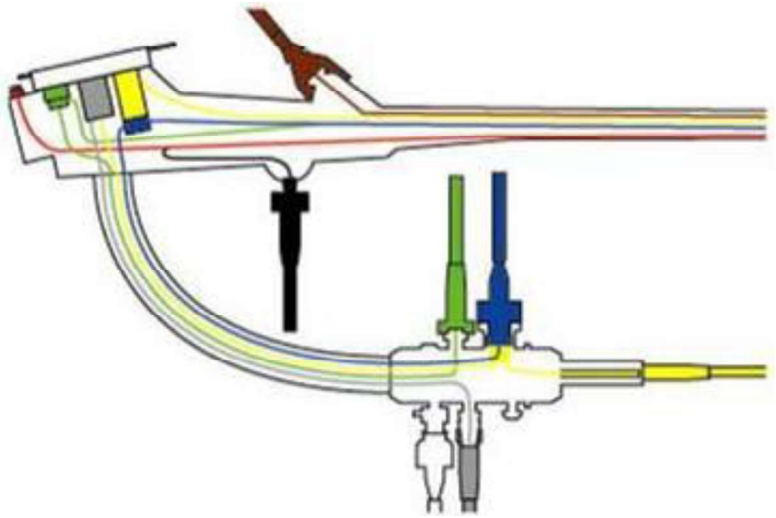
The flexible endoscopes treated in the EW 1 system must fulfil the following requirements:

- Resistance to a temperature between +10ºC and +60ºC;
- Resistance of the endoscope channels to a maximum pressure of 1.5 bar;
- Resistance to a pressure of max. 300 mbar during the leak test;
- Resistance to the detergents and disinfectants used;
- Presence of connections where to attach each of the endoscope channels;
- Waterproof with protection against the effects of immersion and, if applicable, equipped with parts that protect the endoscope from humidity.

In order to facilitate the connection of the endoscopes to the EW 1 system, all connections are identifiable in an unambiguous way by using a color coding system (see following figure).

**ENDOSCOPE CHANNELS**

- Brown: bioptic channel 1
- Green: bioptic channel 2
- Blue: water channel
- Yellow: air channel
- Grey: suction channel
- Red: auxiliary water channel
- Black: elevator wire channel
- Trasparent: leak test channel



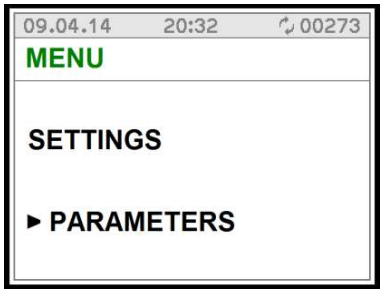
## 3.8 Instruction in case of 24h stop of the machine

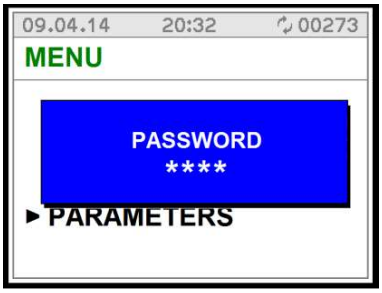
**It is advisable to execute a sanitation cycle every day.**

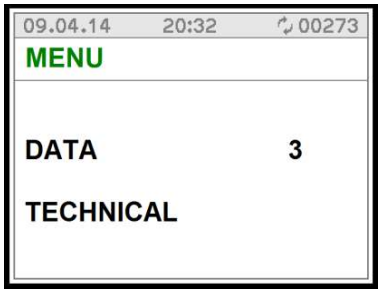
If the machine has not been used for more than 24 hours, it is advisable to carry out a sanitation cycle prior to using the machine.

Iti is possible to program on the machine an automatic sanitation cycle every day at the same time, that can be programmed by parameters P3.44 and P3.45. When this function is active (P3.43 = 1) the machine automatically start the sanitation cycle (B4) at the time set form the parameters.

**WARNING: programming operations are to be performed by the maintenance technician.**




**ATTENTION**: it is important to follow these instruction to allow the correct execution of the self-disinfection procedure.

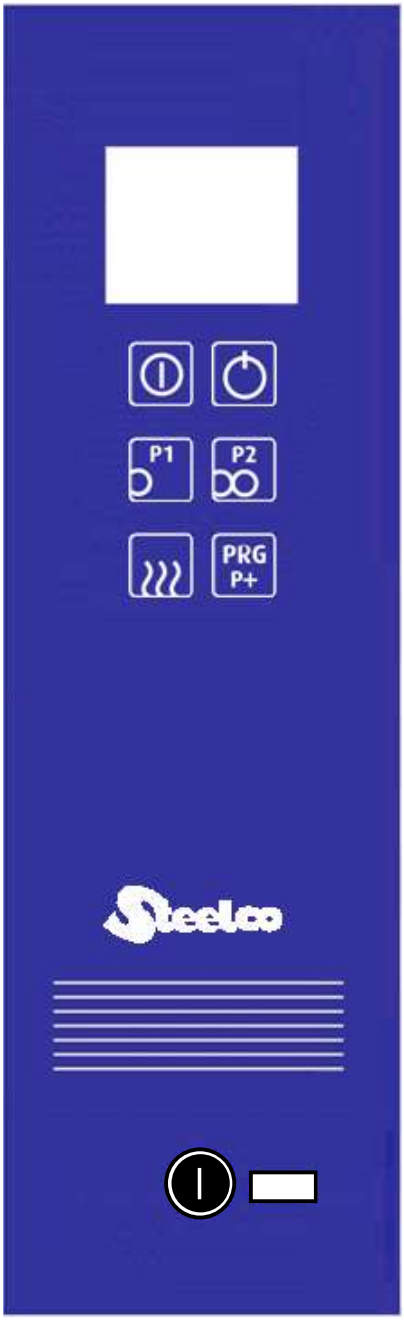
I. **The basket have to be connected to the sanitation circuit as explained on section 3.5.3.**
II. **The machine have to be left with the door shut.**

# 4. CONTROL PANEL AND SYMBOLS USED

## 4.1 Switches (loading side)

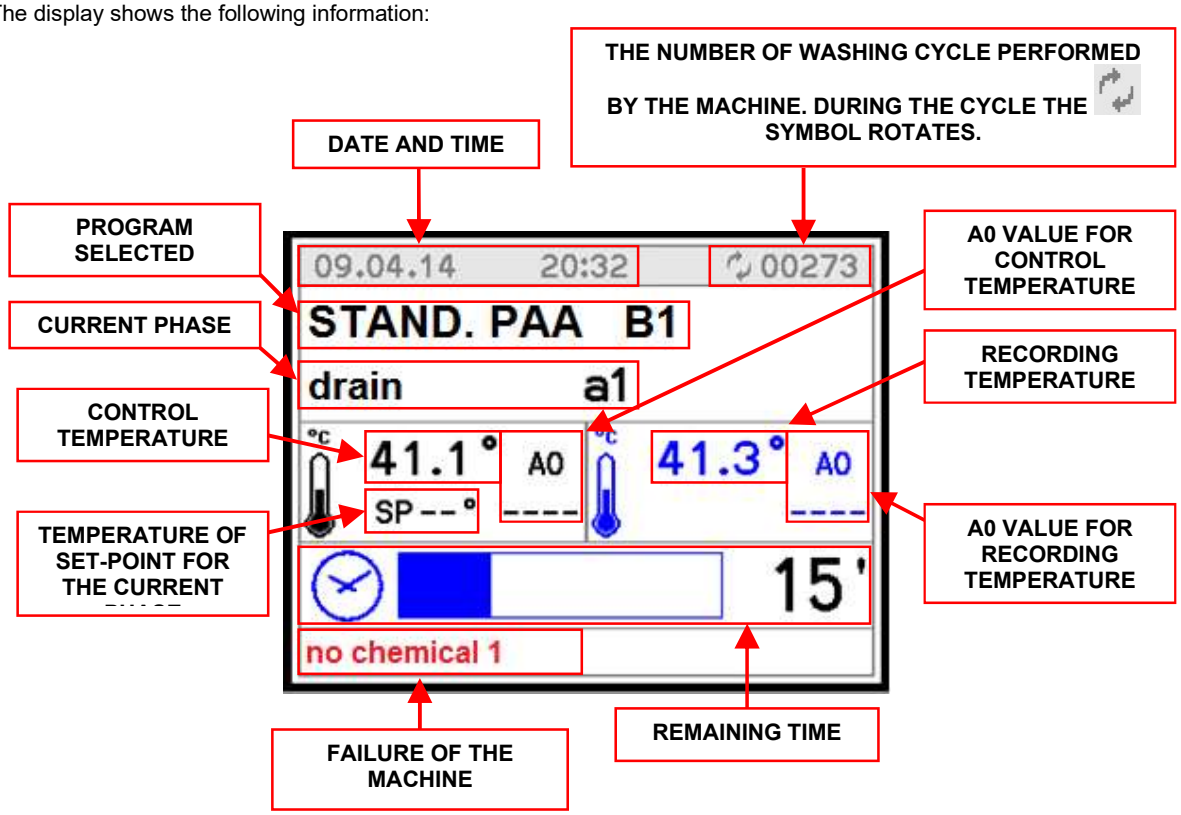
There are 6 switches with the following functions:

| BUTTON | DESCRIPTION |
|---|---|
|  | The switch **STOP** interrupts the cycle in progress, will be displayed a message indicating that disinfection did not take place, keeps the door locked and if necessary, indicates a high temperature inside the chamber.<br>To return the machine to normal conditions wait the safety drain procedure and then press once more the button to unlock the door. |
|  | After having selected the programme to be run, pressing the **START** button to start the cycle. |
|  | Select "**STANDARD**" cycle. |
|  | Select "**SELF-DISINFECTION 80**" cycle. |
|  | Pressing this button after having selected a programme and before starting it, it is possible to disable the forced air drying step (if selected by the parameter 3.20). |
|  | Keep pressed for five seconds during Wait or Shutdown to display the Menu.<br>Press once to display during the cycle information about the water and chemical quantity filled and information about the temperature and pressure measured by the transducers installed. |
| **USB**  | On the control panel board there is an USB port that allows the machine programming and data saving. |



## 4.2 Control panel (loading side)

The display shows the following information:



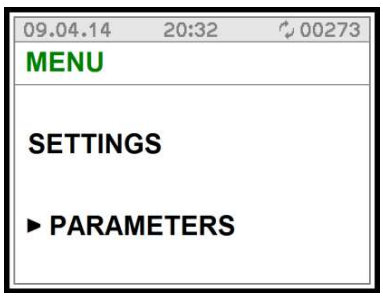

Initially, while the machine is in the stand-by status, it displays the type of program selected, the temperatures, date and time.
By pressing one of the programme switch (P1, P2, P+), the display shows the program selected at the top and at the bottom in red: "press start" or "door open" or any other warnings.
By pressing the switch “P+/PRG” it is possible to scroll all the programs available.

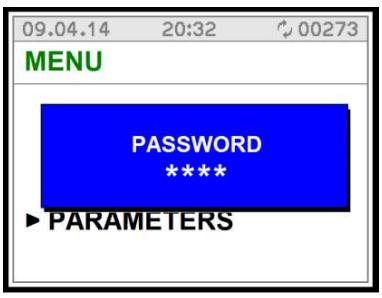
### LED

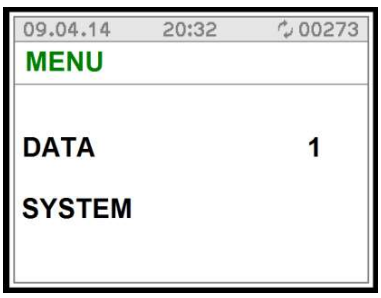
The keys of the glass display are touch-sensitive and backlit.

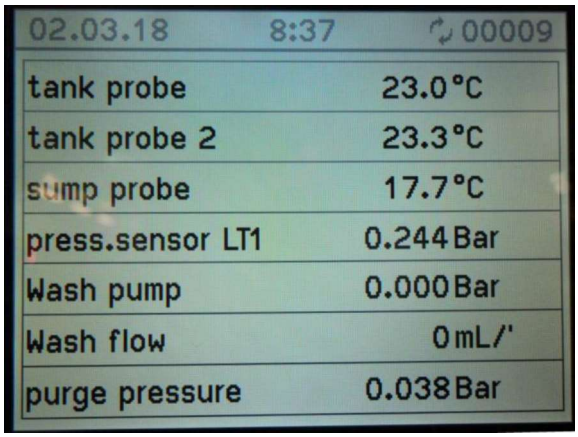
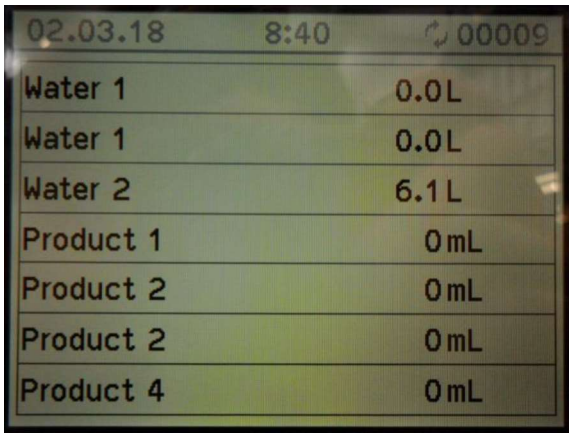
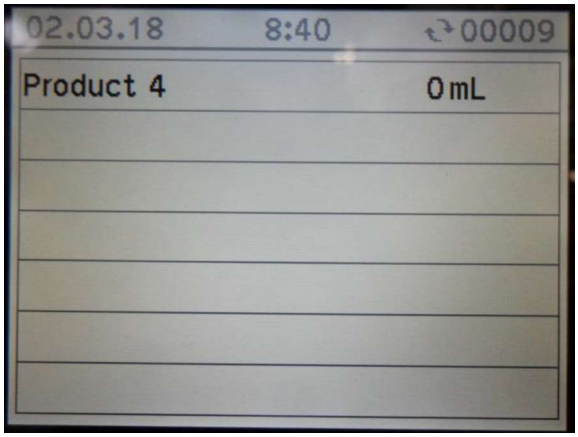

### BUZZER

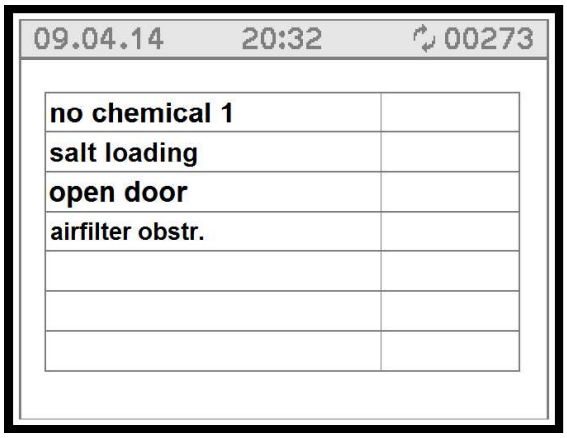
The buzzer sounds each time a key is pressed and intermittently in the case of a machine Shutdown, according to the setting of parameters **P1.7**, **P1.8**, **P1.9** through which is possible to set its volume.

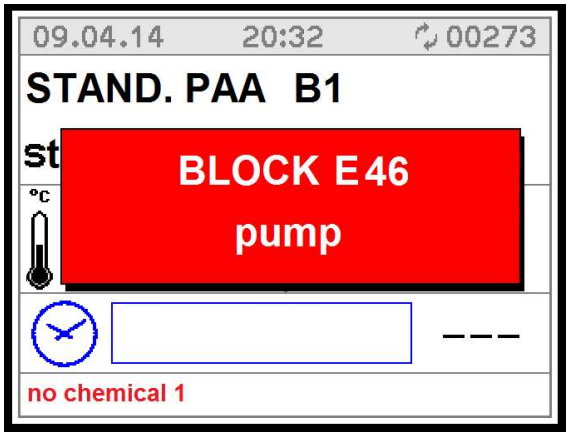
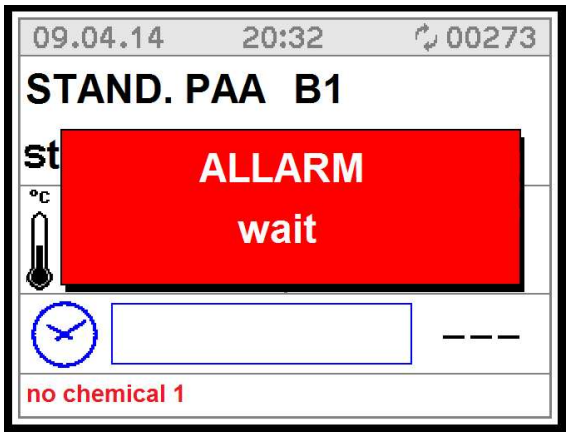


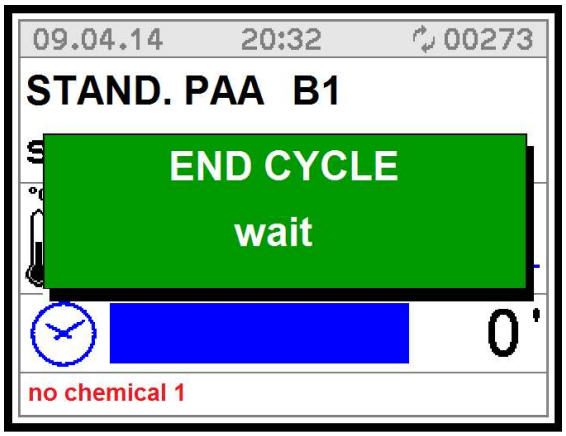
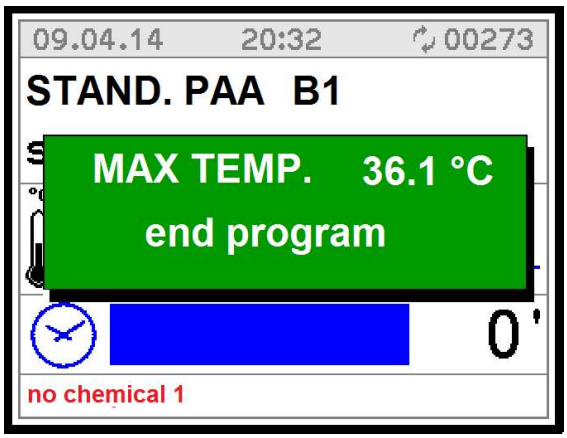



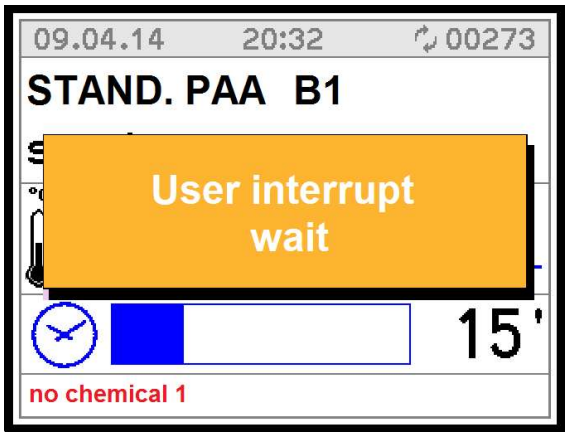
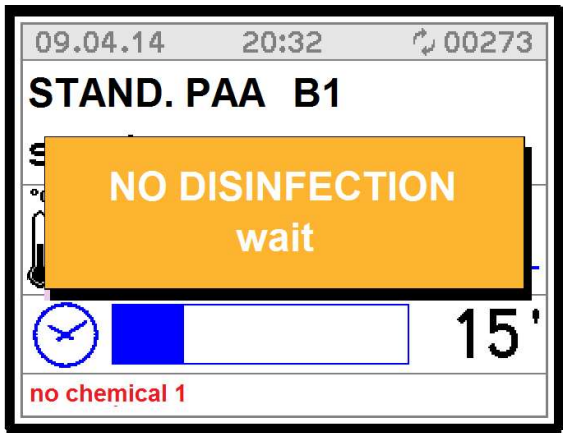
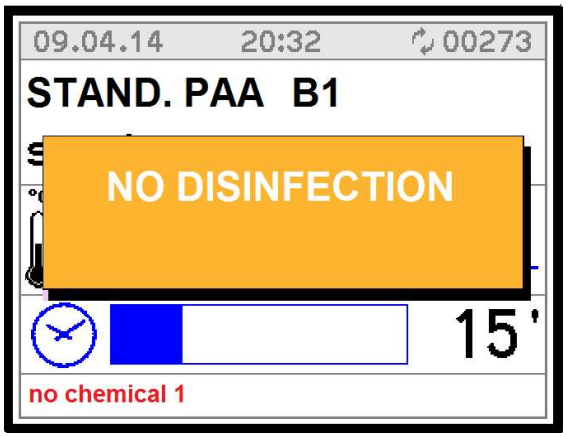
| PIC. 2 | |
|---|---|
|  | During the cycle, by pressing the switch **PRG** PRG P+ it will be displayed the various temperatures of the device and the values associated to the pressure transducers (Pic. 2). |
|  <br>  | It will be displayed also the water quantity filled and the chemical product quantity for each phase, pressing twice the **PRG** PRG P+ switch. |

| PIC. 3 | |
|---|---|
|  | Pressing **PRG** PRG P+ a third time it display the screen with the list of alarms and warnings appears during the cycle (Pic.3). |

| PIC. 4 | |
|---|---|
|  | In case of alarm, a window appears which indicates the identification code and a brief description for the alarm as shown. |
|  | After the failure resolution and the reset procedure (see chap. 8.2), will be displayed the message shown on the picture and the machine will start the safety drain procedure.<br>After this, the machine will show the **ALARM** picture waiting for the manual door unlock: it is sufficient to press the **STOP** switch once. The picture on the side will be shown.<br>After the door unlocking the **ALARM** picture will be shown open the door and after few seconds the message will be re |

In case of failure, which does not lead to a block, (lack of chemical) a message is shown at the bottom of the screen (Pic.1 point 11) or by pressing the **PRG** PRG P+ switch twice as shown in **Pic.3**.

| PIC. 5 | |
|---|---|
|  | At the end of the cycle, a special window appears as shown on the picture. |
|  | After few seconds the final windows will be displayed. Now it is possbile to open the door. |

| PIC. 6 | |
|---|---|
|  | In case of manually stop of the cycle, the machine start the automatic safety drain and purge procedure showing a message as on the picture on the side.<br><br>**NB**: if, on the phase stopped, where loaded a chemical product, the machine execute also a rinsing before the door unlocking. |
|  | After the safety procedure will be displayed a message that warns about the disinfection lack. |
|  | Pressing the **STOP**  switch it is possible to unlock the door. The message is still displayed and will be removed after the door opening. |

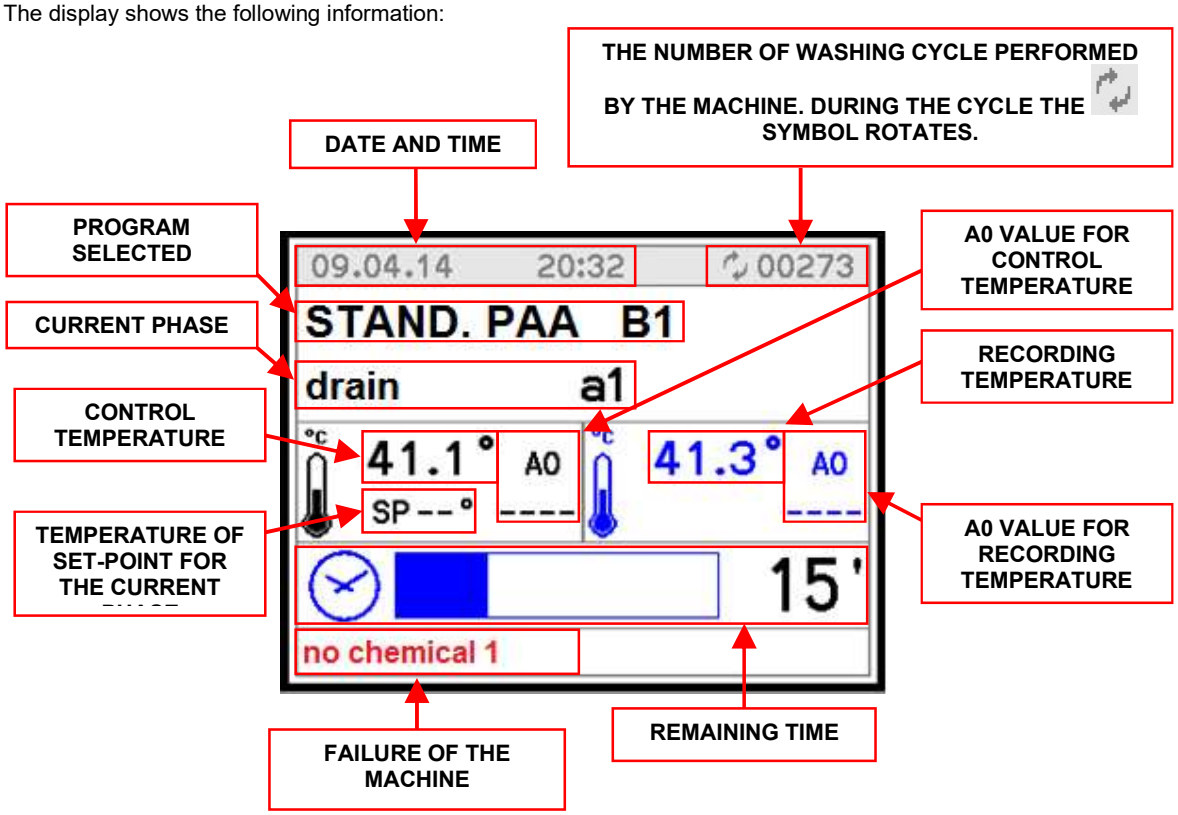
## 4.3 Switches (unloading side – if present)

In case of machine with pass-through door, if the ID operator parameter is disabled (P1.23=0 or 1), at the end of the OK cycle, the unloading door opens automatically.

If this parameter is enabled, P1.23=2 (Ares) or=3 (Steelcodata not Ares with ID unloading machine operator), the ID unloading machine operator procedure at the end of the cycle is:
-at the end of the OK cycle "ended program" popup alternates with "Press start operator" popup;
-the operator must press one of the doors unloading or loading buttons, in order to enter the operator menu (he has to read alternatively "KEY START" or "KEY STOP" bar codes;
-it displays the "ID OPERATOR": the operator must read the operator bar code.
If it is uncorrect, it displays the timed failure message and it comes out the menu.
If it is correct, it displays the operator name and his list number: at that point he must confirm either with the door unloading button or either alternatively with "KEY START" bar code.
The door unlocks and the operator is registered into the supervisor.
-From the unloading machine operator menu, you can exit (return to the OK end cycle screen), by pressing the door locking button or with the "KEY STOP" bar code;
Anyway, you exit automatically by 60 sec. timeout.

## 4.4 Control panel (unloading side – if present)

The display shows the following information:

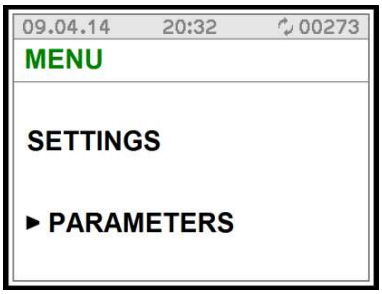


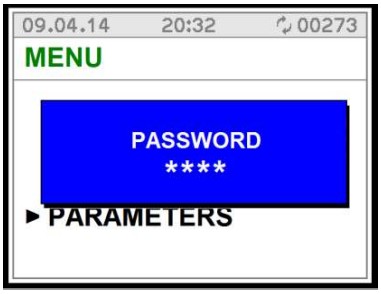

**LED**

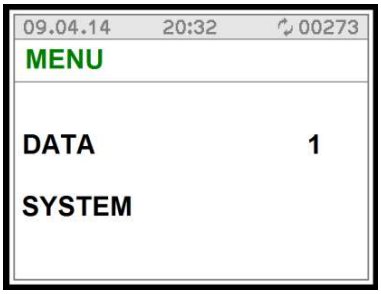
The keys of the glass display are touch-sensitive and backlit.

**BUZZER**

The buzzer sounds each time a key is pressed and intermittently in the case of a machine Shutdown, according to the setting of parameters **P1.10**, **P1.11**, **P1.12** through which is possible to set its volume.



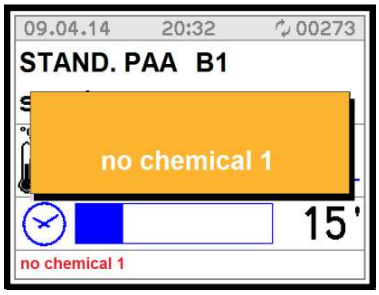



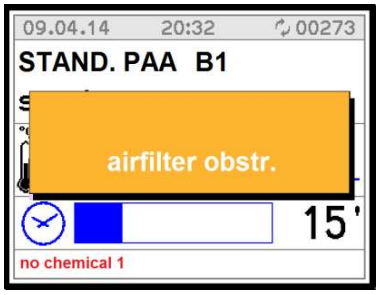
# 5. MACHINE CONDITIONS

The machine has three possible statuses.

## 5.1 Stand-by

The machine is ready to work.
The diagnostic is active.
There will be the possible indication of the door open or warnings: lack of chemical product, full memory (historical) or filter obstructed.

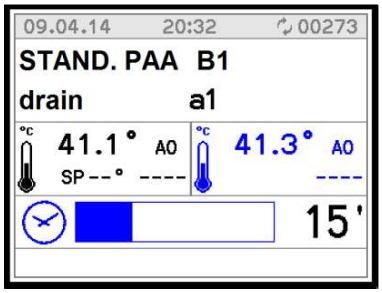



## 5.2 On cycle

You can reach this point in the procedure by selecting the desired cycle and by pressing the **START** key to start the machine up.
The cycle is running according to its phases.
The diagnostic and the regulators are active.

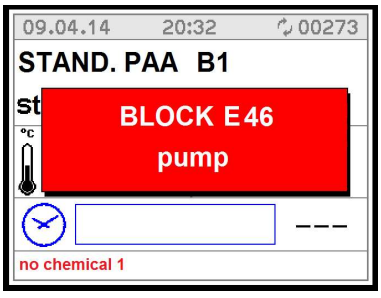
The user interface gives all indications about the different phases and about the chamber temperature.




## 5.3 Alarm

The diagnostic found an anomaly which cause a block, the cycle is interrupted keeping the door blocked.

The anomaly is shown on the display; after the failure solution is necessary to unlock the machine using the reset procedure (see chapter 6.2).




After that the machine start the safety drain procedure, the door is unlocked, and it is possible to start a new operation.

# 6. SPECIAL FEATURES

## 6.1 Power failure

In case of a power failure the machine will remember the state it had before the cut off.

### 6.1.1 Power failure during "WAIT"

When tension is restored after a power failure during WAIT status the machine returns to the WAIT status waiting a command.

### 6.1.2 Power failure during a cycle or during an alarm

If the power failure occurs during a CYCLE or during an ALARM, after the restoration the machine will show an alarm (power fail): to return on the WAIT status is necessary to execute the reset procedure. The machine automatically starts the safety drain procedure and goes on the waiting state.

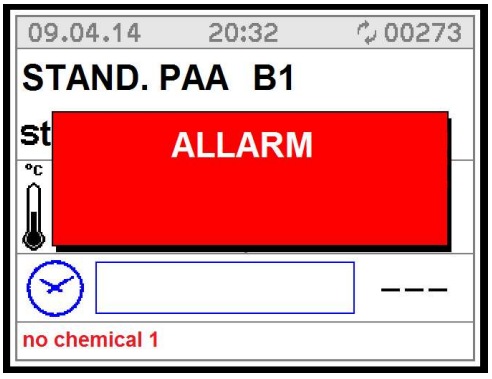
| | **ATTENTION** |
|---|---|
|  | **After performing the procedure described previously, remember that:**<br>• **The items inside the machine could be very hot and contaminated.**<br>• **The entire treatment cycle must be repeat.**<br>• **Material contaminated with peri acetic acid could be present inside the machine.** |

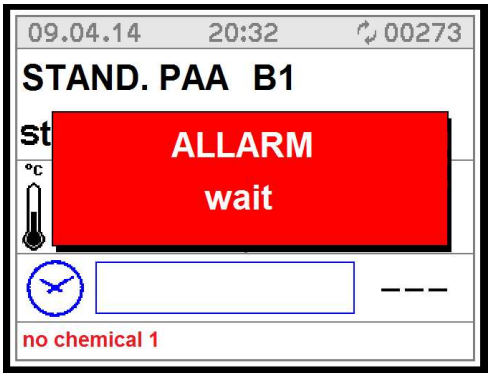
## 6.2 Reset procedure

In the event of a **POWER FAILURE** or an **ALARM**, the door remains locked.

To open the door, the reset procedure must be carried out from the keyboard as follows:

1. Press the  and  switch together and keep pressed for 5".
2. LCD display indicating "**switch procedure**".
3. Press the  switch followed by the  switch.
4. The following screen will be shown: pressing  switch will be displayed the second screen: the machine is unlocking the door.




5. When the control panel shows the first picture again keep the door opened for 5 seconds and wait until the alarm is reset.
6. The machine returns to STAND-BY mode.

***NB**: if the alarm occurs during stand-by status, the procedures descripted on point 4 and 5 are not necessary. After the reset, the machine will automatically return on stand-by status.*

| | ATTENTION |
|---|---|
|  | **If the machine shutdown persists due to a fault in one of its components (e.g.: faulty probe, unsuitable levels, etc.), the door remain locked and the machine remains inactive.**<br>**Seek technical assistance.**<br><br>**Should it be necessary to remove the endoscope, switch the machine off and follow the procedure described in chapter 8.1.2.** |

# 7. WORK PROCEDURES

## 7.1 Introduction

This machine has been designed only and exclusively for the reprocessing of flexible and rigid endoscopes and the thermal-disinfection of washing chambers. Therefore it is subject to continuous contact with aggressive detergents and contaminated instruments.
For this reason it is necessary to provide some useful instructions for the operators who will be using it.

## 7.2 Instructions to personnel

**The machine operator,** in normal operating conditions, is not subject to risks if he works safely using suitable means of protection.
In order to work safely the operator must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Personally take action, or inform appropriate persons in the event of deficiencies in the aforementioned devices and means, as well as any hazardous conditions which he may become aware of, taking action directly in urgent cases within their scope of responsibilities and abilities to eliminate or reduce the deficiencies or hazards.

**The maintenance technicians**, in normal operating conditions, are not subject to risks if they works safely using suitable means of protection.
In order to work safely the maintenance technician must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Use special care in making repairs or replacing mechanical parts (e.g. drain pump, etc.) on malfunctioning machines which have not completed the disinfection cycle.

## 7.3 Sterilization - Warnings (cycle validated in accordance with UNI EN ISO 14937 standards)

**1.** The cycle is valid only with the combination of the following chemicals:

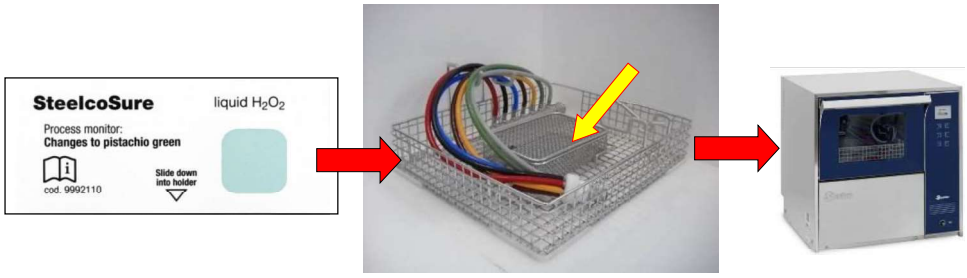
- SteelcoXide-DT
- SteelcoXide-A and SteelcoXide-B

**2.** At the end of the cycle the instrument is sterilized but not sterile, as it has no steril barrier system (SBS).

**3.**The material taken out of the sterilizing chamber must be used immediately and handled using sterile gloves and appropriate PPE.

**4.LOAD VALIDATION**

Chemical product presence indicators are available. The indicator has to be insered into the appropriate rack in order to check the right chemical dosing.
Once the cycle has finished, check the colour of the indicator (cod. 9992110):




(sea green) (pistachio green) (sea green)

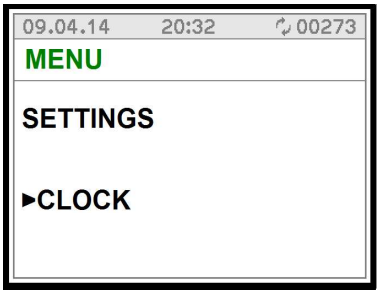
**UNPROCESSED** **PROCESSED - OK** **PRECOSSED - FAILED**

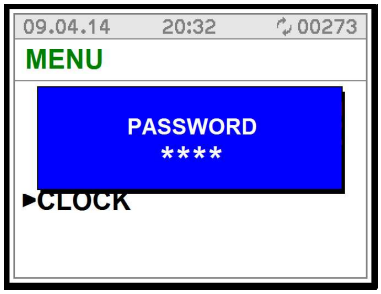
| | |
|---|---|
| | **WARNING** |
| | **IT IS NECESSARY TO REPEAT THE CYCLE IN THE EVENT THAT THE TEST RESULTS AS BEING PROCESSED YET IN REALITY IT HAS FAILED.** |

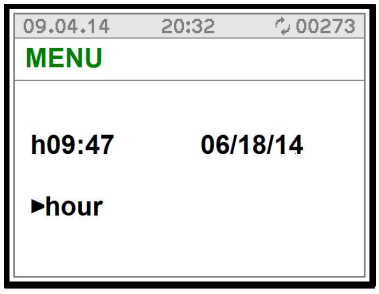
# 8. CLOCK

The main board is equipped with a real time watch. This clock can be set for the following menu:

**SETTING → CLOCK → set date and hour**.



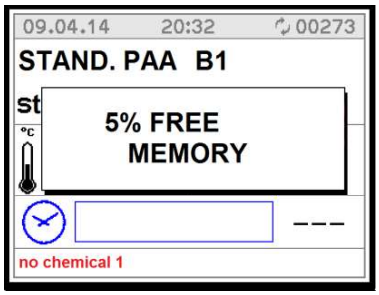




The time shown is also to qualify the events historical.

# 9. HISTORICAL DATA and PRINTOUT

During the working cycle, the machine memorizes on a RAM all the working data of the wash cycles that have been performed.
If a printer is installed the machine print step by step all the information shown on the example below.

The card is able to record the fields described below for up to a maximum of about 600 cycles in the permanent memory.
When 90% of the memory is full, a signalling pop-up with the message ‘‘5% FREE MEMORY’’ appears on the display.
Printing out the whole historical data, the message will be deleted.
The fields given in the example below are recorded for each cycle:




```
**************************************
            ****************
User              :  ****************
Model             :  EW 1
Machine           :  12001
Station           :      0
Software          :   7.00
Operator          :     13


INSTRUMENT 1      :   RC001
                      GD900123
                      GASTROSCOPE
                      STORZ
--------------------------------------
B 6 F. ST. PAA          Record:   00002
......................................
START:            07/06/14     h: 10:14

->  1: drain                   h: 10:14
     T1=  35.9°C  T2=  36.1°C

->  leak test                  h: 10:14

->  2: prewash                 h: 10:15
     T1=  35.4°C  T2=  35.3°C
                  programm.   executed
Water 2               6 L        6 L
```

←Customer/distributor (value set by parameter P2.06)
←User name (value set by parameter P1.01)
←Machine model (value set by parameter P2.01)
←Machine serial number (value set by parameter P2.02)
←Station number (value set by parameter P2.05)
←SW version on main board
←Operator nr (or signature space in case of parameter P1.02=no)

←Endoscope information

←Cycle name and cycle number on historical

←Date and hour of cycle start ***(standard cycle 17 min)***

←Phase number, name and ending time
←Temperature chamber probe 1 e 2

```
->  3: drain                    h: 10:16
     T1=  35.4°C  T2=  35.4°C
     channel drying

->  4: treatment                h: 10:21
     T1=  37.2°C  T2=  37.1°C
                   programm.   executed
Water 2                 6 L        6 L
Product 1= OK          30 mL      32 mL
     T>=  35°C   t=  300 s  t=  300 s
     (T1=  35.8°C) (T2=  35.8°C)

->  5: drain                    h: 10:22
     T1=  37.2°C  T2=  37.1°C
     channel drying

->  6: rinsing 1                h: 10:23
     T1=  36.4°C  T2=  36.4°C
                   programm.   executed
Water 2                 6 L        6 L
     T>=   0°C   t=   20 s  t=   20 s
     (T1=  36.4°C) (T2=  36.4°C)

->  7: drain                    h: 10:24
     T1=  36.4°C  T2=  36.4°C
     channel drying

->  8: disinfect.               h: 10:29
     T1=  37.3°C  T2=  37.3°C
                   programm.   executed
Water 1                 6 L        6 L
Product 2= OK          60 mL      61 mL
     T>=  35°C   t=  300 s  t=  300 s
     (T1=  35.9°C) (T2=  35.8°C)

->  9: drain                    h: 10:29
     T1=  37.3°C  T2=  37.3°C
     channel drying

-> 10: rinsing 4                h: 10:30
     T1=  36.4°C  T2=  36.4°C
                   programm.   executed
Water 1                 6 L        6 L
     T>=   0°C   t=   20 s  t=   20 s
     (T1=  36.5°C) (T2=  36.4°C)

-> 11: drain                    h: 10:31
     T1=  36.4°C  T2=  36.4°C
     channel drying

end program:      07/06/14      h: 10:31

      <><><><><><><><><><><><><><><>
              END CYCLE OK
      <><><><><><><><><><><><><><><>

Doctor _____________________________

Patient _____________________________

><- - - - - - - - - - - - - - - - - ->
```

←Water consumption
←Chemical consumption
←Date and hour of the cycle end ***(standard cycle 17 min)***
←Alarm/warning description (if present)
←Doctor signature
←Patient signature

Repetition tickets header and cycle's result (this part of printout is controlled by parameter 1.19.)

```
****************************************
            ****************
User              :  ****************
Model             :  EW 1
Machine           :  12001
```

←Customer/distributor (value set by parameter P2.06)
←User name (value set by parameter P1.01)
←Machine model (value set by parameter P2.01)
←Machine serial number (value set by parameter P2.02)

```
Station          :      0
Software         :   7.00
Operator         :     13


INSTRUMENT 1     :   RC001
                     GD900123
                     GASTROSCOPE
                     STORZ
---------------------------------------
B 6 F. ST. PAA          Record:   00002
.......................................
START:             07/06/14     h: 10:14
end program:       07/06/14     h: 10:31
      <><><><><><><><><><><><><><><><>
              END CYCLE OK
      <><><><><><><><><><><><><><><><>

Doctor _____________________________

Patient  ___________________________

><- - - - - - - - - - - - - - - - ->< 
```

←Station number (value set by parameter P2.05)
←SW version on main board
←Operator nr (or signature space in case of parameter P1.02=no)

←Endoscope information

←Cycle name and cycle number on historical

←Date and hour of cycle start ***(standard cycle 17 min)***
←Date and hour of the cycle end ***(standard cycle 17 min)***

←Alarm/warning description (if present)

←Doctor signature

←Patient signature

# 10. USB PORT

On the control panel board there is an USB port that allows the machine programming and data saving.
The card is able to record the fields described below for up to a maximum of about 600 cycles in the permanent memory.

## 10.1 Data saving

Insert the USB key on the dedicated port and enter the menu and select the USB menu.



It is possible to download from the machine the following information and files:

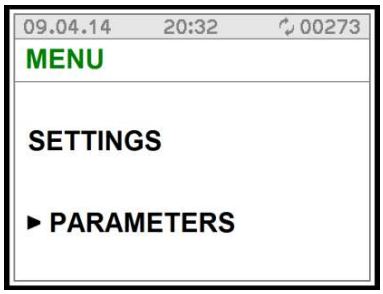
- Cycles
- Parameters
- Historical
- Maintenance historical

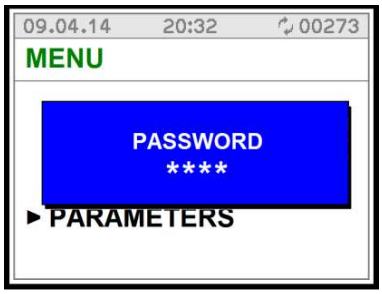
***The cycle and parameter files can be used to program another machine or as back-up of the machine.***

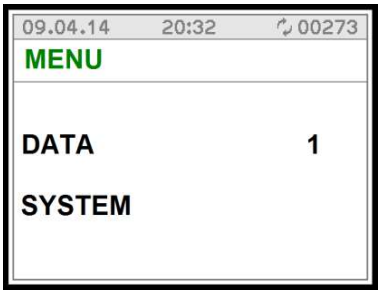
## 10.2 Data saving during the cycle

By means of the activation of the cycle save parameters required by the user and carried out by the (STEELCO) authorised installer/technician, it will be possible to save data at the end of each washing cycle by leaving the USB memory stick and by carrying out the following procedure:

- Set the parameters P1.04 at 3 and P1.05 to 1.



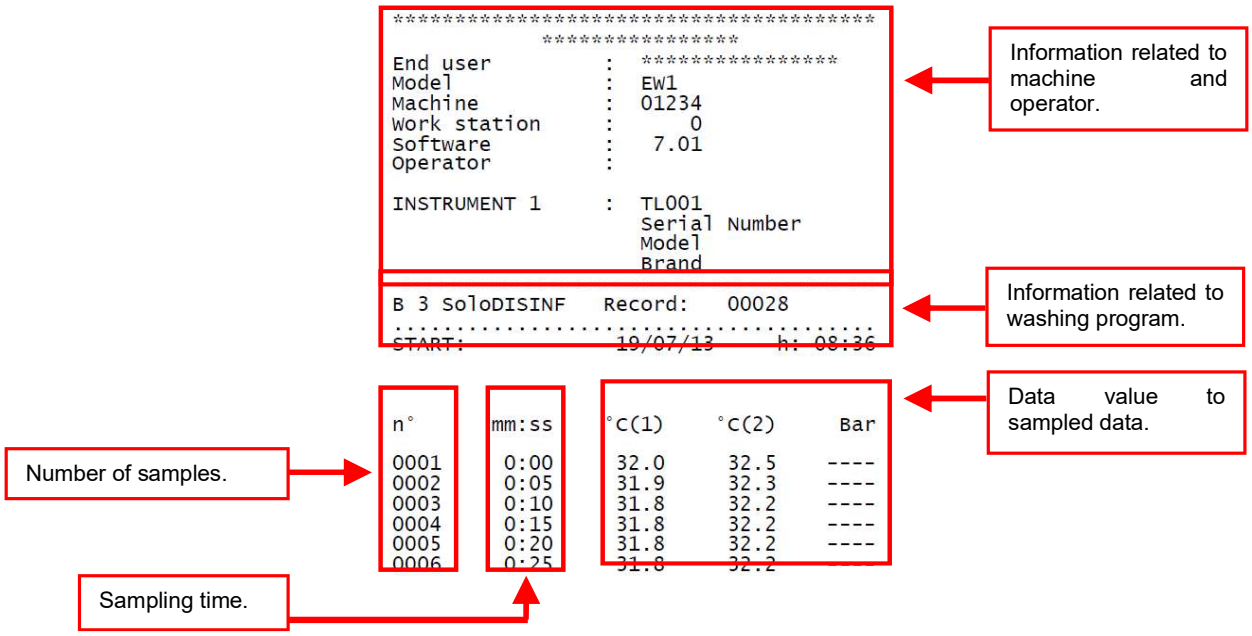

- Start the washing program;
- At the end of the cycle the machine creates the file with the samples of temperature and pressure probes with the information of every washing program phases.

To every washing program are associated two files which contain the data structured as below.

Errore. Non si possono creare oggetti dalla modifica di codici di

The file *****G.TXT contains:

***N.B.: the *****G.TXT will be saved in automatically at the end of the washing program.***




The file *****C.TXT contains:

***N.B.: To save the *****C.TXT, ins ert the key in t he dedicated port, enter the menu, select the USB menu and download from the machine the information of historical .***

```
****************************************
                ****************
End user          :  ****************
Model             :  EW1
Machine           :  01234
Work station      :      0
Software          :   7.01
Operator          :

INSTRUMENT 1      :  TL001
                     Serial Number
                     Model
                     Brand
----------------------------------------
B1 STAND. PAA              Record:   00001
........................................
START:              01/01/12      h: 10:35

->  1: vidange                     h: 10:35
     T1=  18.2°C  T2=  18.3°C

->  2: prelavage                 h: 10:38
     T1=  20.1°C  T2=  20.0°C
                     programm.    termine'
Eau 2                  6.0 L       6.1 L

->  3: vidange                     h: 10:39
     T1=  20.0°C  T2=  19.9°C

->  4: traitement                 h: 10:46
     T1=  37.1°C  T2=  37.3°C
                     programm.    termine'
Eau 1                  6.0 L       6.1 L
Prodotto 2            60.1 mL     60.0 mL

->  5: vidange                     h: 10:47
     T1=  29.9°C  T2=  30.0°C

STOP:               01/01/12      h: 10:48
FIN DU CYCLE         FAIL 91
                User interrupt
```

Information related to machine and operator.

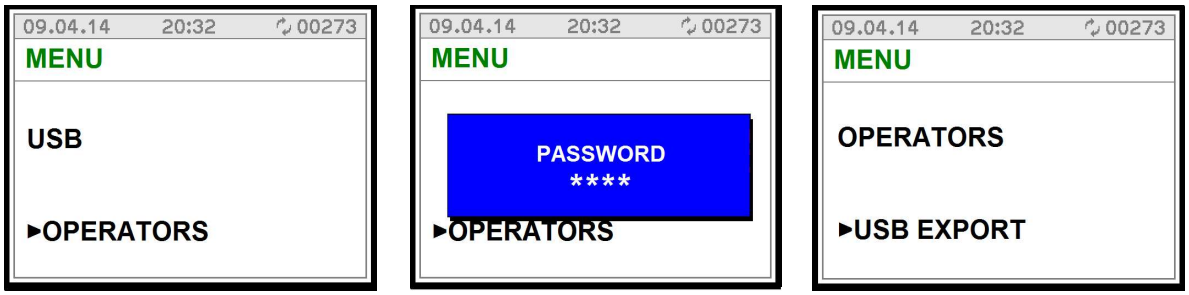
Information related to washing program.

Information related to every washing program phase.

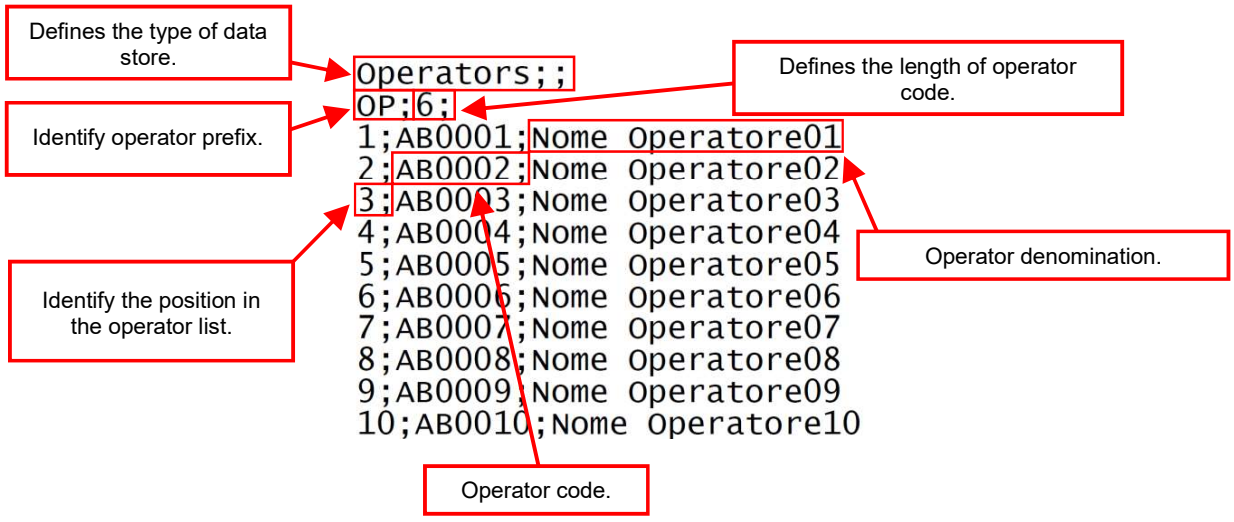
## 10.3 Operator archive management

By means of the activation of the cycle save parameters required by the user and carried out by the (STEELCO) authorised installer/technician, it will be possible to save the file archives of the operators present in the machine memory in a file by carrying out the following procedure:

- Insert the USB key into dedicated port.
- Enter menu: **USB → OPERATOR → Insert 3rd level password → USB EXPORT → Press START button.**

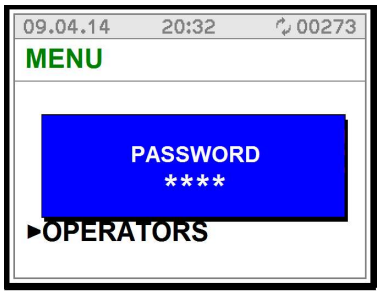



The name of file is "**OPERATxxxxx.CSV**", where "**xxxxx**" stands for an optional generic denomination and it contains the data structured as below:




| FIELD | FIXED CHARACTERISTICS |
|---|---|
| **Type of data store** | Nothing |
| **Operator prefix** | Length = 2<br>Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-"minus sign, "." full stop.<br>**ATTENTION:** set '**OP**' if it is used the barcode reader while set '**00**' if it is used the keyboard (operator identification). |
| **Lenght of operator code** | From 1 to 8 |
| **Position in the operator list** | Progressive order (Maximum number of operators = 60) |
| **Operator code** | Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-"minus sign, "." full stop. |
| **Operator denomination** | Length ≤ 16 (can be empty)<br>Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-"minus sign, "." full stop. |

It is possible to upload the archive operators by insert the USB key into dedicated port and enter the menu: **USB → OPERATOR → Insert 3rd level password → USB IMPORT → Press START button.**



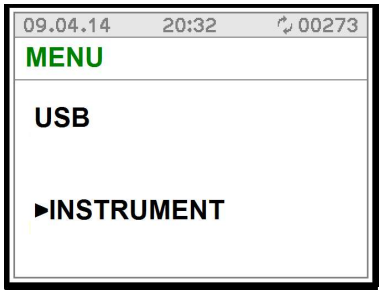
## ATTENTION

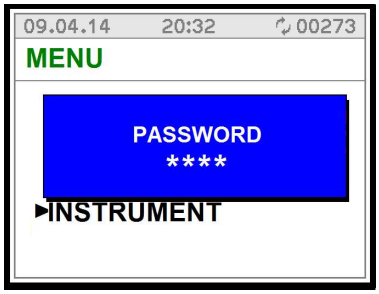
- To modify the operator archive file, it is recommended use a text editor (ex. Notepad).
- If the file contains an operator with the field "**OPERATOR CODE**" null (no character), the file is considered valid up to the previous operator. All subsequent elements are ignored.
- If the file contains values that do not comply with the constraints described above, the file is considered incorrect. During the upload it is displayed the first line where the error is present.

## 10.4 Instrument archive management

By means of the activation of the cycle save parameters required by the user and carried out by the (STEELCO) authorised installer/technician, it will be possible to save the file archives of the instruments present in the machine memory in a file by carrying out the following procedure:

- Insert the USB key into dedicated port;
- Enter menu: **USB → INSTRUMENT → Insert 3rd level password → USB EXPORT → Press START button.**





The name of file is "**INSTRUxxxxx.CSV**", where "**xxxxx**" stands for an optional generic denomination and it contains the data structured as below:

| Instrument | | | | | CHANNELS | | | | AUX. CHANNELS | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| RC | | | | | | | | | | | | | |
| 1 | 1 | G120432 | colonEC-380LKp | pentax | 100 | 30000 | 10 | 2500 | 50 | 130 | 900 | 1100 | 1 |
| 2 | 2 | G124804 | gastroEG-290Kp | pentax | 100 | 30000 | 10 | 2500 | 50 | 130 | 900 | 1100 | 1 |
| 3 | 3 | G120387 | colonEC-380LKp | pentax | 100 | 30000 | 10 | 2500 | 50 | 130 | 900 | 1100 | 0 |
| 4 | 4 | H122654 | colonEC-380LKp | pentax | 100 | 30000 | 10 | 2500 | 50 | 130 | 900 | 1100 | 0 |
| 5 | 5 | generico | colon-gastro | pentax | 100 | 30000 | 10 | 2500 | 50 | 130 | 900 | 1100 | 1 |
| 6 | 6 | generico | colon-gastro | pentax | 100 | 30000 | 10 | 2500 | 0 | 0 | 0 | 0 | 1 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |

ATTENTION*

## TABLE DESCRIPTION

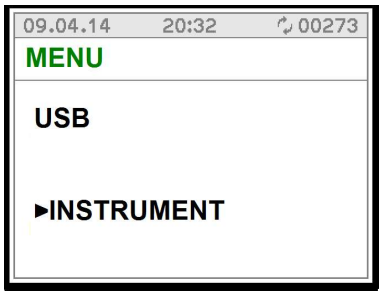
1. Identify the position in the instrument list
2. Instrument code
3. Serial number
4. Instrument denomination
5. Instrument manufacturer
6. Parameter value of endoscope lower washing water flow limit (ml/')
7. Parameter value of endoscope upper washing water flow limit (ml/')
8. Parameter value of endoscope lower limit for washing pressure (mb)
9. Parameter value of endoscope upper limit for washing pressure (mb)
10. Parameter value of aux. channel lower washing water flow limit (ml/')
11. Parameter value of aux. channel upper washing water flow limit (ml/')
12. Parameter value of aux. channel lower limit for washing pressure (mb)
13. Parameter value of aux. channel upper limit for washing pressure (mb)
14. Channels pump

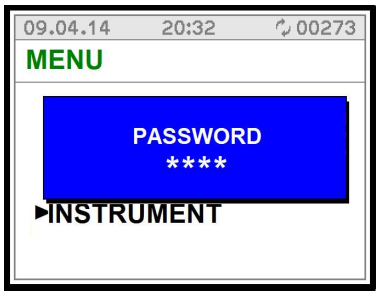
***ATTENTION:**
IF THE INSTRUMENT HAS NO AUX. CHANNEL, SET THE VALUES **10, 11, 12, 13** TO **0.**

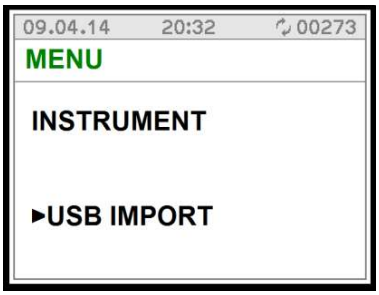
** Channels pump activation;
If it is set to 0=not activated channels pump (When there are small instruments);
If it is set to 1= activated channels pump.

| FIELD | FIXED CHARACTERISTICS |
|---|---|
| **Type of data store** | Nothing |
| **Instrument prefix** | Length = 2<br>Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-" minus sign, "." full stop. |
| **Position in the instrument list** | Progressive order (Maximum number of instruments = 60) |
| **Instrument code** | 1 ≤ Length ≤ 8 characters<br>Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-" minus sign, "." full stop. |
| **Serial number** | Length ≤ 16 (can be empty)<br>Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-" minus sign, "." full stop. |
| **Instrument denomination** | Length ≤ 16 (can be empty)<br>Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-" minus sign, "." full stop. |
| **Instrument manufacturer** | Length ≤ 16 (can be empty)<br>Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-" minus sign, "." full stop. |
| **CHANNELS** | |
| **Parameter value of lower washing water flow limit of endoscope.** | 0 ≤ value ≤ 9999<br>Expressed ml (Es. 115 → 11.5 litres) |
| **Parameter value of upper washing water flow limit of endoscope.** | 0 ≤ value ≤ 9999<br>Expressed ml (Es. 360 → 36.0 litres) |
| **Parameter value of lower limit for washing pressure od endoscope.** | -1000 ≤ value ≤ 2500<br>Expressed millibar (Es. 200 → 0.2 bar) |
| **Parameter value of upper limit for washing pressure of endoscope.** | -1000 ≤ value ≤ 2500<br>Expressed millibar (Es. 1500 → 1.5 bar) |
| **Channels pump** | If it has been setted to 0= no active channels pump<br>(when small instruments are present); |
| **AUX. CHANNELS** | |
| **Parameter value of lower washing water flow limit of endoscope.** | 0 ≤ value ≤ 9999<br>Expressed ml (Es. 115 → 11.5 litres) |
| **Parameter value of upper washing water flow limit of endoscope.** | 0 ≤ value ≤ 9999<br>Expressed ml (Es. 360 → 36.0 litres) |
| **Parameter value of lower limit for washing pressure of endoscope.** | -1000 ≤ value ≤ 2500<br>Expressed millibar (Es. 200 → 0.2 bar) |
| **Parameter value of upper limit for washing pressure of endoscope.** | -1000 ≤ value ≤ 2500<br>Expressed millibar (Es. 1500 → 1.5 bar) |
| **ATTENTION!** | By setting these four values to zero, it means the instrument is without aux. channel. |

It is possible to upload the archive instruments by insert the USB key into dedicated port and enter the menu: **USB → INSTRUMENT → Insert 3rd level password → USB IMPORT → Press START button.**




**ATTENTION**

- To modify the instrument archive file, it is recommended use a text editor (ex. Notepad).
- If the file contains an instrument with the field "**INSTRUMENT CODE**" null (no character), the file is considered valid up to the previous instrument. All subsequent element are ignored.
- If the file contains values that do not comply with the constraints described above, the file is considered incorrect. During the upload it is displayed the first line where the error is present..

# 11. ALARMS and EVENTS LIST

## 11.1 Logical description of alarm interventions

During machine operation, the operator is aided by **ALARMS** or **ALARM MESSAGES** which use visual signals on the display to advise him of possible anomalies in progress and machine alarms which have intervened.
Intervention of an ALARM during operation of the system is signalled by a message on the operator panel.
The alarm which appears on the panel remains active until the cause of intervention is removed, and the alarm reset.
The intervention of an alarm stops the wash cycle currently in progress.

## 11.2 List of alarm messages

The message includes the number of the alarm that has intervened and its name.

| N° AL. | DISPLAY MESSAGE | ALARM DESCRIPTION |
|---|---|---|
| E 1 | **power fail** | It shows power failure during cycle (Diagnostic is active if P3.04≠END CYCLE). |
| E 2 | **open load. door** | Loading door open and/or unlocked during cycle. |
| E 3 | **open unload.door** | Unloading door open and/or unlocked during cycle. |
| E 4 | **load.door fail.** | Loading door locked but open (discrepancy). |
| E 5 | **unload.door fail** | Unloading door blocked but open (discrepancy). |
| E 6 | **doors problem** | Incorrect door position ( both open or unblocked). |
| E 7 | **unblock.door 1** | Loading door problems (loading side):<br>a) Overtime lock door ref. P6.14 (problems on the door lock motor).<br>b) During the door lock, the door has been opened. |
| E 8 | **unblock.door 2** | Loading door problems:<br>• Overtime lock door ref. P6.14 (problems on the door lock motor).<br>• During block door, the door has been opened. |
| E 9 | **unlocking 1fail.** | Overtime unlock loading door ref. P6.13. |
| E10 | **unlocking 2fail.** | Overtime unlock unloading door ref. P6.13. |
| E11 | **water 1 lack** | Interruption of water 1 filling (lack of new flowmeter impulse over P6.11). (Alarm for water dosing flowmeters (if P8.26=0)). |
| E12 | **water 1** | Water 1 filling in the tank is not been completed within the maximum time P6.05. (Diagnostic is active if P6.05≠0) |
| E13 | **water 1** | During water 1 filling in the tank, the water level is deactivated when the quantity measured by the flowmeter reaches or exceeds the parameter P7.09. (Diagnostic is active if P7.09≠0) |

| N° AL. | DISPLAY MESSAGE | ALARM DESCRIPTION |
|---|---|---|
| E14 | water 2 lack | Interruption of water 2 filling (lack of new flowmeter impulse over P6.11) |
| E15 | water 2 | Water 2 filling in the tank is not been completed within the maximum time P6.05. (Diagnostic is active if P6.05≠0) |
| E16 | water 2 | During water 2 filling in the tank, the water level is deactivated when the quantity measured by the flowmeter reaches or exceeds the parameter P7.09. (Diagnostic is active if P7.09≠0) |
| E17 | no chemical 1 | Lack of chemical 1. No impulses within the time defined prom parameter (P6.12) with dosing pump active. (Diagnostic is active if P8.27<2) |
| E18 | no chemical 2 | Lack of chemical 2. No impulses within the time defined prom parameter (P6.12) with dosing pump active. (Diagnostic is active if P8.28<2) |
| E20 | no chemical 4 | Lack of chemical 4. No impulses within the time defined prom parameter (P6.12) with dosing pump active. (Diagnostic is active if P8.30<2) |
| E21 | heating element 1 | Discrepancy between the output control and the feedback input for the heating element (delay on the reading = P6.18) |
| E22 | no tank heating | During the heating phase, the water in the tank is fallen below the level of heating ok. |
| E23 | drain problem | The minimum chamber level during the drain has not been reached within the time defined from parameter P6.03 with drain valve open. (Diagnostic is active if P6.03≠0) |
| E24 | fan problem | Diagnostic enabled if P6.19 ≠ 0, in this cases:<br>- the fan pressure switch is open with the fan running at maximum speed<br>- the fan pressure switch is closed with the fan off |
| E25 | drying min°C | During the dryer the air temperature have not reach the temperature set at parameter P7.13, otherwise the temperature is under the set point if the set point is lower than parameter P7.13. |
| E26 | prewash max°C | Tank temperature over maximum setup (P7.14) during prewashing. |
| E27 | tank probe lim°C | Tank temperature over maximum value P7.31 during the working cycles, or P7.32 during sanitation cycle. |
| E28 | dryingprobelim°C | Dryer temperature over maximum value P7.35. |
| E29 | drying max°C | Tank temperature over maximum value P7.33 during the drying phase of working cycles, or P7.34 during sanitation cycle. |
| E30 | tank probe | Tank temperature probe 1 failure. |
| E31 | tank probe 2 | Tank temperature probe 2 failure. |
| E32 | drying probe | Dryer temperature probe 1 failure. |
| E33 | drying probe 2 | Dryer temperature probe 2 failure. |
| E34 | check temp. | Appears when P3.02 = YES, only during the treatment phase and if all of these situations are occurred:<br>a) Tank temperature over value P7.12.<br>b) The temperature between the two probes has a difference higher than P7.11.<br>c) The conditions a) and b) are present by over thirty seconds. |
| E35 | Serial connect.1 | No connection between main board and control panel board. |
| E36 | Serial connect.2 | No serial connection between expansion board to the keyboard (unloading side). |
| E37 | CAN serialconnec. | No connection between main and slave board (can bus). |
| E38 | TIME | During a treatment phase, the temperature after reaching the set point had a oscillation upon and under the set point. The delay on this reading is fixed at 30”. The alarm can be shown also with wrong setting of the chemical loading temperature: chemical loading temperature higher than the set point temperature. |
| E39 | no tank heating | During tank heating phase, the temperature does not increase of 1°C into the time given by parameter P6.01. |
| E40 | chan.obstructed | When the washing pump is ON, the water flowmeter (in the washing cycle with instruments) measure a flow lower than the minimum value defined than:<br>• parameter for single instrument.<br>• parameter P7.36 for selection of 2 instruments.<br>• parameter P7.60 for selection of 3(+) instruments.<br>(Diagnostic is active if P3.48≠0) |

| N° AL. | DISPLAY MESSAGE | ALARM DESCRIPTION |
|---|---|---|
| E41 | chan.disconnect. | When the washing pump is ON, the water flowmeter (in the washing cycle with instruments) measure a flow higher than the maximum value defined than:<br>• parameter for single instrument.<br>• parameter P7.37 for selection of 2 instruments.<br>• parameter P7.61 for selection of 3(+) instruments.<br>(Diagnostic is active if P3.48≠0) |
| E44 | instrum.leakage | During the cycle, activation number of leak valve (endoscope 1) has reached the maximum limit set by parameter P7.58. (it is excluded the first activation to put under pressure the instrument). (Diagnostic is active if P3.47≠0, P3.50=0 and P7.58>0) |
| E45 | instrum.leakage | During the cycle, activation number of leak valve (endoscope 1) has reached the maximum limit set by parameter P7.58. (it is excluded the first activation to put under pressure the instrument). (Diagnostic is active if P3.47≠0, P3.50=0 and P7.58>0) |
| E46 | washing flow | Failure of the flowmeter or washing pump:<br>• When the washing pump is ON, the water flowmeter doesn't read a new impulse within P6.07.<br>• When the washing pump is OFF, the water flowmeter read a number of impulses that exceed P7.20.<br>(Diagnostic is active if P3.48≠0) |
| E47 | flowmeter fail.1 | The chemical flowmeter 1 had count an impulse number higher than set point + P7.21. (Diagnostic is active if P8.27<2) |
| E48 | flowmeter fail.2 | The chemical flowmeter 2 had count an impulse number higher than set point + P7.21. (Diagnostic is active if P8.27<2) |
| E50 | flowmeter fail.4 | The chemical flowmeter 4 had count an impulse number higher than set point + P7.21. (Diagnostic is active if P8.30<2) |
| E51 | water 1 flowmeter | The water 1 flowmeter (control) had count an impulse number higher than set point + P7.20. |
| E52 | water 1 flowmeter | The redundancy water flowmeter 1 had count an impulse number higher than set point + P7.20. (Diagnostic is active if P8.26=0) |
| E53 | water 1 flowmeter | Discrepancy between control and redundancy flowmeters higher than P7.10. (Diagnostic is active if P8.26=0) |
| E54 | Purge pressure | After the time set by P6.16 from the command to open the drain purge valve has been given (following the purge procedure pressurisation stage), the purge pressure has not dropped below the [P7.54 - P7.61] threshold or below the [P7.03 - P7.61] threshold.<br>Active diagnostic if P3.39 is not =0 and P3.50=0. |
| E55 | Conductivity probe | Fault in conductivity probe |
| E56 | Conductivity | The conductivity value exceeds the maximum P7.60 threshold level, with a 5-second debounce |
| E57 | flowmeter fail.1 | Discrepancy between the measured value by time and by flowmeter higher than P7.10. (DETERGENT). (Diagnostic is active if P8.27=0) |
| E58 | flowmeter fail.2 | Discrepancy between the measured value by control flowmeter and redundancy flowmeter higher than P7.10. (DISINFECTANT). (Diagnostic is active if P8.28=0) |
| E60 | flowmeter fail.4 | Discrepancy between the measured value by control flowmeter and redundancy flowmeter higher than P7.10. (DISINFECTANT – bi-component). (Diagnostic is active if P8.30=0) |
| E61 | no water 1 | During water 1 filling in the break tank, the water level is not reaches level within time set by P6.06. |
| E62 | break tank | Emergency level is active. |
| E63 | break tank | Lower level is deactive when work level is active. |
| E64 | drain problem | The minimum break tank level during the drain has not been reached within the time defined from parameter P6.04 with drain valve open. |
| E65 | tank probe lim°C | The chamber temperature has exceeded of 5°C the set point during the treatment phase (controlled by the control probe), in case of:<br>• Temperature set point ≠ 0.<br>• Water filling completed; |

| N° AL. | DISPLAY MESSAGE | ALARM DESCRIPTION |
|---|---|---|
| E66 | **dryingprobelim°C** | The air temperature has exceeded of 5°C the set point during the drying phase (controlled by the control drying probe), when the temperature set point ≠ 0. |
| E67 | **check temp.** | Appears when P3.33=2, only during the drying phase and if all of these situations are occurred:<br>a) Air temperature is over P7.06 value.<br>b) Discrepancy between the two probes is over the P7.05 value.<br>c) The conditions a) and b) are present by over thirty seconds. |
| E68 | **chan.obstructed** | When the washing pump is ON, the water flowmeter (in the washing cycle without instrument) measure a flow lower than P7.44. (Diagnostic is active if P3.48≠0) |
| E69 | **chan.disconnect.** | When the washing pump is ON, the water flowmeter (in the washing cycle without instrument) measure a flow higher than P7.45. (Diagnostic is active if P3.48≠0) |
| E70 | **press.sensor LT1** | Failure on the leak test pressure transducer (instrument 1). (Diagnostic is active if P3.47≠0) |
| E71 | **press.sensor LT2** | Failure on the leak test pressure transducer (instrument 2). (Diagnostic is active if P3.47≠0) |
| E72 | **max pressure LT1** | The leak test pressure is higher than P7.38. (Diagnostic is active if P3.47≠0) |
| E73 | **max pressure LT2** | The leak test pressure is higher than P7.38. (Diagnostic is active if P3.47≠0) |
| E74 | **low pressure LT1** | During a cycle, the leak test pressure is lower than the minimum value, defined by one of the following conditions:<br>• The set point P7.39 is not reached within P6.54<br>• Pressure lower than P7.39 – P.7.40 within P6.56<br>• Pressure lower than P7.39 –P.7.41 during the washing cycle.<br>This alarm occurs also if the endoscope LT is failed, i.e. if the endoscope channel has a leakage. (Diagnostic is active if 3.47≠0) |
| E75 | **low pressure LT2** | During a cycle, the leak test pressure is lower than the minimum value, defined by one of the following conditions:<br>• The set point P7.39 is not reached within P6.54<br>• Pressure lower than P7.39 – P.7.40 within P6.56<br>• Pressure lower than P7.39 –P.7.41 during the washing cycle.<br>This alarm occurs also if the endoscope LT is failed, i.e. if the endoscope channel hasa leakage. (Diagnostic is active if P3.47≠0) |
| E76 | **LT1 drain failure** | The leak test pressure is not fallen under the max pressure value (P7.42) after the drain. (Diagnostic is active if P3.47≠0) |
| E77 | **LT2 drain failure** | The leak test pressure is not fallen under the max pressure value (P7.42) after the drain. (Diagnostic is active if P3.47≠0) |
| E78 | **water 2 flowmeter** | The water 2 flowmeter count a number of impulses that exceeds P7.20 with water filling solenoid valve OFF. |
| E79 | **water 2 lack** | During water 2 filling in the break tank, the water level is not reached level within time set by P6.06. |
| E80 | **washing pump** | Washing pump pressure transducer failure. (Diagnostic is active if P3.48≠0) |
| E81 | **chan.obstructed** | When the washing pump is ON, the transducer measures a pressure higher than:<br>• parameter for single instrument.<br>• parameter P7.47 for selection of 2 instruments.<br>• parameter P7.63 for selection of 3(+) instruments.<br>(Diagnostic is active if P3.48≠0). |
| E82 | **chan.disconnect.** | When the washing pump is ON, the transducer measures a pressure lower than:<br>• parameter for single instrument.<br>• parameter P7.46 for selection of 2 instruments.<br>• parameter P7.62 for selection of 3(+) instruments.<br>(Diagnostic is active if P3.48≠0) |
| E83 | **chan.obstructed** | When the washing pump is ON, the transducer measures a pressure higher than P7.49.<br>This alarm occurs during a treatment cycle or during a self-disinfection cycle. Check the filter and if necessary, replace. (Diagnostic is active if P3.48≠0). |
| E84 | **chan.disconnect.** | When the washing pump is ON, the transducer measures a pressure lower than the P7.48.<br>This alarm occurs during a treatment cycle or during a self-disinfection cycle. (Diagnostic is active if P3.48≠0) |

| N° AL. | DISPLAY MESSAGE | ALARM DESCRIPTION |
|---|---|---|
| E88 | lim °C sump probe | Functional limit for the over temperature protection.<br>The temperature measured form the sump probe is higher than the value of parameter P7.31 on working cycle and P7.32 on sanitation cycles. (Diagnostic is active if P3.49≠0) |
| E89 | Sump probe | Failure on the sump probe. (Diagnostic is active if P3.49≠0) |
| E90 | lim °C sump probe | The temperature measured from the sump probe is 5°C higher than the set point set for that phase (only if the set point is different form 0°C) (Diagnostic is active if P3.49≠0) |
| E91 | flowmeter fail.1 | The disinfectant redundancy flowmeter measures an excess of impulses higher than P7.21 with dosing pump OFF. (Diagnostic is active if P8.27≠0) |
| E92 | flowmeter fail.2 | The disinfectant redundancy flowmeter measures an excess of impulses higher than P7.21 with dosing pump OFF. (Diagnostic is active if P8.28≠0) |
| E94 | flowmeter fail.4 | The disinfectant redundancy flowmeter (for bi-component disinfectant) measure an excess of impulses higher than P7.21 with dosing pump OFF. (Diagnostic is active if P8.30≠0) |
| E95 | sanificat. Flow | - The pressure switch of the sanitation circuit is OFF, but the sanitation valve is open and the pump is ON<br>- The pressure switch of the sanitation circuit is ON, but the sanitation valve is OFF<br>Delay on the pressure switch status reading = P6.52 |
| E96 | purge pressure | Failure on air pressure sensor for purge. (Diagnostic is active if P3.39≠0) |
| E97 | purge pressure | The setpoint set by P7.54 is not reached within maximum time set by P6.59. (Diagnostic is active if P3.39≠0) |
| E98 | Max. air pressure | The air pressure measured from the purge transducer (when the purge activity is in progress) has exceeds the maximum limit set by P7.57. (Diagnostic is active if P3.39≠0) |
| E99 | Min. air pressure | The air pressure measured from the purge transducer (when the purge activity is in progress) has exceeds the minimum limit set by P7.59. (Diagnostic is active if P3.50=YES) |
| E100 | CAN serialconnec. | (Diagnostic is active if P1.23≠0)<br>No connection between main board and gateway (CAN/Ethernet) for interface the supervisor (Diagnostic is active when the machine is in wait mode). |
| E101 | AUX chan block | (Diagnostics are enabled if p3.48 = 2)<br>Possible damage has been caused to the flow meter or to the auxiliary instrument channel pump:<br>- When the aux channel pump is active, the aux channel flow meter does not signal any new pulses beyond the time specified in p6.07;<br>- When the aux channel pump is not in use, the aux channel flow meter signals an excessive amount of pulses exceeding the threshold specified in p7.20<br>(diagnostics are disabled during fan operation). |
| E102 | AUX press probe | (Diagnostics are enabled if p3.48 = 2)<br>Failure of the auxiliary instrument channel pump pressure sensor |
| E103 | AUX chan block | (Diagnostics enabled if p3.48 = 2 and a single instrument is selected)<br>- When the aux channel pump is active, the aux channel water circulation flow meter in cycles with instruments in the chamber has measured a flow rate lower than the min. threshold defined by the parameter of the instrument itself in the instrument file (blocked aux instrument channel) in the following conditions:<br>- The calculation of the water flow rate is updated every 5 seconds while diagnostics are updated every 10 seconds after the first minute by the activation of the water circulation system;<br>- An alarm is triggered if the flow rate remains continuously below the threshold for a period of time exceeding that specified in<br>p6.26;<br>- Diagnostics are disabled in case multiple instruments are selected. |

| N° AL. | DISPLAY MESSAGE | ALARM DESCRIPTION |
|---|---|---|
| E104 | **AUX chan disc** | (Diagnostics are enabled if p3.48 = 2 and a single instrument is selected)<br>- When the aux channel pump is active, the aux channel water circulation flow meter in cycles with instruments in the chamber has measured a flow rate exceeding the max. threshold defined by the parameter of the instrument itself in the instrument file (disconnected aux instrument channel) in the following conditions:<br>- The calculation of the water flow rate is updated every 5 seconds while the diagnostics are updated every 10 seconds after the first minute by the activation of the water circulation system;<br>- An alarm is triggered if the flow rate remains continuously above the threshold for a period of time exceeding that specified in p6.26;<br>- Diagnostics are disabled in case multiple instruments are selected. |
| E105 | **AUX chan block** | Diagnostics are enabled if p3.48 = 2 and a single instrument is selected)<br>- When the aux channel pump is active, the aux channel pressure transducer in cycles with instruments in the chamber has measured pressure exceeding the max. threshold defined by the parameter of the instrument itself in the instrument file (blocked aux instrument channel) in the following conditions:<br>- An alarm is triggered if the pressure remains continuously above the threshold for a period of time exceeding that specified in p6.27;<br>- Diagnostics are enabled after the first minute by the activation of the water circulation system;<br>- Diagnostics are disabled in case multiple instruments are selected. |
| E106 | **AUX chan disc** | (Diagnostics are enabled if p3.48 = 2 and a single instrument is selected)<br>- When the aux channel pump is active, the aux channel pump pressure transducer in cycles with instruments in the chamber has measured pressure lower than the min. threshold defined by the parameter of the instrument itself in the instrument file (disconnected aux instrument channel) in the following conditions:<br>- An alarm is triggered if the pressure remains continuously below the threshold for a period of time exceeding that specified in p6.27;<br>- Diagnostics are enabled after the first minute by the activation of the water circulation system;<br>- Diagnostics are disabled in case multiple instruments are selected. |
| E107 | **AUX press probe** | (Diagnostics are enabled if p3.48 = 2)<br>When the water pressure of the aux instrument channel exceeds the maximum tolerance level of the instrument (2000 mbar).<br>Diagnostics are enabled only when cycle is in progress (not while in stand-by status). |
| E108 | **Sanif. flow** | With sanification valve open and washing pump activated, the water flow is not detected in the hydraulic field of the water flowmeters 1 (lack of new flowmeter pulse from beyond P6.11).<br>Alarm active when for at least one of the two water dosing flowmeters this condition is verified (if P8.26=0). |

## 11.3 List of warnings messages

| DISPLAY MESSAGE | DESCRIPTION |
|---|---|
| **press start** | It is possible to start a cycle during a stand-by state. |
| **no chemical 1** | It informs that the product (DETERGENT) is:<br>• run out if P8.27=2.<br>• ending if P8.27<2. |
| **no chemical 2** | It informs that the product (DISINFECTANT) is:<br>• run out if P8.28=2.<br>• ending if P8.28<2. |
| **no chemical 4** | It informs that the product (DISINFECTANT – BI-COMPONENT) is:<br>• run out if P8.30=2.<br>• ending if P8.30<2. |
| **salt loading** | Warning to carry out loading procedure increases following the performance of a certain number of softener resin re-generations defined in p7.27 (as for configured regeneration, see p7.26 > 10). |
| **- open door -** | Inform that the door is open. |
| **wait** | Generic warn that inform to wait before to do a new action. |
| **close door!** | It warns to close the door open to allow proper initialization of the door. |
| **ON PRINT** | It appears when you try to start a cycle during the printing of the previous cycle. |
| **UNBLOCKING wait** | Automatic unlocking procedure after the unblock switch sequence after an alarm that interrupted a cycle. |
| **ALARM** | The safety procedure after an alarm is completed. It requests the manual unlock of the door pressing the STOP switch. |
| **User interrupt wait** | It warns that is in progress the safety procedure after a manual stop of working cycle. |
| **NO DISINFECTION** | Message shown at the end of the safety procedure after user interruption of the cycle. It requests the manual unlock of the door pressing the STOP switch. |
| **END CYCLE** | It is in progress the end cycle procedure after the last phase of cycle (the door remains locked). |
| **airfilter obstr.** | The air filter is obstructed. |
| **Supervisor wait** | It is in progress the data download of the performed cycle. It is necessary to wait to start new washing cycle. |
| **NO Authorization** | Response from Ares relating to denial of required instrument authorisation |
| **Unidentified instrument** | Response from Ares relating to required instrument not recognised by the supervisor's archive of reference |
| **X REPETITION** | (x = 1, 2, 3) states that repetition number "x" of the stage is in progress (as for stages which can be set with repetitions) |

## 11.4 List of historical events

| EVENT | DISPLAY MESSAGE | DESCRIPTION |
|---|---|---|
| FROM 1 TO 107 | **SAME LIST OF ALARMS** | (SEE ALARMS LIST) |
| 100 | **OK** | CYCLE ENDS WITH SUCCESS |
| 101 | **NO DISINFECTION** | CYCLE HAS BEEN INTERRUPTED |

# 12. INSTALLATION AND OPERATION

As highlighted in Annex A.3 of the ISO 15883:4 2009 standard, from the moment in which the EW 1 system has been installed on the site where it will subsequently be used, the customer/user shall be held responsible for its proper installation and operation.
This includes:

- Checks and installation tests;
- Operational tests;
- Performance qualification tests;
- Periodic tests;
- The use of process chemicals recommended by the manufacturer;
- The use of the EW 1 system in accordance with the manufacturer's instructions (by limiting the use of re-processable devices in the EW 1 system in favor of those recommended by the manufacturer).

# 13. RACK VERSION

**The main device can be in vertical RACK configuration.**
**It refers to a configuration dealing with the disposing of two identical EW1, which are vertically placed, one on the machine top and the other one on the machine bottom.**
**Both these machines are equipped with:**

- **2 screens (one corresponding to the machine top and the other one corresponding to the machine bottom);**
- **2 printers (one corresponding to the machine top and the other one corresponding to the machine bottom);**
- **a barcode reader system (one corresponding to the machine top and the other one corresponding to the machine bottom);**
- **a system of filters dedicated to each machine;**
- **a single chemical compartment in common for the two machines;**
- **a single electrical cabinet situated on the top of the machine.**
  **That system has been designed so that each machine is able to work on its own;**

# 14. MAINTENANCE

## 14.1 General recommendations on maintenance

This machine has been designed only and exclusively for the reprocessing of flexible and rigid endoscopes and the thermal-disinfection of washing chambers. Therefore it is subject to continuous contact with aggressive detergents and contaminated instruments.
For this reason it is necessary to provide some useful instructions for the operators who will be performing maintenance on it.

**The maintenance technicians,** in normal operating conditions, are not subject to risks if they work safely using suitable means of protection.
In order to work safely the maintenance technician must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Use special care in making repairs or replacing mechanical parts (e.g. drain pump, etc.) on malfunctioning machines which have not completed the thermal disinfection cycle.

Maintenance operations for the machine described in this manual can be divided into "**Routine Maintenance**" and "**Special Maintenance**".

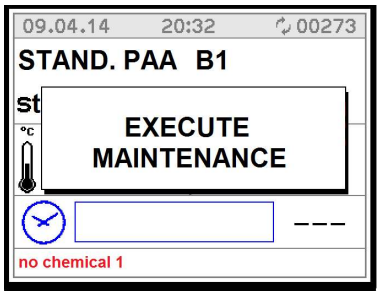
**GENERAL GUIDELINES:**

***MACHINE STATUS***
The machine must not be powered electrically and the dedicated safety device must be in the OFF position.
The person performing the task must ensure that there is no-one around the machine during this operation.

***SAFETY SYSTEMS TO BE ADOPTED***
The operation must be carried out in compliance with standards governing the use of disinfectant substances used (see technical information for the product being used), in compliance with standards concerning contact with parts of the machine which may be contaminated by pathogenic materials and with use of individual protection gear.

### 14.1.1 Maintenance request

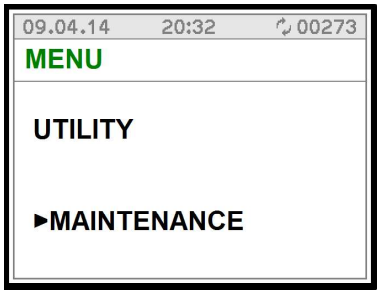
The machine displays the "**MAINTENANCE**" warning after a specified time or after a specified numbers of working hours according to parameter **P6.48.** This warning doesn't affect the normal use of machine. The service technician must do the maintenance operations in the shortest possible time.

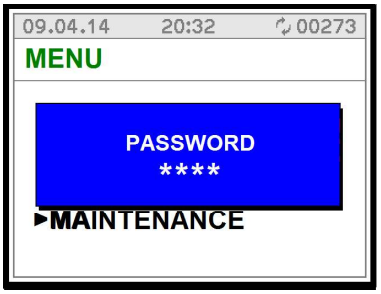



To clear the "**MAINTENANCE**" warning, follow the procedure:

1. Do the general maintenance of machine;
2. Enter the menu:

   **UTILITY → MAINTENANCE (level password request) → MAINTENANCE → REGISTER → press button.**




## 14.2 Table of routine maintenance

The following table shows the various routine maintenance tasks, their frequency, who is to perform them and the reference to the specific intervention form.
Each single task is more fully explained in the single reference forms.

Even if the water supply is relatively soft, the high temperature can cause the formation of residues which may create problems with the heating element, compromising the correct wash cycle and the reaching of the disinfection temperature.
For these reasons it is advisable to carry out regular cleaning as described below.

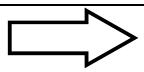
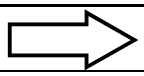
## TABLE OF ROUTINE MAINTENANCE TASKS

**ENDOSCOPES WASHER**

**Programmed maintenance scheme**

| Components | Step: make every..... | months: 3 | 6 | 9 | 12 | 15 | 18 | 24 | Activity | TIME | REFERENCE |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Chamber filters | make every day | | | | | | | | Take off filters and cleaning. | 10' | M1 |
| Water solenoid filter | make every..... | | x | | | | x | | Check, clean and if necessary replace. | 10' | M4 |
| Pre filter dryer F5 | make every 100 hours | | | | | | | | Replace. | 2' | M5 |
| Dryer HEPA filter | make every 300 hours | | | | | | | | Replace. | 2' | M5 |
| Temperature probes | make every..... | | | | x | | | x | During periodic validation, check the sensor status. | 60' | M2 |
| Safety thermostat | make every..... | | | | x | | | x | Verify the sensor. | 5' | |
| Chemical dosing pump | make every..... | | x | | x | | x | x | Check the presence of leakage. | 5' | |
| Chemical tank level sensor | make every..... | | x | | x | | x | x | Check and clean the suction filter. | 4' | |
| Connection pipe of dosing pump | make every..... | | x | | x | | x | x | Check of crashing, any leakage or hardening. | 10' | |
| Washing arms | every week | | | | | | | | Check for free rotation.<br>Open the cleaning caps and wash inside: check and in case cleaning the nozzle. | 30' | M3 |
| Door gasket | make every... | | x | | x | | x | x | Verify the gasket and replace after 1000 cycles. | 20' | |
| Washing pumps | make every... | | | | x | | | x | Check for water leakage from the arm seal. | 5' | |
| Water heating element | make every... | | | | x | | | x | Check for water leakage fro the gasket. | 1' | |
| Dryer heating elements (OPTIONAL) | none | | | | | | | | Operation is checked by the control system. | | |
| Water solenoid valves | make every... | | | | x | | | x | Check for any leaks, if necessary remove and clean the membrane seat. | 3' | |
| Drain pump | make every... | | | | x | | | x | Check for any leaks, if necessary remove and clean the membrane seat. | 3' | |
| Pressure switches | make every... | | | | x | | | x | Operation is checked by the control system.<br>In case of defect of control system of water levels, go on by empting the tank, blowing inside the black pipe connected to the pressure switch, in oder to free from obstructions. | 10' | |
| Pipe of unloading water | make every... | | | | x | | | x | Check the situation of pipe and the seal. | 3' | |
| Pipes of loading water | make every... | | | | x | | | x | Check the situation of pipe and the seal. | 3' | |

**N.B.:**
**Routine maintenance tasks must be performed at the intervals set forth in the table.**
**It is however advisable to carry out single cleaning tasks anytime you feel they may be necessary.**

| | |
|---|---|
| In case the machine requires the replacement of one or more components, please refer to the manufacturer's spare part list. | |
|  | **It is advisable to carry out a general check-up and to clean the appliance regularly, particularly if the supply water is very hard.** |
|  | **Particular attention should be paid to heating element and the probe of thermostats.** |

## WARNING:

- **Do not clean the machine outside with high pressure water.**
- **Please contact the retailer that supplies your cleaning products for details of recommended methods and products for sanitizing the machine regularly.**
- **The machine has a safety thermostat that shuts down the power supply to the heating elements in the event of overheating.**
  **To re-start the appliance the fault that caused overheating must be corrected.**
- **Empty the tank of compressor before performing the maintenance.**

## Every 12 months

- **Clean the diaphragms of solenoid valves and replace if necessary.**
- **Clean the thermostat probe.**

Even if the supply water is soft, the high working temperatures may cause limescale to build-up. Apart from damaging the resistors, limescale can also clog the nozzles in which case the correct tank temperature for thermodisinfection may not be reached.

## ATTENTION

**Before undertaking any sort of special maintenance or movement of machine, empty tanks and chemical dosing circuit from the chemical. It is advised to execute a treatment cycle without chemical.**

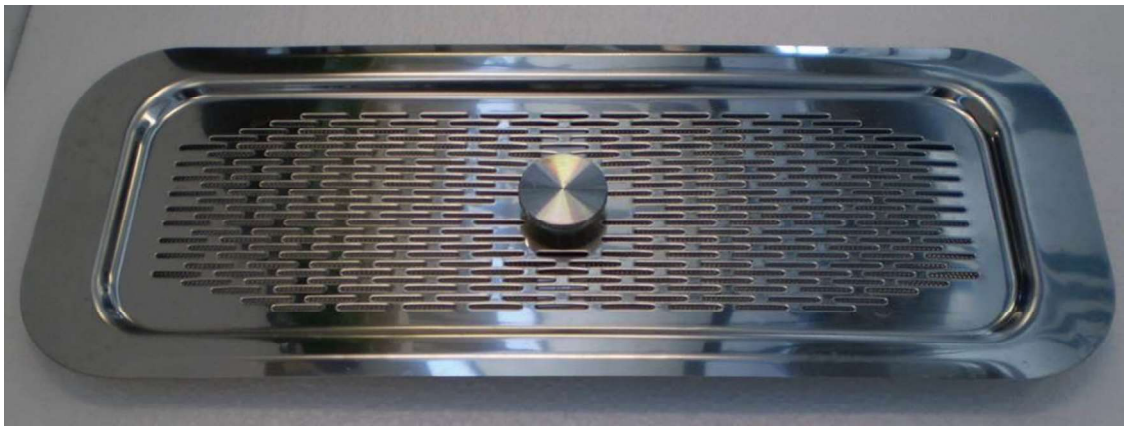
**This procedure must be carried out in order to prevent contact of the chemical product with body parts and machine components that can be damage.**

## CLEANING OF WASHING CHAMBER DRAIN FILTERS

| M1 | Worker: **Ac** | Frequency of Intervention: **every day** |
|---|---|---|

***METHOD OF INTERVENTION:*** clean the washing chamber drain filters in the following manner:

- Open the washing chamber door and extract the basket.
- Extract the drain water filtering assembly from the chamber.



- Unscrew the threaded pin and remove the cover of the drain water filter basket.

- Clean the drain water filter basket. Remove residues deposited during various wash cycles.
- Remove and clean any deposits and incrustations from the wash chamber drain.
- Replace the clean filter on the wash chamber drain.
- Put the cover for the drain water filter back in place. Lock it in position with the threaded pin.
- Put the drain water filter group back in the washing chamber.

## CLEANING OF WASHING CHAMBER TEMPERATURE PROBE

| M2 | Worker: **Is** | Frequency of Intervention: **6 months** |
|---|---|---|

***METHOD OF INTERVENTION:*** clean the washing chamber temperature probe in the following manner:

- Open the washing chamber door and extract the basket.
- Check the washing chamber thermostat probe and clean it of any deposits or lime incrustations using a damp cloth and an appropriate detergent.

**Take care not to damage or move the probe**

## CLEANING OF WASHING ARMS

| M3 | Worker: **Ac** | Frequency of Intervention: **every week** |
|---|---|---|

***METHOD OF INTERVENTION:*** clean the washing arms as follows:

- Open the washing chamber door and extract the basket.

- Unscrew the fastening pin of the two rotors and extract them from the chamber.
- Unscrew the closure plug of the rear part of the nozzle and remove it.

- Carefully cleaned and remove any incrustations from the wash rotor nozzles using appropriate detergents.
- Put the plugs back in place at the ends of the wash arms. Make sure the gasket is properly positioned and in good condition. Replace it if necessary.
- Put the rotors back on the machine. Lock them in place with the previously removed fastening pin.

| CHECK OF WASHING ARMS ROTATION | | |
|---|---|---|
| | Worker: **Ac** | Frequency of Intervention: **every day** |

***METHOD OF INTERVENTION:*** check the washing arms rotation as follows:

- Open the washing chamber door and extract the basket.
- Check the free washing arm rotation for both upper and lower arms checking that no slowdown is shown from the washing arms.

| CLEANING THE EXTERNAL BODY OF THE MACHINE | | |
|---|---|---|
| | Worker: **Ac** | Frequency of Intervention: **every day** |

***METHOD OF CLEANING OUTER BODY***

Use a damp cloth to clean the outer body of the machine.
Use only neutral detergents.
Do not use abrasive detergents or solvents and/or thinners of any kind.

***METHOD OF CLEANING MARKING LABEL***

Use a damp cloth to clean the marking label surface. Use only water or isopropyl alcohol.
Do not use abrasive detergents or solvents and/or thinners of any kind.

***METHOD OF CLEANING CONTROL PANEL***

Clean the control panel using only a soft cloth dampened with a product for the cleaning of plastic materials.

| LIMESCALE REMOVAL TREATMENT | | |
|---|---|---|
| | Worker: **Ac** | Frequency of Intervention: **whenever necessary** |

***METHOD OF INTERVENTION:***

Use a descaling agent (we recommend vinegar) during an empty washing cycle with cold water (this is usually carried out every week unless the quality of the water requires a daily treatment in order to prevent the build-up of limescale and the blockage of the water jets).
As regards the quantity of the product to use, please comply with the instructions given on the technical data sheet of the product itself. In case vinegar is used, use 0.5 litres.
The descaling product must be poured into a container of the same size, positioned on an empty loading basket.
Use a washing programme with water at room temperature, without activating the drying cycle.

**ATTENTION**

**Even if the feed water only contains a small amount of limescale, high temperatures can generate the formation of limescale residues. This, as well as problems that could be caused to the heating element, may cause the blockage of the nozzles, jeopardising the correct washing process and preventing the ideal disinfection temperature in the tank to be reached.**

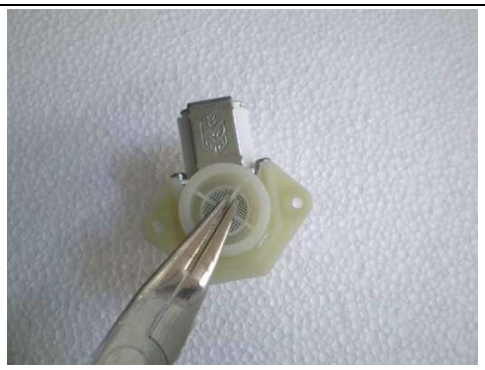
## 14.4 Procedure for special maintenance work

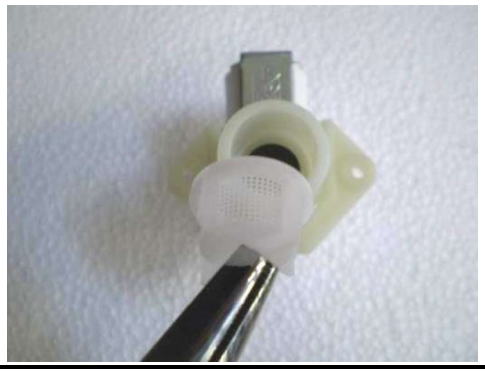
All special maintenance work is to be performed only by qualified, skilled personnel.
A table is shown below which includes possible special maintenance work that may be required.
If your machine should require special maintenance, please contact your retailer/distributor.

# 14.5 Table of special maintenance

See scheduled maintenance table.

| CLEANING OF WATER SOLENOID VALVES INLET FILTERS | | |
|---|---|---|
| **M4** | Worker: **Is** | Frequency of Intervention: **6 months or when necessary** |
| ***METHOD OF INTERVENTION:*** clean (or replace) the water solenoid valve filter as described below: | | |
| • Close the water supply tap.<br>• Loosen and completely unscrew the water supply pipe.<br>• Remove the filter located inside the water supply pipe fitting and clean it, removing any incrustation or deposits by immersing it in a container of water, or in appropriate lime removal products if required. | | |





## CLEANING OF DRYING PRE-FILTER

| M5 | Worker: **Is** | Frequency of Intervention: **100 hours** |
|---|---|---|

***METHOD OF INTERVENTION:*** clean (or replace) the drying system filter as described below:

- Remove the two screws from the drying system filter protective front panel and remove it from the machine.



- Extract the filter and clean it of any dust. If the filter is no longer usable, replace it with another filter of the same type.
- Carefully put the clean (or new) filter back in place. Use the screws to fasten the previously removed protective front panel.

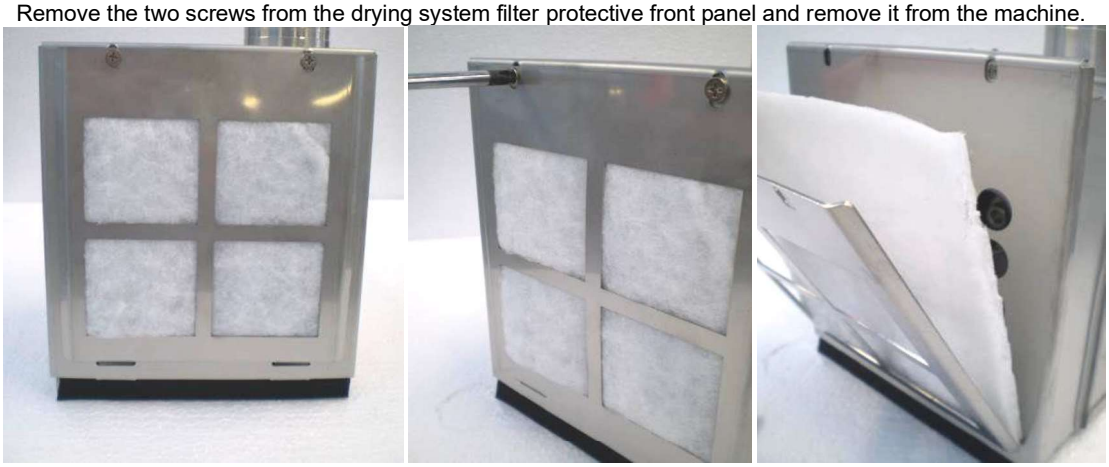


## CLEANING OF DRYING HEPA FILTER

| M6 | Worker: **Is** | Frequency of Intervention: **300 hours** |
|---|---|---|

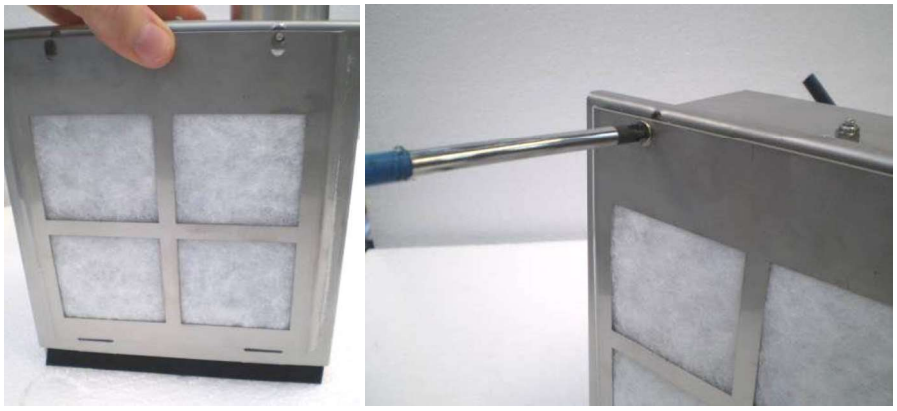
***METHOD OF INTERVENTION:*** clean (or replace) the drying system filter as described below:

- Remove the two screws from the drying system filter protective front panel and remove it from the machine.



- Extract the pre-filter and than the HEPA filter: replace it with another filter of the same type.

- Carefully put the pre-filter back in place. Use the screws to fasten the previously removed protective front panel.

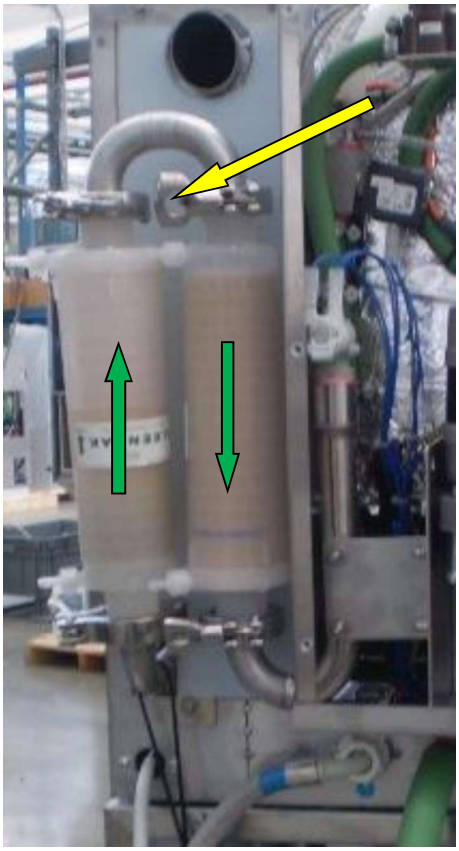


## REPLACEMENT OF WATER FILTERS

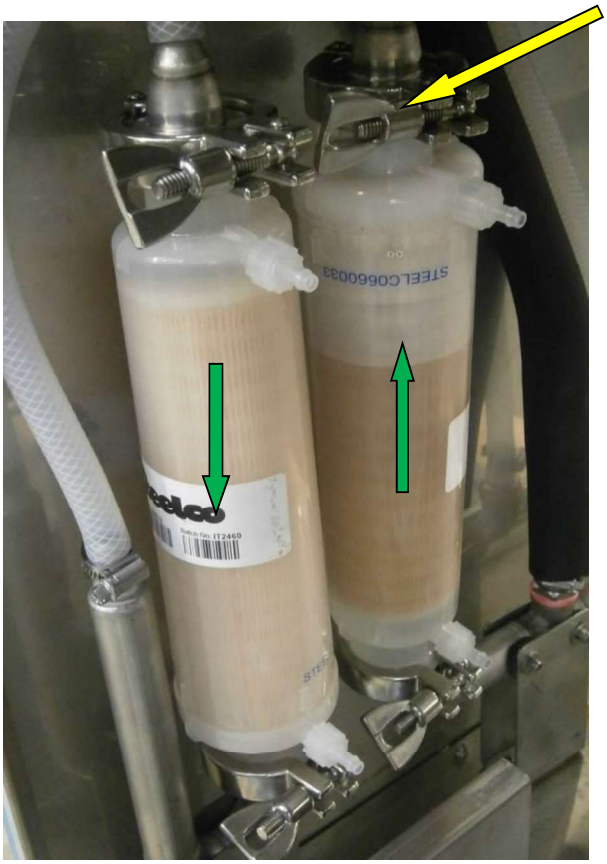
| M7 | Worker: **Is** | Frequency of Intervention: **every year** |
|---|---|---|

***METHOD OF INTERVENTION:*** replace water filters (0,1 micron and 0,45 micron) as described below:

- Remove water filters by unscrew pin of clamp (yellow arrow) and remove gasket between filters and machine pipe fitting.
- Replace water filters. Pay attention to flow direction (green arrow). Every filter has an arrow on the body to indicate the correct flow of water.
- Insert the gasket.
- Check the absence of leak.



**MACHINE WITH ONE DOOR**



**MACHINE WITH TWO DOORS**

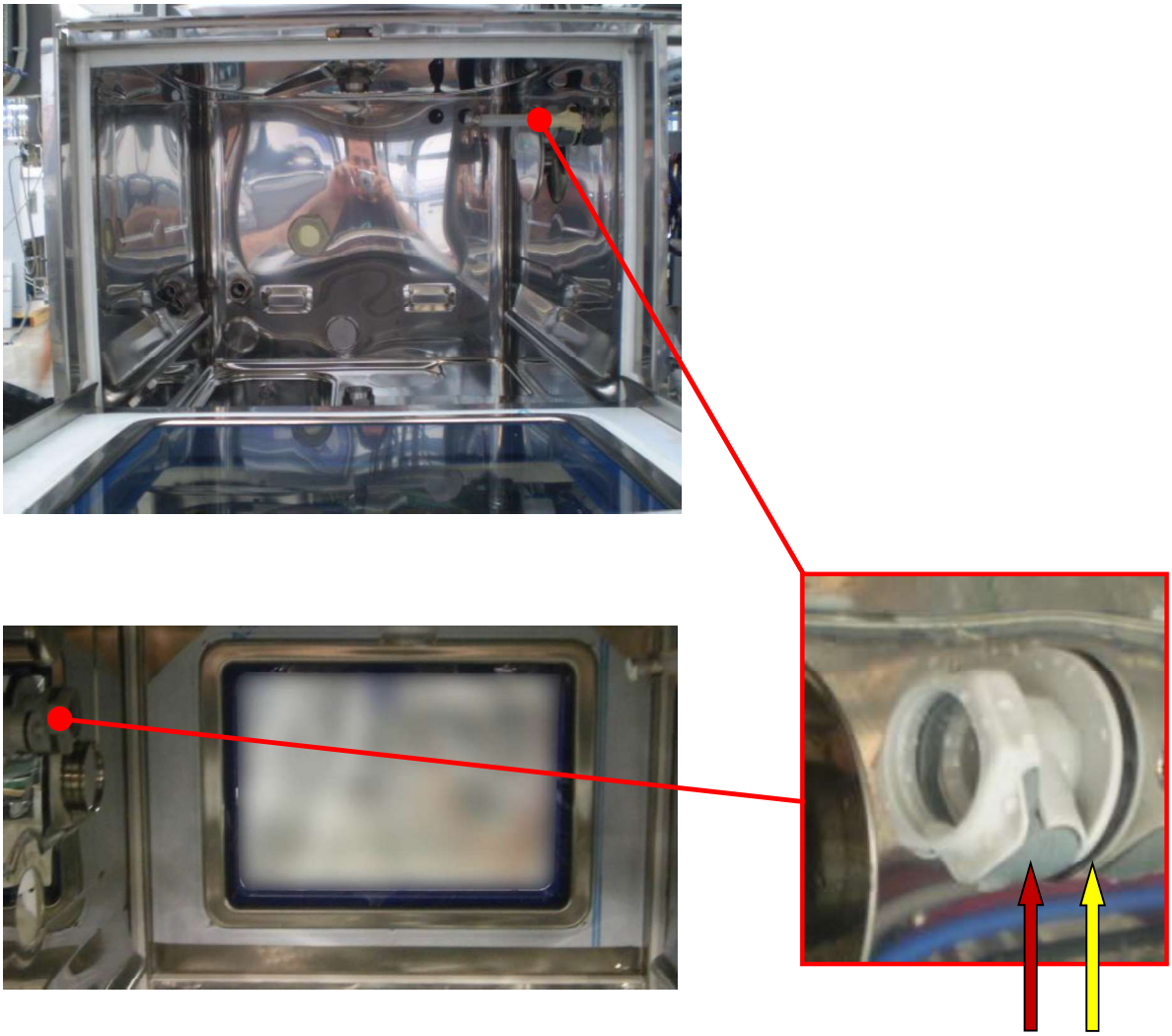
## CHECKING OF SELF-DISINFECTION CONNECTOR

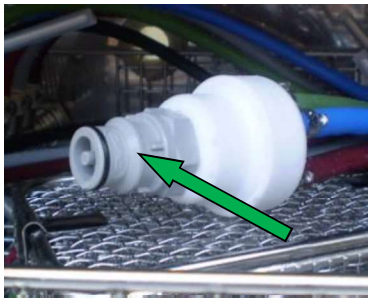
| M8 | Worker: **Is** | Frequency of Intervention: **every 3 months** |
|---|---|---|

***METHOD OF INTERVENTION:*** check the self-disinfection connector into the washing chamber as described below:

- Check that self-disinfection female connector (yellow arrow) is fixed in its place and that the gasket doesn't have leakage (check during self-disinfection cycle).
- Check that male connector (green arrow) can be freely connected/disconnected to/from female connector. To disconnect male connector, press grey button placed on female connector (red arrow).

**ATTENTION:**
Do not force the connection or disconnection of male connector when it is inserted to do not damage the gasket or the female connector.





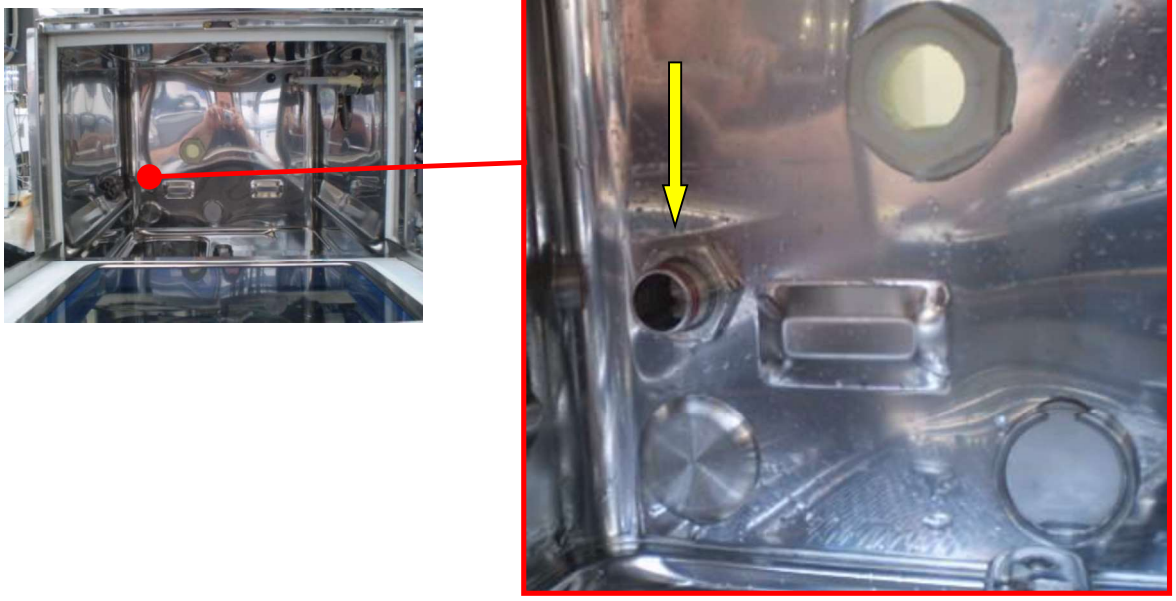
## CHECKING/REPLACEMENT OF BASKET CONNECTION GASKET (only for one door version)

| M9 | Worker: **Is** | Frequency of Intervention: **every 3 months** |
|---|---|---|

***METHOD OF INTERVENTION:*** check of integrity of gasket for the connection between machine and basket, as described below:

- Check and/or replace the OR gasket on the connector machine and basket (yellow arrow).

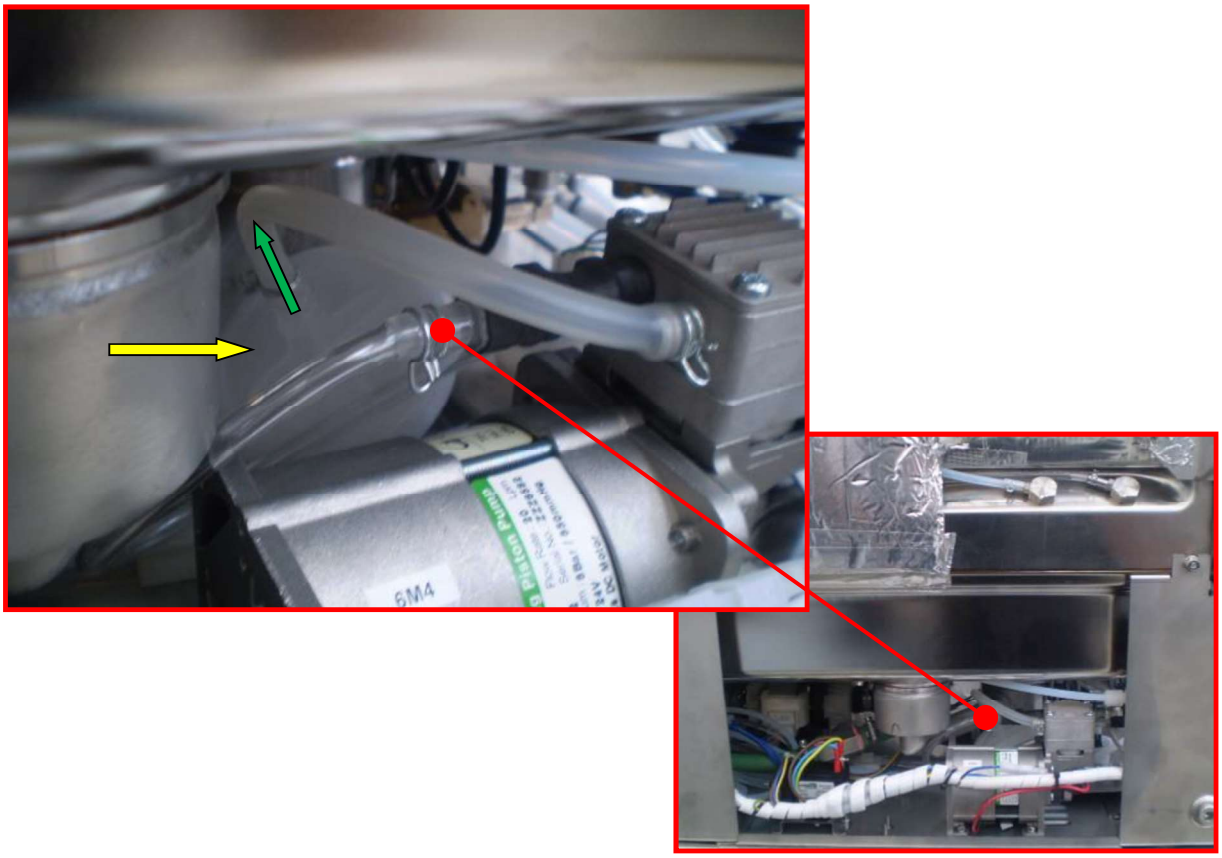
**ATTENTION:**
In case the OR-gasket is broken or too worn, the machine will show a disconnection alarm of endoscope channels.



| REPLACEMENT OF AIR FILTER FOR LEAK TEST | | |
|---|---|---|
| **M10** | Worker: **Is** | Frequency of Intervention: **every year** |

***METHOD OF INTERVENTION:*** replace leak test filter (0,2 micron) as described below:

- Remove cover panels from the machine.
- The filter is placed on the left side of machine, looking from unloading side.
- Replace the filter (yellow arrow). Pay attention to the suction direction indicated on the filter body (green arrow).

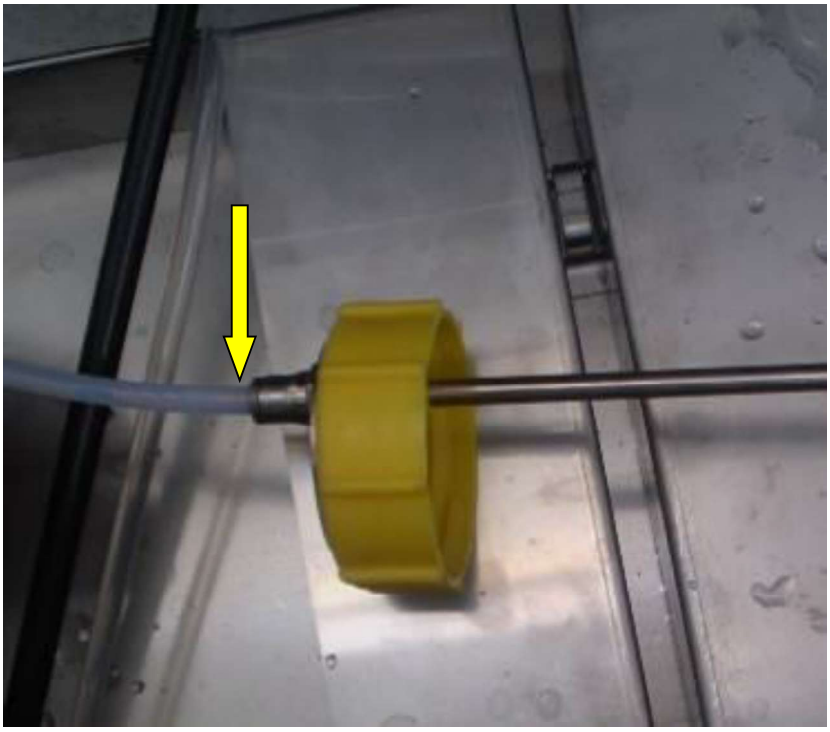


## CHECKING THE SUCTION LANCE OF CHEMICAL PRODUCT 2 (DESINFECTANT)

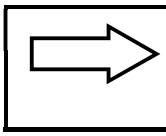
| M11 | Worker: **Is** | Frequency of Intervention: **every 3 months** |
|---|---|---|

***METHOD OF INTERVENTION:*** check the suction lance of chemical product 2 as described below:

- Check pipe integrity in the point indicated with yellow arrow, without remove the suction lance from container of chemical 2. In case the pipe is damaged or crushed, remove pipe from the connector (Inox fast coupling, rotating at 360°) and cut the damaged component.
- Check the suction pipe is not damaged throughout its length.

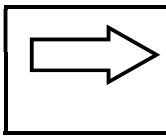


| CLEANING OF SAFETY SIGNALS SURFACES | | |
|---|---|---|
| | Worker: **Is** | Frequency of Intervention: **1 year** |
| ***METHOD OF INTERVENTION:*** | | |
| Clean the safety signals surfaces with water or isopropyl alcohol, using a cloth. | | |



**WARNING**

**Use a specific product to remove the lime scale. Avoid using products highly corrosive.**



**ASSISTANCE**

Should your machine not work properly even after ordinary maintenance has been carried out, contact the Technical Support Centre of reference, describing the fault and giving the machine model and serial numbers.

# 15. PROBLEMS - CAUSES – SOLUTIONS

## 15.1 Introduction

This chapter includes possible problems which may occur during machine operation, along with their cause and solution. Should the inconveniences continue or take place frequently even after having carried out all the instructions stated in this chapter, please contact the Technical Support Centre of reference.

## 15.2 Problems - Causes - Solutions

**P. MACHINE WILL NOT START:**

**C.** Circuit breaker de-activated.

**S.** Place it in the "ON" working position.

**C.** Machine start switch de-activated.

**S.** Press the start button.

**P. UPON GIVING START-UP COMMAND, WASHING CYCLE DOES NOT START:**

**C.** The door is not correctly closed or locked.

**S.** Check door closure. Check that the door micro-switch is properly activated.

**C.** Micro-switch failure.

**S.** Check operation and replace as necessary.

**C.** No detergent in tank.

**S.** Turn the machine off and fill the tank.

**P. MACHINE DOES NOT REACH THE SET TEMPERATURE FOR THE SELECTED WASHING CYCLE:**

**C.** The thermostat probe of the washing chamber is dirty or covered with lime.

**S.** Clean the thermostat probe of the wash chamber, performing the routine maintenance described in chapter 13.

**P. MACHINE DOES NOT PROPERLY RUN WASHING CYCLE:**

**C.** The nozzles of the washing rotors are clogged by deposits or lime.

**S.** Clean the washing arms by carrying out the routine maintenance set forth in chapter 13.

**C.** The correct amount of water required for correct washing cycle does not arrive.

**S.** Ensure that the water is supplied at the correct pressure and that there are no obstructions.

**C.** The correct amount of water required for correct washing cycle does not arrive.

**R.** Completely close the tap for connection to the plumbing system located upstream from the machine and clean the filter as described in chapter 13.

**P. DETERGENT FILLING PHASE DOES NOT OCCUR CORRECTLY:**

**C.** Chemical dispensing pump not very efficient.

**S.** Perform the routine maintenance set forth in chapter 13.

**C.** Chemical dispensing pump failed.

**S.** Contact the Technical Support Centre of reference and ask for the assistance of an **authorized workshop technician** for the repair or replacement of the pump.

**I. MACHINE DOES NOT PERFORM DRYING PHASE:**

**C.** Air filter of drying system is dirty or clogged.

**R.** Clean the filter by carrying out the routine maintenance set forth in chapter 13.

**C.** The fan of the drying system does not work.

**R.** Check the electrical connections of the drying system.

**R.** Contact the Technical Support Centre of reference and ask for the assistance of an **authorized workshop technician** for the repair or replacement of the motor.

# 16. DECOMMISSIONING

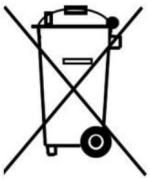
## 16.1 Instructions for disassembly of the machine

For demolition and subsequent disposal of your machine, proceed as follows:

- Disconnect the machine from the electrical power and water supply, and from the drain. With the machine disconnected, check that the water circuit is not pressurized.
- Contact the organization responsible for reporting and certifying machine demolition, in accordance with the laws in the country where the machine is installed.
- Carry out draining, storage and subsequent disposal of substances such as oils and grease which may be in the lubrication tanks in accordance with the law.
- When disassembling the machine, make sure to divide the materials it is made of according to their chemical makeup (iron, aluminium, bronze, plastic, etc.).
- Ensure that the floor where the machine or any parts of it are placed is made of washable materials, non-absorbent, and provided with adequate drainage to protect against accidental oil leaks or rust.
  These drains must carry any leakage to watertight collection containers.
- Cover the machine or parts of it with insulating covers to prevent rain or humidity from damaging the structure through oxidation or rust.

**Following the legal requirements where the machine is installed and used, dispose of all materials and substances resulting from its disassembly.**

## 16.2 Machine disposal



- For the dispose of the equipment get through to the manufacturer or distributor.
- Do not dispose of this equipment as miscellaneous solid municipal waste but arrange to have it collected separately.
- The re-use or correct recycling of the electronic and electrical equipment (EEE) is important in order to protect the environment and the well-being of humans.
- In accordance with European Directive WEEE 2012/19/EC, special collection points are available to which to deliver waste electrical and electronic equipment and the equipment can also be handed over to a distributor at the moment of purchasing a new equivalent type.
- The public administration and producers of electrical and electronic equipment are involved in facilitating the processes of the re-use and recovery of waste electrical and electronic equipment through the organisation of collection activities and the use of appropriate planning arrangements.
- Unauthorized disposal of waste electrical and electronic equipment is punishable by law with the appropriate penalties.

# ANNEX A – TRAINING CERTIFICATE

devoted to hygiene

Certificate N° 569

## Training Certificate

We certify that Mr. **XXXXXXXX** of the company **XXXXXXX** has attended the training course for

**EW1**

Riese Pio X, 17/10/2013

Person in charge for training

D. Alessi

**Steelco S.p.A.**

Via Balegante, 27 - 31039 - Riese Pio X (TV) - Italy
Tel. +39 0423.7561 Fax +39 0423.755528
Website: www.steelcospa.com

"For the Environmentally conscious"

MD 18#10 Rev.00

# ANNEX B – WATER SAMPLING DURING THE FINAL RINSING CYCLE

Annex B provides both the instructions and the methods to take the microbiological sample by using the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check) as well as the relative key for the decoding and the reading of the results obtained.
In any case, please refer to current Legislation, National Guidelines and/or internal protocols.

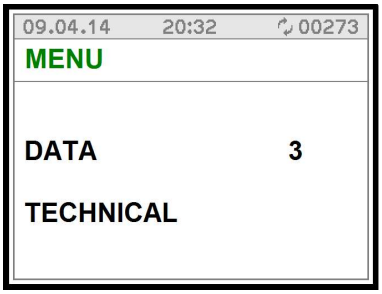
**Q water BSK**
**Professional Sampling Kit for Bacterial Check**
**(code 99911268)**

Endoscopes can be re-processed in the cycle dedicated to biological sampling. The only difference compared to a normal disinfection cycle refers to the interruptions during the final rinsing phase.

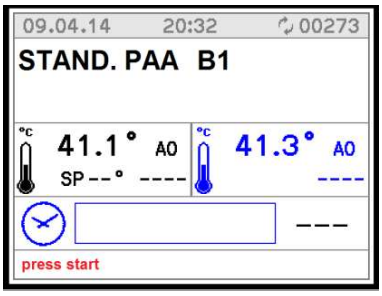
Water samples are taken during the final rinsing stage following the disinfection stage. The final rinsing cycle consists of two stages.
The sample must be taken during the final rinsing stage.

It is possible to take a water sample from the washing chamber by carrying out the following procedure:

- Set the parameter P3.42 = YES.
- Note: at the end of the water sample-taking cycle, restore the value to NO.




- Start the cycle to be tested.




- The machine will stop at the end of every stage and the door lock will be released.
- The **START** button will be flashing.
- Press the **START** button again to continue the cycle up to the desired point in order to take the water sample from the washing chamber.

- Open the door of the washing chamber and pick up the water sampling from the sump by using the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check). Be sure to perform the sampling in an aseptic way.



- Close the door and press the **START** button again to continue the cycle.

It is possible to activate the validation cycle by using the barcode reader, instead of changing the parameters.
The modification is valid for a cycle, then it will automatically reset.

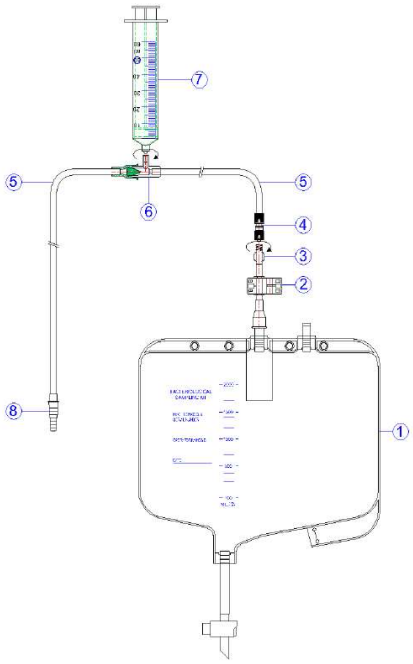
ENABLE C.V.T.

## ATTENTION

- **Adequate measures must be implemented to avoid contamination of the sample during the water sample-taking stage. It is recommended to use the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check).**
- **The water samples for the microbiological test must be taken only during the final rinsing stage. Samples must not be taken during other stages of the process.**
- **Correct, periodic maintenance of the equipment prevents the risk of contamination. Follow the manufacturer's instructions for bacteriological filters as well as any pre-filters.**
- **It is important to schedule appropriate thermal disinfection and chemical self-disinfection cycles in accordance with the manufacturer's**

## SAMPLE TAKING

In order to take water samples during the final rinsing stage use the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check - code 99911268) and follow the instructions below:




1. Insert the 80 cm PVC pipe **(5)** into the sump of the washing chamber;
2. Suck the water from the washing chamber using the 60 ml syringe **(7)**;
3. Push the plunger of the syringe **(7)** to drain the water into the collection bag for biological fluids **(1)**;
4. Disconnect the collection bag for biological fluids **(3)** from the Kit and hand it to the microbiology laboratory quickly.
5. Compile the fields on the bag with the appropriate information:
   - Model and serial number of the machine;
   - Name and ID of the operator (that takes the water sampling);
   - Date.

## REPROCESSING CYCLE EFFECTIVENESS TEST CARRIED OUT IN THE SUCTION CHANNEL

**It is also possible to test the effectiveness of the entire re-conditioning cycle of the endoscope suction channel in the following way:**

- Put 20 ml of sterile water in the suction channel (by using a sterile syringe) collecting it from a sterile container situated at the distal part of the tool;
- Clean the same channel using a special cleaning brush by cutting it directly inside the sterile water container. **WARNING:** the cleaning brush **MUST** be sterile.
- Remember to close all air and water channel valves before carrying out this procedure.
- Every single container must be accompanied not only by the request form but also by the endoscope type and serial number, the type of channel on which the brushing has been carried out, the name of the operator performing the sampling procedure as well as the report relating to the re-conditioning cycle carried out.

## INTERPRETATION OF THE RESULTS

As for the interpretation of the results, please refer to the following table and criteria.

| NUMBER OF COLONIES/100 ml | INTERPRETATION | ACTION |
|---|---|---|
| **0** | **SATISFACTORY** | --------- |
| **1-9 (carried out on a regular basis)** | **ACCEPTABLE** | Count under reasonable control |
| **10-100** | **UNSATISFACTORY** | Investigate by implementing opportune thermal disinfection and chemical self-disinfection cycles |
| **>100** | **UNACCEPTABLE** | Stop the endoscope washer. Start two thermal disinfection and two chemical self-disinfection cycles. Repeat the test of control and take necessary actions as regards decontamination. |

After interpreting the results, take opportune measures in accordance with the 2 attached tables.

| NUMBER OF COLONIES (NOT PSEUDOMONAS) | | |
|---|---|---|
| **TVC LEVEL** | | **ACTION** |
| **SATISFACTORY** | **< 1cfu/100 ml** | • No action required. |
| **ACCEPTABLE** | **1 – 9 cfu/100 ml** | • The personnel must have carried out a self-disinfection cycle in the morning in accordance with the instructions provided by the endoscope washer manufacturer as well as internal protocols.<br>• The carrying out of a daily self-disinfection cycle. |
| **UNSATISFACTORY** | **10 – 50 cfu/ ml** | • The personnel must carry out two thermal disinfection cycles (one after another - 80°C for 10 min) and a special chemical disinfection cycles (35°C for 10 min double chemical). |
| | **51 – 100 cfu/ ml** | • The personnel must carry out a special chemical disinfection cycle as well as a thermal disinfection cycle (one after another 80°C for 10 min one after another 55°C for 10 min double chemical).<br>• Take another water sample. |
| **UNACCEPTABLE** | **> 100 cfu/100 ml** | **STOP USING THE ENDOSCOPE WASHER.**<br>The person in charge of the endoscope washer must:<br>• Carry out a special chemical disinfection cycle (55° double chemical for 10 min).<br>• Carry out 2 thermal disinfections cycles (one after another to 80°C for 10 min).<br>• Take another water sample.<br><br>The personnel must:<br>• Do not use the endoscope washer until it has been confirmed that the water sample has a contamination value of < 100 cfu/100 ml.<br>• Continue to carry out a self-disinfection cycle on a daily basis.<br>• Carry out a special thermal disinfection cycle on a daily basis.<br><br>**Note: Advice will be obtained from the Lead Doctor for Infection Prevention and Control if there are recurring unacceptable TVC levels.** |

| NUMBER OF COLONIES (PSEUDOMONAS) | | |
|---|---|---|
| **TVC LEVEL** | | **ACTION** |
| **SATISFACTORY** | **< 1cfu/100 ml** | • No action required. |
| **ACCEPTABLE** | **1 – 9 cfu/100 ml** | • The personnel must have carried out a self-disinfection cycle in the morning in accordance with the instructions provided by the endoscope washer manufacturer as well as internal protocols.<br>• The carrying out of a daily self-disinfection cycle.<br>• Do not re-process endoscopes until it has been confirmed that the water sample has a contamination value of < 6 cfu/100 ml. |
| **UNSATISFACTORY** | **10 – 50 cfu/ ml** | • The personnel must carry out two thermal disinfection cycles (one after another - 80°C for 10 min) and a special chemical disinfection cycles (35°C for 10 min double chemical).<br>• Do not re-process endoscopes until it has been confirmed that the water sample has a contamination value of < 6 cfu/100 ml. Do not re-process cystoscopes or bronchoscopes until it has been confirmed that water sample has a contamination value of < 10 cfu/100 ml. |
| | **51 – 100 cfu/ ml** | • The personnel must carry out two special chemical disinfection cycles (55°C for 10 min double chemical) and two thermal disinfection cycle (one after another 80°C for 10 min).<br>• Take another water sample.<br>• Do not re-process endoscopes until it has been confirmed that the water sample has a contamination value of < 6 cfu/100 ml. Do not re-process cystoscopes or bronchoscopes until it has been confirmed that water sample has a contamination value of < 10 cfu/100 ml.<br><br>**Note: Advice will be obtained from the Lead Doctor for Infection Prevention and Control if there are recurring unacceptable TVC levels.** |
| **UNACCEPTABLE** | **> 100 cfu/100 ml** | **STOP USING THE ENDOSCOPE WASHER.**<br>The person in charge of the endoscope washer must:<br>• Replace all internal filters and clean the filter cases. Carry out 2 special chemical disinfection cycles (55° double chemical for 10 min).<br>• Carry out 2 thermal disinfection cycles (one after another to 80°C for 10 min).<br>• Take another water sample.<br><br>The personnel must:<br>• Do not use the endoscope washer until it has been confirmed that the water sample has a contamination value of < 100 cfu/100 ml.<br>• Continue to carry out the thermal disinfection cycle on a daily basis.<br>• Carry out a chemical self-disinfection cycle on a daily basis.<br><br>• Do not re-process endoscopes until it has been confirmed that the water sample has a contamination value of < 6 cfu/100 ml. Do not re-process cystoscopes or bronchoscopes until it has been confirmed that water sample has a contamination value of < 10 cfu/100 ml.<br><br>**Note: Advice will be obtained from the Lead Doctor for Infection Prevention and Control if there are recurring unacceptable TVC levels.** |

# ANNEX C – TEST PROCEDURE WHEN INSTALLING

**ATTENTION**

During the first installation of the equipment upon the site of use, with the aim of eliminating the risk of contamination of the endoscope washer, following maintenance operations that influence critical parts of the endoscope washer (wash pumps, etc.) or after transferring the endoscope washer to another operational centre, the following procedure **MUST** be carried out:

- 3 empty cycles carried out using only detergent;
- 2 complete cycles with detergent + disinfectant;
- 1 thermal disinfection cycle carried out at 80°C.

**ATTENTION**

**USE ONLY CHEMICAL PRODUCTS THAT HAVE BEEN TESTED AND APPROVED BY THE MANUFACTURER AND IN USE WITH THIS SYSTEM.**

Steelco

Miele Group Member

# AERs

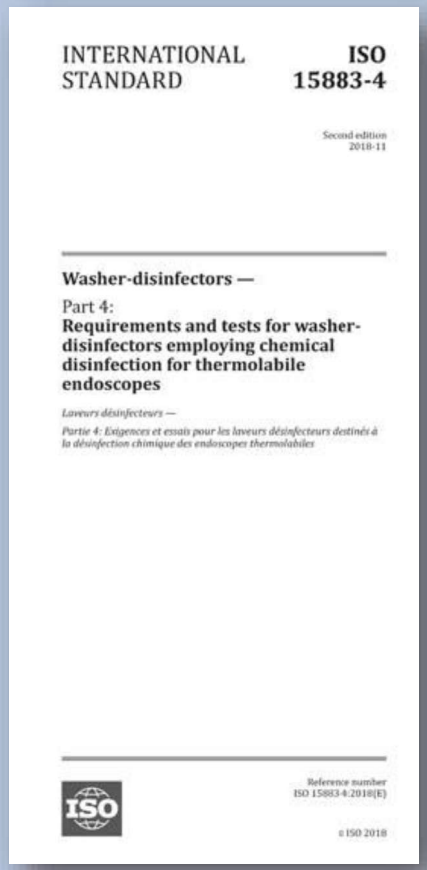
# CLOSED SYSTEM REQUIREMENTS RATIONALE


# RATIONALE

*Main reasons why it's important to keep ISO 15883:4 compliance according with international and National Standard Requirements, Guidelines, Manufaturer Technical Features and Safety Rules:*

1. ISO 15883-4 validation
2. Level 2 Script of the wfhss (World Federation for Hospital Sterilization Science) education group Reprocessing Endoscopes
3. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018
4. Legal implications linked to the Endoscopy Department Risk Management
5. Infections & MDRs
6. Patient Safety

# RATIONALE 1



INTERNATIONAL STANDARD

**ISO 15883-4**

Second edition
2018-11

**Washer-disinfectors —**

Part 4:
**Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes**

*Laveurs désinfecteurs —*

*Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles*

ISO

Reference number
ISO 15883-4:2018(E)

© ISO 2018

## ISO 15883-4 REQUIREMENTS

# RATIONALE 1

## ISO/FDIS 15883-4:2018(E) requirements:

### Clause 8 Information to be supplied by the manufacturer

n) the detergent(s) and disinfectant(s) type tested with the WD, (see 4.3.3 and 4.4.5);

# RATIONALE 1

## ISO/FDIS 15883-4:2018(E)

**ANNEX A**

**A.2 Before installation of the WD**

It is expected that the WD manufacturer will:

— state with which endoscopes the WD can be used;

**— provide test data demonstrating the performance of the WD with respect to both cleaning and disinfection using process chemicals specified by the WD manufacturer; this is to be done in the light of information provided by the process chemical manufacturer;**

**ANNEX 3**

**A.3 Installation and operation of the WD**

It is the responsibility of the purchaser/user facility to ensure that the WD is installed and operated correctly.

**The responsibility for ensuring that the WD is correctly installed and functions correctly usually falls to the purchaser/user.**

**This includes:**

— performance qualification tests;

**— use of the recommended process chemicals;**

# RATIONALE 1

**A full ISO Validation means a Technical Dossier made of 20 Type Test provided by the manufacturer** (on top of this the manufacturer has to guarantee full compatibility of machine components with chemicals and chemicals compatibility with endoscopes). Type test must be performed by an independent certified Microbiological LAB.

**A PQ (performance Qualification)** enclose **8 recomended test** and it's not to be intended as a full compliance with ISO 15883:4.

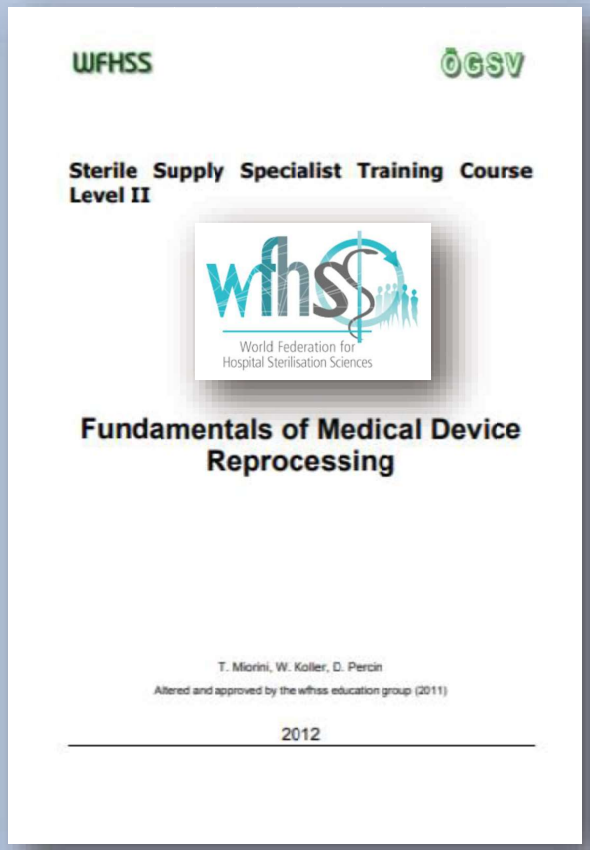
Table C.2 — Summary of tests in addition to ISO 15883-1:2006+Amd 1:2014

| Brief description of test | Requirement subclause | Test sub-clause | Type test | Works test | Operational qualification test | Performance qualification test | Routine[a] test |
|---|---|---|---|---|---|---|---|
| 1. Leak test failure alarm | 4.2.3 | 6.5.3.3 | X | X | X | B | X (Q) |
| 2. Leak test non-connection test | 4.2.4<br>4.2.5 | 6.5.3.4 | X | X | B | X | ~~B~~<br>X(Q) |
| 3. Leak test over-pressurization prevention test | 4.2.4 d) | 6.5.3.2 | X | X | B | B | B |
| 4. Cleaning efficacy | 4.3.5 | 6.11 | X | B | X | X | X (Q) |
| 5. *in vitro* disinfectant efficacy | 4.4.2.2 | 6.12.2 | X | B | B | B | B |
| 6. Disinfection efficacy — Type test | 4.4.2.5 | 6.12.6.1 | X | B | B | B | B |
| 7. Complete process — Operational and performance qualification | 4.1.3 | 6.12.6.2<br>6.12.6.3 | O<br>O | B<br>B | X<br>B | O<br>X | X<br>X (Q) |
| 8. Drying | 4.7 | 6.8 | X | O | X | B | X |
| 9. Disinfection of liquid transport system — Type test | 4.8.5 | 6.12.5.1 | X | B | B | B | B |
| 10. Disinfection of liquid transport system — Operational qualification and routine test | 4.8.5 | 6.12.5.2 | O | B | X | B | X |
| 11. Self-disinfection test — Type test | 4.8.7 | 6.12.3.1 | X | B | B | B | B |
| 12. Self-disinfection test — Operational qualification and routine test | 4.8.7 | 6.12.3.2 | O | B | X | B | X |
| 13. Disinfection of water treatment equipment | 4.9.2 | 6.12.4.1 | X | B | O | B | B |
| 14. Final rinse water treatment — Microbial quality | 4.5.2 | 6.12.4.2 | O | B | X | B | B |
| 15. Channels non-obstruction test | 5.2.2.1 | 6.6 | X | X | B | X | X(Q) |
| 16. Channels non-connection test | 5.2.2.2 | 6.7 | X | X | B | X | X (Q) |
| X – Recommended<br>B – Not recommended<br>O – Optional<br>Q – Quarterly, W – Weekly<br>[a] Frequency of routine testing may be established based on risk assessment using trend analysis. | | | | | | | |

Table C.2 *(continued)*

| Brief description of test | Requirement subclause | Test sub-clause | Type test | Works test | Operational qualification test | Performance qualification test | Routine[a] test |
|---|---|---|---|---|---|---|---|
| 17. Temperature throughout process | 4.4.3<br>5.4.2<br>5.4.3 | 6.9 | X | X | X | X | X (Q) |
| 18. Minimum process temperature test | 5.4.4 | 6.9.2 | X | X | X | X | X (Q) |
| 19. Water quality | 4.5.2<br>4.9.2.3 a)<br>4.9.2.3 b) | 6.3 | B | B | X | X | X (W)<br>X (Q) |
| 20. Chemical dosing test (single-dose container) | 5.7 | 6.10 | X | X | X | B | O |
| X – Recommended<br>B – Not recommended<br>O – Optional<br>Q – Quarterly, W – Weekly<br>[a] Frequency of routine testing may be established based on risk assessment using trend analysis. | | | | | | | |

# RATIONALE 2




**LEVEL 2 SCRIPT OF THE World Federation Hospitals Sterilisation Science EDUCATION GROUP REPROCESSING ENDOSCOPES**

# RATIONALE 2

World Federation for Hospital Sterilisation Sciences

**The WFHSS dedicates itself to the promotion of the worldwide harmonization of sterilization departments and of decontamination practices especially by providing:**

1. a meeting place for national and regional non-profit sterilization societies, thus stimulating cooperation and the exchange of information and best practices;
2. information via its website to all our stakeholders and interested parties.

# RATIONALE 2

In the **Level 2 Script of the wfhss education group Reprocessing Endoscopes** is stated the following:

*Compatibility of the chemical substances used for reprocessing (i.e. compatible detergent and disinfectant) is an important factor for successful reprocessing. If incompatible substances are used together, this can give rise to massive chemical reactions (e.g. white deposits on the endoscope). Ask the supplier to give a written confirmation of safety and compatibility!*

*There is a European (and international) standard (EN ISO 15883-4) regulating endoscope washer-disinfectors, which sets out the requirements for an EWD as well as its performance criteria.*

The above statement shows that the ISO 15883-4 compliance means the use of certified and validated chemistries by the AER manufacturer.

# RATIONALE 3

Position Statement

Thieme

**Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018**

ESGE ESGENA


Authors

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ABSTRACT

This Position Statement from the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology Nurses and Associates (ESGENA) sets standards for the reprocessing of flexible endoscopes and endoscopic devices used in gastroenterology. An expert working group of gastroenterologists, endoscopy nurses, chemists, microbiologists, and industry representatives provides updated recommendations on all aspects of reprocessing in order to maintain hygiene and infection control.




**REPROCESSING OF FLEXIBLE ENDOSCOPES AND ENDOSCOPIC ACCESSORIES USED IN GASTROINTESTINAL ENDOSCOPY:**

**POSITION STATEMENT OF THE EUROPEAN SOCIETY OF GASTROINTESTINAL ENDOSCOPY (ESGE) AND EUROPEAN SOCIETY OF GASTROENTEROLOGY NURSES AND ASSOCIATES (ESGENA) – UPDATE 2018**

# RATIONALE 3

ESGENA Update 2018

All Steelco AERs are fully compliant to EN ISO 15883:4 standard.

Certifications have been released by European Certified Labs:

20/30 Labs

HYGCEN GERMANY

BIOTECH·GERMANDE

**RECOMMENDATION**

EWDs compliant with EN ISO 15883 standard series should be the first choice for endoscope cleaning and disinfection, in order to:

- Provide a standardized and validated reprocessing cycle in a closed environment;
- Document the process steps automatically (via a printer or electronically);
- Provide reliable and reproducible reprocessing;
- Minimize staff contact with chemicals and contaminated equipment;
- Minimize contamination of the environment;
- Facilitate the work involved for personnel;
- Lower the risk of damage to endoscopes

PROCESS VALIDATED

# RATIONALE 4

**LEGAL IMPLICATIONS**
**LINKED TO THE ENDOSCOPY DEPARTMENT**
**RISK MANAGEMENT**

# RATIONALE 4

**Risk Management/Legal issues**

Patients **claims against physicians and health institutions** are increasing and becoming a serious problem in health economy.

**Strategies for decreasing these claims and reducing financial losses are an important part of every health plan.**

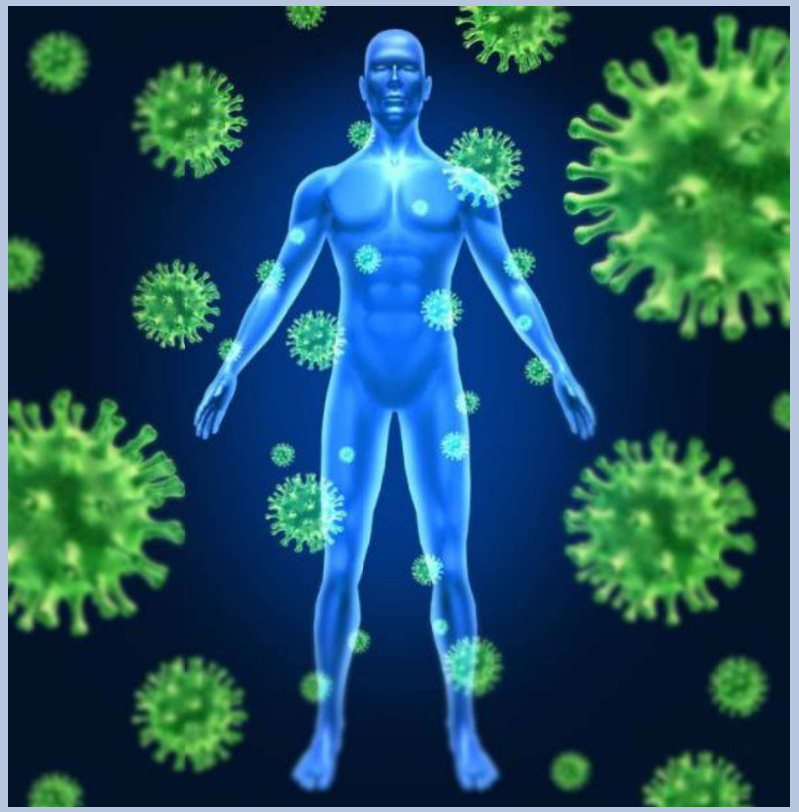
**Reporting adverse events, complications and fulfilling protocols, guidelines, standards and norms should be an integral part of daily routine daily work in gastroenterology units and endoscopy departments.**

Being prepared in case of patients potential claims is important for several reasons:

- To prove that all the endoscopes reprocessing procedures have been put in place according with the most recent protocols, standard, guidelines, norms and are fully traced & documented
- To prove that all the reprocessing devices have been installed, served and used according to manufacturer instructions *(use of approved & validated chemistry is part of it) → IQ, OQ, PQ*
- To prove endoscope compatibility with the chemistry in use, with the AER and connectors and when possible demonstrate the safer traceability of the chemistry by the AER by the adoption of RFID labels able to read batch number, exipiration date and residual quantity to run cycles

# RATIONALE 5

## INFECTIONS & MDRS



# RATIONAL 5

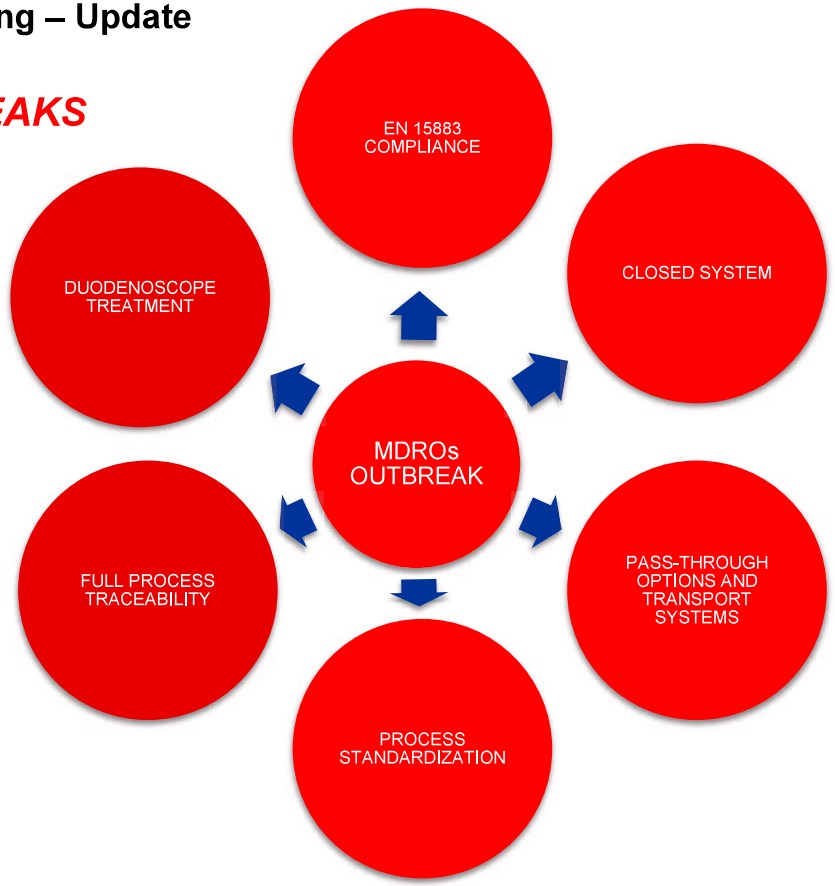
**Prevention of multidrug resistant infections from contaminated duodenoscopes Position Statement of ESGENA**

Safe and effective endoscope reprocessing is crucial to patient safety in endoscopy. Noncompliance with guidelines as well as deviations from standardized and validated reprocessing protocols may lead to ineffective reprocessing, with the possibility of patient-to-patient transmission. Recent MDRO outbreaks show how narrow the margin of safety is, despite compliance with reprocessing protocols.

# RATIONAL 5

**ESGENA Position Statement on Endoscopes Reprocessing – Update 2018:**

***HOW TO FIGHT AGAINST MDROS OUTBREAKS***



# RATIONALE 6

## PATIENT SAFETY

# RATIONALE 6

**Patients Safety & Nurses Piece of mind means that:**

- Every gastroenterology unit should adopt quality indicators and quality improvement plans for advancing patient safety.

- Endoscopy staff is responsible for individual, comprehensive patient care, technical assistance including reprocessing, documentation and management of endoscopy units.

**Why?:**

- Several studies reported a lack of compliance with established guidelines for endoscope reprocessing.

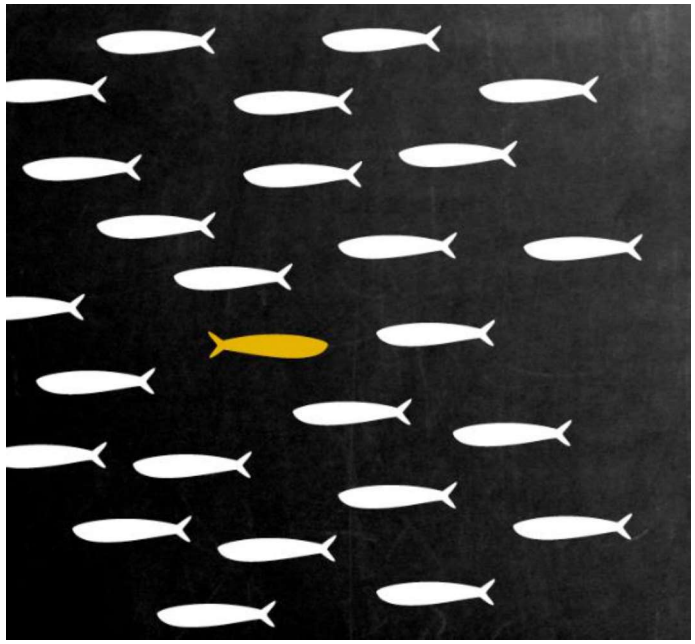
**An increased risk of infection transmission has been associated with:**

- endoscope and AER use
- human error
- inadequate or delayed reprocessing
- failure to sterilize accessory equipment
- incorrect selection of disinfectants
- improper drying

Steelco Miele Group Member

Question ourselves then …

Why should we take the risk to «swim against the tide»?



Steelco

Miele Group Member

# THANK YOU
for your
# ATTENTION!

# CERTIFICATO CE

Certificato n. 909/MDD

## Dichiarazione di approvazione del sistema qualità

*(Sistema completo di garanzia qualità)*

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

**STEELCO SPA**

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (ITA) - Italy

mantiene nello stabilimento di:

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (ITA) - Italy

31039 RIESE PIO X (TV) - VIA DEL LAVORO 3 (ITA) - Italy

31039 RIESE PIO X (TV) - VIA DEL LAVORO 9/A (ITA) - Italy

31039 RIESE PIO X (TV) - VIA DEL LAVORO 12 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

**Lavapadelle a termodisinfezione per uso medicale**

**Termodisinfettori per uso medicale**

**Lavaendoscopi per uso medicale**

**Lavastrumenti per decontaminazione ad uso medicale**

**Lava disinfettatrice-sterilizzatrice chimica per endoscopi**

**Sterilizzatore al perossido di idrogeno**

**Soluzione sterilizzante al perossido di idrogeno**

**Disinfettori termici e/o chimici per uso medicale**

**Soluzione sterilizzante alla formaldeide**

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

| | |
|---|---|
| *Emesso il:* | 2006-03-10 |
| *Data aggiornamento:* | 2020-09-11 |
| *Sostituisce:* | 2020-07-03 |
| *Data scadenza:* | 2024-05-26 |

Giorgi Fulvio
IMQ DocuSign

# CERTIFICATO CE

Certificato n. 909/MDD

## Dichiarazione di approvazione del sistema qualità

*(Sistema completo di garanzia qualità)*

Riferimento pratiche IMQ:

DM17-0017730-01; DM17-0016713-01; DM17-0020271-01; DM18-0027447-01; DM18-0030229-01; DM18-0032276-01; DM19-0034875-01; DM18-0033656-01; DM19-0040534-01; DM19-0044781-01; DM20-0048677-01; DM20-0048683-01; DM20-0052515-01; DM20-0052521-01; DM20-0048679-01; DM20-0055248-01.

**Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.**

| | |
|---|---|
| *Emesso il:* | 2006-03-10 |
| *Data aggiornamento:* | 2020-09-11 |
| *Sostituisce:* | 2020-07-03 |
| *Data scadenza:* | 2024-05-26 |

Giorgi Fulvio
IMQ

DocuSign

# CERTIFICATO CE

Certificato n. 909/MDD

## Allegato

**Lavapadelle a termodisinfezione per uso medicale**

**Termodisinfettori per uso medicale**

**Lavaendoscopi per uso medicale**

**Lavastrumenti per decontaminazione ad uso medicale**

**Lava disinfettatrice-sterilizzatrice chimica per endoscopi**

**Sterilizzatore al perossido di idrogeno**

**Soluzione sterilizzante al perossido di idrogeno**

**Disinfettori termici e/o chimici per uso medicale**

**Soluzione sterilizzante alla formaldeide**

Modd. come da documento allegato "ELENCO PRODOTTI" rev. 02 del 02/09/2020, valido solo se provvisto del timbro IMQ; tale allegato costituisce parte integrante e sostanziale del presente certificato.

| | |
|---|---|
| *Emesso il:* | 2006-03-10 |
| *Data aggiornamento:* | 2020-09-11 |
| *Sostituisce:* | 2020-07-03 |
| *Data scadenza:* | 2024-05-26 |

Giorgi Fulvio
IMQ

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# EC CERTIFICATE

Certificate No 909/MDD

## Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

**STEELCO SPA**

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (ITA) - Italy

manages in the factory of:

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (ITA) - Italy

31039 RIESE PIO X (TV) - VIA DEL LAVORO 3 (ITA) - Italy

31039 RIESE PIO X (TV) - VIA DEL LAVORO 9/A (ITA) - Italy

31039 RIESE PIO X (TV) - VIA DEL LAVORO 12 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

**Flusher disinfectors / Bedpan washers**

**Washer disinfectors**

**Endoscope washers**

**Decontamination clenears**

**Chemical washer disinfector and sterilizer for endoscopes**

**Hydrogen peroxide sterilizer**

**Hydrogen peroxide sterilizing agent**

**Thermal and/or chemical washer disinfectors for medical purpose**

**Formaldehyde sterilizing solution**

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

| | |
|---|---|
| *Date:* | 2006-03-10 |
| *Updated:* | 2020-09-11 |
| *Substitution Date:* | 2020-07-03 |
| *Expiry Date:* | 2024-05-26 |

Giorgi Fulvio
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# EC CERTIFICATE

Certificate No 909/MDD

## Full Quality Assurance System Approval Certificate

Reference to IMQ files Nos:

DM17-0017730-01; DM17-0016713-01; DM17-0020271-01; DM18-0027447-01; DM18-0030229-01; DM18-0032276-01; DM19-0034875-01; DM18-0033656-01; DM19-0040534-01; DM19-0044781-01; DM20-0048677-01; DM20-0048683-01; DM20-0052515-01; DM20-0052521-01; DM20-0048679-01; DM20-0055248-01.

**This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.**

| | |
|---|---|
| *Date:* | 2006-03-10 |
| *Updated:* | 2020-09-11 |
| *Substitution Date:* | 2020-07-03 |
| *Expiry Date:* | 2024-05-26 |

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# EC CERTIFICATE

Certificate No 909/MDD

## Annex

**Flusher disinfectors / Bedpan washers**

**Washer disinfectors**

**Endoscope washers**

**Decontamination clenears**

**Chemical washer disinfector and sterilizer for endoscopes**

**Hydrogen peroxide sterilizer**

**Hydrogen peroxide sterilizing agent**

**Thermal and/or chemical washer disinfectors for medical purpose**

**Formaldehyde sterilizing solution**

Type ref. as to attached document "LIST OF PRODUCTS" rev. 02 dated 2020/09/02, valid only if provided with IMQ stamp; this annex is integral and substantial part of this certificate.

| | |
|---|---|
| *Date:* | 2006-03-10 |
| *Updated:* | 2020-09-11 |
| *Substitution Date:* | 2020-07-03 |
| *Expiry Date:* | 2024-05-26 |

Giorgi Fulvio
IMQ

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**Lavapadelle a termodisinfezione per uso medicale** della serie **BP** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE | | CARROZZERIA | | ALLESTIMENTO |
|---|---|---|---|---|---|---|---|
| | | | NUMERO | MOVIMENTO | LARGHEZZA | ALTEZZA | |
| Serie: **BP**<br>Marca: Steelco | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 750W<br>a 9900 W | 1 o 2 | MANUALE<br>/<br>SEMI-AUTOMATICA<br>/<br>AUTOMATICA | STANDARD<br>/<br>RIDOTTA<br>/<br>MAGGIORATA | STANDARD<br>/<br>ALTA | STANDARD<br>/<br>E |

Nomi commerciali modelli: — Fascicolo tecnico:

**BP 100 M, BP 100 M9, BP 100 A, BP 100 A9, BP 100 H, BP 100 H5, BP 100 HS, BP 100 HA, BP 100 HA5, BP 100 HE, BP 100 HSE, BP 100 HAE, BP 100 HSER, BP 100 HL, BP 100 HLS, BP 100 HLA, BP 100 HL2MM, BP 100 HL2AM, BP 100 HXL** — **DT-FT-01_M**

**Termodisinfettori per uso medicale** della serie **DS** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE | | CARROZZERIA | OPTIONAL |
|---|---|---|---|---|---|---|
| | | | NUMERO | MOVIMENTO | | |
| Serie: **DS**<br>Marca: Steelco | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 2200W<br>a 37000W | 1 o 2 | MANUALE<br>/<br>AUTOMATICA | STANDARD<br>/<br>ALTA | ASCIUGATURA<br>/<br>3 o 4 DOSATORI<br>/<br>DEPURATA |

Nomi commerciali modelli: — Fascicolo tecnico:

**DS 50, DS 50 D, DS 50 DRS, DS 50 DRSD, DS 50 HDRS, DS 50 HDRSD, DS 50/2, DS 50/2 D, DS 50/2 DRS, DS 50/2 DRSD** — **DT-FT-04_M**

**DS 500, DS 500 D, DS 500 DRS, DS 500 DRSD, DS 500 DRS4, DS 500 LED, DS 500 LEDD, DS 500 SC, DS 500 SCD, DS 500 SCL, DS 500 SCDL, DS 500 CL, DS 500 CDL, DS 600/1, DS 600/1 D, DS 600/2, DS 600/2 D, DS 600 C, DS 600 CD, DS 600/1 1S, DS 600/2 1S, DS 610/1, DS 610/1 D, DS 610/2, DS 610/2 D, DS 610/1 1S, DS 610/1 2S, DS 610/2 1S, DS 610/2 2S, DS 610/1 SL, DS 610/1 SLD, DS 610/2 SL, DS 610/2 SLD, DS 610/1 SL1S, DS 610/1 SL2S, DS 610/2 SL1S, DS 610/2 SL2S** — **DT-FT-03_M**

**DS 650, DS 700, DS 750, DS 750 1S, DS 750 2S, DS 750 3S, DS 800, DS 800 1S, DS 800 2S, DS 800 3S,** — **DT-FT-06_M**

**DS 900, DS 900 1S, DS 900 2S, DS 900 3S, DS 1000, DS 1000 1S, DS 1000 2S, DS 1000 3S, DS 900 N, DS 900 N1S, DS 900 N2S, DS 900 N3S, DS 1000 N, DS 1000 N1S, DS 1000 N2S, DS 1000 N3S** — **DT-FT-05_M**

**Termodisinfettori per uso medicale** della serie **WD** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA |
|---|---|---|
| Serie: **WD**<br>Marca: Steelco | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 13500 W<br>a 25000W |

Nomi commerciali modelli: — Fascicolo tecnico:

**WD 1110** — **DT-FT-06_M**

**WD 1115** — **DT-FT-05_M**

2020-09-11

| Redatto da: PC | Verificato da: QA | Approvato da: TD |
|---|---|---|

**Termodisinfettori per uso medicale** della serie **TW** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | STAZIONI<br>NUMERO |
|---|---|---|---|
| Serie: **TW**<br>Marca: Steelco | *Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 3000W<br>a 140000W | Da 2<br>a 5 |

Nomi commerciali modelli: **TW 3000/2, TW 3000/3, TW 3000/4, TW 3000/5**
Fascicolo tecnico: **DT-FT-09_M**

**Termodisinfettori per uso medicale** della serie **LC** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE | | DIMENSIONI LONGITUDINALI |
|---|---|---|---|---|---|
| | | | NUMERO | MOVIMENTO | |
| Serie: **LC**<br>Marca: Steelco | *Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 1200W<br>a 201000W | 1 o 2 | MANUALE<br>/<br>AUTOMATICA | /2 = Da 1500 mm a 2999 mm<br>/3 = Da 3000 mm a 3999 mm<br>/4 = Da 4000 mm a 4999 mm |

Nomi commerciali modelli: **LC 20/1, LC 20/2**
Fascicolo tecnico: **DT-FT-12_M**

**Disinfettori termici e/o chimici per uso medicale*** della serie **LC** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE<br>MOVIMENTO | DIMENSIONI LONGITUDINALI |
|---|---|---|---|---|
| Serie: **LC**<br>Marca: Steelco | *Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 1200W<br>a 201000W | MANUALE<br>/<br>AUTOMATICA | /2 = Da 1500 mm a 2999 mm<br>/3 = Da 3000 mm a 3999 mm<br>/4 = Da 4000 mm a 4999 mm |

Nomi commerciali modelli: **LC 70/2, LC 70/3, LC 80/2, LC 80/3, LC 80/4, LC 80/2 BOT, LC 80/3 BOT, LC 80/4 BOT**
Fascicolo tecnico: **DT-FT-08_M**

***Nota:** Per la Serie LC 80 e LC 70 esistono due tipologie di disinfezione: termica o ibrida (termica o chimica). Tale distinzione è garantita e riconoscibile dal codice prodotto finito riportato in etichetta matricola.

**Lavastrumenti per decontaminazione ad uso medicale** con ausilio di ultrasuoni della serie **US** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE<br>NUMERO |
|---|---|---|---|
| Serie: **US**<br>Marca: Steelco | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Fino a<br>14000W | 1 o 2 |

Nomi commerciali modelli:
**US 80** — Fascicolo tecnico: **DT-FT-20_M**
**US 100, US 200/1, US 200/2, US 200/3, US 200/4, US 100 XL** — **DT-FT-13_M**
**US 300** — **DT-FT-21_M**
**US 900, US 1000** — **DT-FT-07_M**

2020-09-11

**Lavastrumenti per decontaminazione ad uso medicale** della serie **DC** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE<br>NUMERO |
|---|---|---|---|
| Serie: **DC**<br>Marca: Steelco | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Fino a 10000W | 1 o 2 |

Nomi commerciali modelli:
**DC 100, DC 200/1, DC 200/2**
**DC 1000/1, DC 1000/2**

Fascicolo tecnico:
**DT-FT-17_M**
**DT-FT-19_M**

**Lavaendoscopi per uso medicale** della serie **EW 2** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE<br>NUMERO |
|---|---|---|---|
| Serie: **EW 2**<br>Marca: Steelco | *Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Fino a 9100W | 1 o 2 |

Nomi commerciali modelli:
**EW 2/1, EW 2/2, EW 2/1 2S, EW 2/2 2S, EW 2/1 3S, EW 2/2 3S**

Fascicolo tecnico:
**DT-FT-10_M**

**Lava disinfettatrice-sterilizzatrice chimica per endoscopi** della serie EW 1 comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE<br>NUMERO |
|---|---|---|---|
| Serie: **EW 1**<br>Marca: Steelco | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Fino a 6100 W | Da 1 a 4 |

Nomi commerciali modelli:
**EW 1, EW 1 S, EW 1 DUAL H**

Fascicolo tecnico:
**DT-FT-18_M**

**Sterilizzatore al perossido di idrogeno** della serie **PL** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE<br>NUMERO |
|---|---|---|---|
| Serie: **PL**<br>Marca: Steelco | *Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Fino a 5000 W | 1 o 2 |

Nomi commerciali modelli:
**PL 70/1, PL 70/2, PL 130/1, PL 130/2, PL 40/1**

Fascicolo tecnico:
**DT-FT-27_M**

2020-09-11

**Soluzione sterilizzante al perossido di idrogeno** della serie **SteelcoPro PL** comprende le seguenti varianti e denominazioni:

| | CONCENTRAZIONE |
|---|---|
| Serie: **SteelcoPro PL**<br>Marca: | **58% di $H_2O_2$** |

| Nomi commerciali modelli: | Fascicolo tecnico: |
|---|---|
| **SteelcoPro PL** | **DT-FT-17_C** |

**Soluzione sterilizzante alla formaldeide** della serie **SteelcoPro LTSF** comprende le seguenti varianti e denominazioni:

| | CONCENTRAZIONE |
|---|---|
| Serie: **SteelcoPro LTSF**<br>Marca: | **Dal 10% al 20%** |

| Nomi commerciali modelli: | Fascicolo tecnico: |
|---|---|
| **SteelcoPro LTSF 4; SteelcoPro LTSF 6; SteelcoPro LTSF 8** | **DT-FT-13_C** |

2020-09-11

**Lavapadelle a termodisinfezione per uso medicale** della serie **BP** comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE | | CARROZZERIA | | ALLESTIMENTO |
|---|---|---|---|---|---|---|---|
| | | | NUMERO | MOVIMENTO | LARGHEZZA | ALTEZZA | |
| Serie: **PWD**<br>Marca:<br>Miele | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 750W<br>a 6900 W | 1 o 2 | MANUALE<br>/<br>SEMI-AUTOMATICA<br>/<br>AUTOMATICA | STANDARD<br>/<br>RIDOTTA<br>/<br>MAGGIORATA | STANDARD<br>/<br>ALTA | STANDARD<br>/<br>E |

| Nomi commerciali modelli: | Fascicolo tecnico: |
|---|---|
| **PWD 8541 MD, PWD 8541 AD, PWD 8545 MD, PWD 8545 SAD, PWD 8545 AD, PWD 8546, PWD 8546 AD, PWD 8549, PWD 8543** | **DT-FT-01_M** |

**Termodisinfettori per uso medicale** della serie comprende le seguenti varianti e denominazioni:

| | ALIMENTAZIONE | POTENZA | PORTE | | CARROZZERIA | ALLESTIMENTO |
|---|---|---|---|---|---|---|
| Serie: **PWD**<br>Marca:<br>Miele | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 2220W<br>a 37000W | 1 o 2 | MANUALE<br>/<br>AUTOMATICA | STANDARD<br>/<br>ALTA | ASCIUGATUIRA<br>/<br>3 O 4 DOSATORI<br>/<br>DEPURATA |

| Nomi commerciali modelli: | Fascicolo tecnico: |
|---|---|
| **PWD 8531, PWD 8531 WS, PWD 8532, PWD 8532 WS, PWD 8534, PWD 8534 WS** | **DT-FT-04_M** |
| **PWD 6121, PWD 6122, PWD 6121 TH1, PWD 6122 TH1, PWD 6121 TH2, PWD 6122 TH2** | **DT-FT-03_M** |

2020-09-11

**Flusher Disinfectors / Bedpan washers for medical purpose BP line** includes the following variants and names:

| | FEEDING | POWER | DOORS | | BODY | | SET UP |
|---|---|---|---|---|---|---|---|
| | | | NUMBER | MOVEMENT | WIDTH | HEIGHT | |
| Line: **BP**<br>Trade Mark: Steelco | *Single-phase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Three-phase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | From 750W<br>to 9900W | 1 or 2 | MANUAL<br>/<br>SEMI-AUTOMATIC<br>/<br>AUTOMATIC | STANDARD<br>/<br>REDUCED<br>/<br>INCREASED | STANDARD<br>/<br>HIGH | STANDARD<br>/<br>E |

Trade names: Technical file:

**BP 100 M, BP 100 M9, BP 100 A, BP 100 A9, BP 100 H, BP 100 H5, BP 100 HS, BP 100 HA, BP 100 HA5, BP 100 HE, BP 100 HSE, BP 100 HAE, BP 100 HSER, BP 100 HL, BP 100 HLS, BP 100 HLA, BP 100 HL2MM, BP 100 HL2AM, BP 100 HXL** — **DT-FT-01_M**

**Washer Disinfectors for medical purpose DS line** include the following variants and names:

| | FEEDING | POWER | DOORS | | BODY | OPTIONALS |
|---|---|---|---|---|---|---|
| | | | NUMBER | MOVEMENT | | |
| Line: **DS**<br>Trade Mark: Steelco | *Single-phase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Three-phase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | From 2220W<br>to 37000W | 1 or 2 | MANUAL<br>/<br>AUTOMATIC | STANDARD<br>/<br>HIGH | WITH DRYING<br>/<br>3 or 4 DOSING PUMPS<br>/<br>WITH WATER SOFTNER |

Trade names: Technical file:

**DS 50, DS 50 D, DS 50 DRS, DS 50 DRSD, DS 50 HDRS; DS 50 HDRSD; DS 50/2, DS 50/2 D, DS 50/2 DRS, DS 50/2 DRSD** — **DT-FT-04_M**

**DS 500, DS 500 D, DS 500 DRS, DS 500 DRSD, DS 500 DRS4, DS 500 LED, DS 500 LEDD, DS 500 SC, DS 500 SCD, DS 500 SCL, DS 500 SCDL, DS 500 CL, DS 500 CDL, DS 600/1, DS 600/1 D, DS 600/2, DS 600/2 D, DS 600 C, DS 600 CD, DS 600/1 1S, DS 600/2 1S, DS 610/1, DS 610/1 D, DS 610/2, DS 610/2 D, DS 610/1 1S, DS 610/1 2S, DS 610/2 1S, DS 610/2 2S, DS 610/1 SL, DS 610/1 SLD, DS 610/2 SL, DS 610/2 SLD, DS 610/1 SL1S, DS 610/1 SL2S, DS 610/2 SL1S, DS 610/2 SL2S** — **DT-FT-03_M**

**DS 650, DS 700, DS 750, DS 750 1S, DS 750 2S, DS 750 3S, DS 800, DS 800 1S, DS 800 2S, DS 800 3S** — **DT-FT-06_M**

**DS 900, DS 900 1S, DS 900 2S, DS 900 3S, DS 1000, DS 1000 1S, DS 1000 2S, DS 1000 3S DS 900 N, DS 900 N1S, DS 900 N2S, DS 900 N3S, DS 1000 N, DS 1000 N1S, DS 1000 N2S, DS 1000 N3S.** — **DT-FT-05_M**

**Washers Disinfectors for medical purpose WD line** include the following variants and names:

| | FEEDING | POWER |
|---|---|---|
| Line: **WD**<br>Trade Mark: Steelco | *Single-phase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Three-phase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | From 13500W<br>to 25000W |

Trade names: Technical file:

**WD 1110** — **DT-FT-06_M**

**WD 1115** — **DT-FT-05_M**

2020-09-11

**Washer Disinfectors for medical purpose TW line** includes the following variants and names:

| | FEEDING | POWER | STATIONS NUMBER |
|---|---|---|---|
| Line: **TW**<br>Trade Mark: Steelco | *Three-phase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | From 3000W<br>to 140000W | From 2<br>to 5 |

Trade names: **TW 3000/2, TW 3000/3, TW 3000/4, TW 3000/5**

Technical file: **DT-FT-09_M**

**Thermal Washer Disinfectors for medical purpose LC line** includes the following variants and names:

| | FEEDING | POWER | DOORS NUMBER | DOORS MOVEMENT | LONGITUDINAL DIMENSIONS |
|---|---|---|---|---|---|
| Line: **LC**<br>Trade Mark: Steelco | *Three-phase*<br>200-230V /50-60Hz<br>380-480V / 50-60Hz | From 1200W<br>to 201000W | 1 or 2 | MANUAL<br>/<br>AUTOMATIC | /2 = From 1500 mm to 2999 mm<br>/3 = From 3000 mm to 3999 mm<br>/4 = From 4000 mm to 4999 mm |

Trade names: **LC 20/1, LC 20/2.**

Technical file: **DT-FT-12_M**

**Thermal and/or Chemical Washer Disinfectors for medical purpose* LC line** includes the following variants and names:

| | FEEDING | POWER | DOORS MOVEMENT | LONGITUDINAL DIMENSIONS |
|---|---|---|---|---|
| Line: **LC**<br>Trade Mark: Steelco | *Three-phase*<br>200-230V /50-60Hz<br>380-480V / 50-60Hz | From 1200W<br>to 201000W | MANUAL<br>/<br>AUTOMATIC | /2 = From 1500 mm to 2999 mm<br>/3 = From 3000 mm to 3999 mm<br>/4 = From 4000 mm to 4999 mm |

Trade names: **LC 70/2, LC 70/3, LC 80/2, LC 80/3, LC 80/4, LC 80/2 BOT, LC 80/3 BOT, LC 80/4 BOT**

Technical file: **DT-FT-08_M**

***Note:** For the LC 80 and LC 70 Series there are two types of disinfection: thermal or hybrid (thermal or chemical). This distinction is guaranteed and recognizable by the finished product code shown on the label.

**Decontamination cleaners for medical purpose with ultrasonic function US line** includes the following variants and names:

| | FEEDING | POWER | DOORS NUMBER |
|---|---|---|---|
| Line: **US**<br>Trade Mark: Steelco | *Single-phase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Three-phase*<br>200-230V /50-60Hz<br>380-480V / 50-60Hz | Up to<br>14000W | 1 or 2 |

Trade names:

Technical file:

**US 80** — **DT-FT-20_M**

**US 100, US 200/1, US 200/2, US 200/3, US 200/4, US 100 XL** — **DT-FT-13_M**

**US 300** — **DT-FT-21_M**

**US 900, US 1000** — **DT-FT-07_M**

2020-09-11

**Decontamination cleaners for medical purpose DC line** includes the following variants and names:

| | FEEDING | POWER | DOORS NUMBER |
|---|---|---|---|
| Line: **DC**<br>Trade Mark: Steelco | *Single-phase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Three-phase*<br>200-230V /50-60Hz<br>380-480V / 50-60Hz | Up to 10000W | 1 or 2 |

| Trade names: | Technical file: |
|---|---|
| **DC 100, DC 200/1, DC 200/2** | **DT-FT-17_M** |
| **DC 1000/1, DC 1000/2** | **DT-FT-19_M** |

**Endoscope washers for medical purpose EW 2 line** includes the following variants and names:

| | FEEDING | POWER | DOORS NUMBER |
|---|---|---|---|
| Line: **EW 2**<br>Trade Mark: Steelco | *Three-phase*<br>200-230V /50-60Hz<br>380-480V / 50-60Hz | Up to 9100W | 1 or 2 |

| Trade names: | Technical file: |
|---|---|
| **EW 2/1, EW 2/2, EW 2/1 2S, EW 2/2 2S, EW 2/1 3S, EW 2/2 3S** | **DT-FT-10_M** |

**Chemical washer disinfector and sterilizer for endoscopes EW 1 line** includes the following variants and names:

| | FEEDING | POWER | DOORS NUMBER |
|---|---|---|---|
| Line: **EW 1**<br>Trade Mark: Steelco | *Single-phase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Three-phase*<br>200-230V /50-60Hz<br>380-480V / 50-60Hz | Up to 6100 W | From 1 to 4 |

| Trade names: | Technical file: |
|---|---|
| **EW 1, EW 1 S, EW 1 DUAL H** | **DT-FT-18_M** |

**Hydrogen peroxide sterilizer PL line** includes the following variants and names:

| | FEEDING | POWER | DOORS NUMBER |
|---|---|---|---|
| Line: **PL**<br>Trade Mark: Steelco | *Three-phase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Up to 5000 W | 1 or 2 |

| Trade names: | Technical file: |
|---|---|
| **PL 70/1, PL 70/2, PL 130/1, PL 130/2, PL 40/1** | **DT-FT-27_M** |

2020-09-11

**Hydrogen peroxide sterilizing agent SteelcoPro PL line** includes the following variants and names:

| | CONCENTRATION |
|---|---|
| Line: **SteelcoPro PL**<br>Trade Mark: | 58% of $H_2O_2$ |

| | |
|---|---|
| Trade names:<br>**SteelcoPro PL** | Technical file:<br>**DT-FT-17_C** |

**Formaldehyde sterilizing agent SteelcoPro LTSF line** includes the following variants and names:

| | CONCENTRATION |
|---|---|
| Line: **SteelcoPro LTSF**<br>Trade Mark: | From 10% to 20% |

| | |
|---|---|
| Trade names:<br>**SteelcoPro LTSF 4; SteelcoPro LTSF 6; SteelcoPro LTSF 8** | Technical file:<br>**DT-FT-13_C** |

2020-09-11

**Flusher Disinfectors / Bedpan washers for medical purpose PWD line** includes the following variants and names:

| | FEEDING | POWER | DOORS | | BODY | | SET UP |
|---|---|---|---|---|---|---|---|
| | | | NUMBER | MOVEMENT | WIDTH | HEIGTH | |
| Line: **PWD**<br>Trade Mark: Miele | *Monofase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Trifase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | Da 750W<br>a 6900 W | 1 o 2 | MANUAL<br>/<br>SEMI-AUTOMATIC<br>/<br>AUTOMATIC | STANDARD<br>/<br>REDUCED<br>/<br>INCREASED | STANDARD<br>/<br>HIGH | STANDARD<br>/<br>E |

Trade name:
**PWD 8541 MD, PWD 8541 AD, PWD 8545 MD, PWD 8545 SAD, PWD 8545 AD, PWD 8546, PWD 8546 AD, PWD 8549, PWD 8543**

Technical file:
**DT-FT-01_M**

**Washer Disinfectors for medical purpose PWD line** include the following variants and names:

| | FEEDING | POWER | DOORS | | BODY | SET UP |
|---|---|---|---|---|---|---|
| | | | NUMBER | MOVEMENT | | |
| Line: **PWD**<br>Trade Mark: Miele | *Single-phase*<br>110V / 60Hz<br>220-240V / 50-60Hz<br>*Three-phase*<br>200-230V / 50-60Hz<br>380-480V / 50-60Hz | From 2220W<br>to 37000W | 1 OR 2 | MANUAL<br>/<br>AUTOMATIC | STANDARD<br>/<br>HIGH | WITH DRYING<br>/<br>3 or 4 DOSING PUMPS<br>/<br>WITH WATER SOFTNER |

Trade name:
**PWD 8531, PWD 8531 WS, PWD 8532, PWD 8532 WS, PWD 8534, PWD 8534 WS**
**PWD 6121, PWD 6122, PWD 6121 TH1, PWD 6122 TH1, PWD 6121 TH2, PWD 6122 TH2**

Technical file:
**DT-FT-04_M**
**DT-FT-03_M**

2020-09-11

# CERTIFICATO CE

Certificato n. 1879/MDD

## Dichiarazione di approvazione del sistema qualità

*(Sistema completo di garanzia qualità)*

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

**STEELCO SPA**

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (ITA) - Italy

mantiene nello stabilimento di:

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (ITA) - Italy

31039 RIESE PIO X (TV) - VIA DEL LAVORO 12 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

**Soluzione disinfettante per dispositivi medici invasivi**

Mod. SteelcoXide-A, SteelcoXide-B e SteelcoXide-DT
Marca STEELCO

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:
DM16A0650339-01; DM17-0007338-01; DM19-0040534-01.

**Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.**

| | |
|---|---|
| *Emesso il:* | 2016-05-16 |
| *Data aggiornamento:* | 2019-09-18 |
| *Sostituisce:* | 2017-02-02 |
| *Data scadenza:* | 2024-05-26 |

**IMQ**

# EC CERTIFICATE

Certificate No 1879/MDD

## Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

**STEELCO SPA**

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (ITA) - Italy

manages in the factory of:

31039 RIESE PIO X (TV) - VIA BALEGANTE 27 (ITA) - Italy

31039 RIESE PIO X (TV) - VIA DEL LAVORO 12 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

**Disinfectant solution for invasive medical devices**

Type ref. SteelcoXide-A, SteelcoXide-B e SteelcoXide-DT

Trade mark STEELCO

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM16A0650339-01; DM17-0007338-01; DM19-0040534-01.

**This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.**

| | |
|---|---|
| *Date:* | 2016-05-16 |
| *Updated:* | 2019-09-18 |
| *Substitution Date:* | 2017-02-02 |
| *Expiry Date:* | 2024-05-26 |

**IMQ**

Tuesday, May 19, 2020

# COMPATIBILITY DECLARATION LETTER

To whom it may concern,

Based on the declaration letter which issued by Fabio Zardini, President & CEO of STEELCO SPA on 15 May 2020.
We undersigned, Aohua Endoscopy Co., Ltd., with registered office in Aohua Endoscopy Building, No.66, Lane133, Guangzhong Road, Minhang District, Shanghai, China, 201100, hereby declare following compatibility between Aohua endoscope and Steelco systems:

- **VGT-Q30J Gastroscope** can be properly connected with Steelco systems EW1-EW1 S-EW2-EW2 2S-EW2 3 S-ED200 S- EPW100 S by using **Steelco connectors**:

Biopsy channel code 660538
Air channel code 660128
Channels separator code 660088
Suction channel code 660528
Air Water channel code 660116
Auxiliary Water Jet channel code 660089
*Leak test original AOHUA connector has to be used*

- **VGT-Q30J Gastroscope** can be properly connected with Steelco Drying Storage Cabinets models ED100-ED150-ED200-ED250 by using **Steelco connector kit: 99911466**

- **VRL-1T30 Bronchoscope** can be properly connected with Steelco systems EW1-EW1 S-EW2-EW2 2S-EW2 3 S-ED200 S- EPW100 S by using **Steelco connectors**:

Biopsy channel code 660538
Suction channel code 660510
*Leak test original AOHUA connector has to be used*

- **VRL-1T30 Bronchoscope** can be properly connected with Steelco Drying Storage Cabinets models ED100-ED150-ED200-ED250 by using **Steelco connector kit:9991658**

Yours sincerely

Jiang Suping 2020.5.19
Service Development Manager
Aohua Endoscopy Co., Ltd.

# DICHIARAZIONE UE DI CONFORMITÁ
# EU DECLARATION OF CONFORMITY
# DÉCLARATION UE DE CONFORMITÉ
# EU KONFORMITÄTS-ERKLÄRUNG
# DECLARACIÓN UE DE CONFORMIDAD

CE 0051

**Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:**
*The undersigned, officer of the under-written company, hereby declares that the product:*
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
*Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:*
El firmante, como representante legal de la empresa indicada, declara que el producto:

**Nome/Modello:**
*Name/Type:*
Nom/Modèle:
*Name/Model:*
Nombre/Modelo:
**SteelcoXide-A**

**N° di Serie/Lotto:**
*Serial/Lot N.:*
N° de Série/Lot :
*Serial N./ Reihe-Zahl:*
N° de Serie/Lote:
**19XXXXXXXXXX**

[ GMDN: 44835 ]

**in riferimento** alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1879/MDD con validità fino al **26/05/2024**.
.

*referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules. This declaration is written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..*
*The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.*
*Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1879/MDD valid till **2024/05/26**.*
.

en référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
Cette déclaration est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1879/MDD avec validité jusqu'à **26/05/2024**.
.

*Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.*
*Diese Erklärung bestätigt auch die Konformität zu Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.*
*Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.*
*Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1879/MDD, gültig bis zum **26/05/2024**, bestätigt wird..*
.

en referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1879/MDD con validez hasta a **26/05/2024**.
.

**Direttive applicate:** **93/42/EEC (Medical Devices Directive** and s.m.i. - 2007/47/EC**)**
*Applied directives:*
Directives appliquées:
*Angewandte Richtlinien:*
Directivas aplicadas:

RIESE PIO X, 20 / 09 / 2019

**Direttore Generale**
*Managing Director*
Director Général
*Geschäftsführer*
Gerente
Fabio Zardini
Steelco S.p.A.

# DICHIARAZIONE UE DI CONFORMITÁ
# EU DECLARATION OF CONFORMITY
# DÉCLARATION UE DE CONFORMITÉ
# EU KONFORMITÄTS-ERKLÄRUNG
# DECLARACIÓN UE DE CONFORMIDAD

CE 0051

**Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:**
*The undersigned, officer of the under-written company, hereby declares that the product:*
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
*Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:*
El firmante, como representante legal de la empresa indicada, declara que el producto:

**Nome/Modello:**
*Name/Type:*
Nom/Modèle:
*Name/Model:*
Nombre/Modelo:
**SteelcoXide-B**

**N° di Serie/Lotto:**
*Serial/Lot N.:*
N° de Série/Lot :
*Serial N./ Reihe-Zahl:*
N° de Serie/Lote:
**19XXXXXXXXXX**

[ GMDN: 44835 ]

**in riferimento** alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1879/MDD con validità fino al **26/05/2024**.
.

*referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules. This declaration is written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..*
*The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.*
*Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1879/MDD valid till **2024/05/26**.*
.

en référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
Cette déclaration est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1879/MDD avec validité jusqu'à **26/05/2024**.
.

*Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.*
*Diese Erklärung bestätigt auch die Konformität zu Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.*
*Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.*
*Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1879/MDD, gültig bis zum **26/05/2024**, bestätigt wird..*
.

en referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1879/MDD con validez hasta a **26/05/2024**.
.

**Direttive applicate:** **93/42/EEC (Medical Devices Directive** and s.m.i. - 2007/47/EC**)**
*Applied directives:*
Directives appliquées:
*Angewandte Richtlinien:*
Directivas aplicadas:

RIESE PIO X, 20 / 09 / 2019

**Direttore Generale**
*Managing Director*
Director Général
*Geschäftsführer*
Gerente
Fabio Zardini
Steelco S.p.A.

# DICHIARAZIONE UE DI CONFORMITÁ
# EU DECLARATION OF CONFORMITY
# DÉCLARATION UE DE CONFORMITÉ
# EU KONFORMITÄTS-ERKLÄRUNG
# DECLARACIÓN UE DE CONFORMIDAD

CE 0051

**Il sottoscritto, come legale rappresentante della azienda sotto indicata, dichiara che il prodotto:**
*The undersigned, officer of the under-written company, hereby declares that the product:*
Le représentant juridique soussigné de l'usine sous indiquée, il déclare que le produit:
*Der Unterzeichner, Handlungsbevollmächtigter des oben genannten unter hingewiesen, erklärt hiermit, daß das Produkt:*
El firmante, como representante legal de la empresa indicada, declara que el producto:

**Nome/Modello:**
*Name/Type:*
Nom/Modèle:
*Name/Model:*
Nombre/Modelo:
**SteelcoXide-DT**

**N° di Serie/Lotto:**
*Serial/Lot N.:*
N° de Série/Lot :
*Serial N./ Reihe-Zahl:*
N° de Serie/Lote:
**19XXXXXXXXXX**

[ GMDN: 44835 ]

**in riferimento** alla Direttiva 93/42/CEE e s.m.i., è classificato in classe **IIb**, in accordo alla regola 15 dell'allegato IX, è stato progettato e costruito in conformità ai requisiti essenziali dell'allegato I, applicando le disposizioni delle norme armonizzate.
La presente dichiarazione è redatta sulla base dei requisiti dell'allegato II della direttiva 93/42/CEE e s.m.i..
La persona giuridica autorizzata a costituire il fascicolo tecnico è la Steelco S.p.A. con sede in via Balegante, 27 – Riese Pio X (TV) - Italia.
Il sistema di garanzia di qualità del prodotto, esclusivamente in accordo all'allegato II della Direttiva 93/42/CEE e s.m.i., è mantenuto sotto controllo dall'organismo notificato IMQ S.p.A con numero identificativo 0051 come da certificato IMQ n.1879/MDD con validità fino al **26/05/2024**.
.

*referring to 93/42/EEC Medical Device Directive and s.m.i., is classified on **IIb** class, according to rule 15 of the annex IX, designed and manufactured in conformity with the annex I, under the harmonized rules. This declaration is written in conformity with the annex II of 93/42/EEC Medical Device Directive and s.m.i..*
*The juridical person authorized to compile the technical file is Steelco S.p.A., at via Balegante, 27 - Riese Pio X (TV) - Italy.*
*Exclusively in conformity at annex II of 93/42/EEC Medical Device Directive and s.m.i., the product quality system is guaranteed from the notified authority IMQ S.p.A, under number 0051 as IMQ certificate n.1879/MDD valid till **2024/05/26**.*
.

en référence de la Directive 93/42/CEE et s.m.i., est classifiée en classe **IIb**, en accord à la règle 15 annexe IX, a été projetée et construit en conformité aux qualités essentielles de l'annexe I, en appliquant les dispositions des normes harmonisées.
Cette déclaration est rédigée sur la base des qualités de l'annexe II de la Directive 93/42/CEE et s.m.i..
La personne juridique autorisée à constituer le dossier technique est la Steelco S.p.A. avec siège en via Balegante, 27 – Riese Pio X (TV) - Italie.
Le système de garantie de qualité du produit, exclusivement en accord à l'annexe II de la Directive 93/42/CEE et s.m.i., est maintenu sous contrôle de l'organisme déclaré IMQ S.p.A. avec numéro identificateur CE0051 selon le certificat IMQ n.1879/MDD avec validité jusqu'à **26/05/2024**.
.

*Welche gemäß der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen, als Medizinprodukt der Klasse **IIb** klassifiziert ist, konform zur Regel 15 der Anhang IX, wurde geplant und hergestellt, gemäß der wesentlichen Anforderungen laut beiliegender Anlage I, unter der harmonisierten Normen.*
*Diese Erklärung bestätigt auch die Konformität zu Anhang II der Richtlinie 93/42/EWG und zusätzliche Änderungen und Ergänzungen.*
*Die juristische autorisierte Person, die die technischen Unterlagen zusammenzustellen hat ist Steelco S.p.A. an via Balegante, 27 - Riese Pio X (TV) - Italien.*
*Ausschließlich konform zu Anhang II der Richtlinie 93/42/EWG über Medizinprodukte, hat der oben genannten Hersteller ein Qualitätsmanagementsystem eingeführt,wie durch die benannte Stelle IMQ S.p.A. mit der Nummer 0051, durch das Zertifikat mit der Nummer IMQ 1879/MDD, gültig bis zum **26/05/2024**, bestätigt wird..*
.

en referencia a la Directiva 93/42/CEE y s.m.i., es clasificado en clase IIb, en acuerdo a la regla 15 del anexo IX, ha sido diseñado y construida en conformidad con los requisitos esenciales del anexo I, aplicando las disposiciones de las normas armonizadas.
La presente declaración es redactada sobre la base de los requisitos del anexo II de la norma 93/42/CEE y s.m.i..
La persona jurídica lícita a constituir el expediente técnico es la Steelco S.p.A. con sede en via Balegante, 27 – Riese Pio X (TV) - Italia.
El sistema de garantía de calidad del producto, exclusivamente en acuerdo al anexo II a la Directiva 93/42/CEE y s.m.i., es controlado por el organismo notificado IMQ S.p.A. con número identificativo 0051 como de certificado IMQ n.1879/MDD con validez hasta a **26/05/2024**.
.

**Direttive applicate:** **93/42/EEC (Medical Devices Directive** and s.m.i. - 2007/47/EC**)**
*Applied directives:*
Directives appliquées:
*Angewandte Richtlinien:*
Directivas aplicadas:

RIESE PIO X, 20 / 09 / 2019

**Direttore Generale**
*Managing Director*
Director Général
*Geschäftsführer*
Gerente
Fabio Zardini
Steelco S.p.A.

FUJIFILM

**FUJIFILM ITALIA S.p.A.**

S.S. n° 11 Padana Superiore, 2/B
20063 Cernusco sul Naviglio (MI) - Italy
Tel. 02.92974.1 - Fax 02.92974.591
http:\\www.fujifilm.it - info@fujifilm.it

**TO WHOM IT MAY CONCERN**

Cernusco Sul Naviglio, June 23rd, 2016
Prot. n° **33761**/2016/GV/dm

The undersigned Giovanni Ettore Valtorta, born in Sovico (MB) – Italy – on January 31st, 1959 and living in Sovico (MB) – Italy – Via San Francesco d'Assisi, 8 in his capacity as Special Attorney of FUJIFILM Italia S.p.A., having its register office in Cernusco sul Naviglio (MI) – Italy – S.S. n° 11 Padana Superiore, 2/b – Fiscal Code 09435590154, VAT n° 11025740157, under his responsibility,

**DECLARES**

That FUJIFILM endoscopes are fully compatible with Steelco AERs series EW.

Your successfully.

**FUJIFILM Italia S.p.A.**
**A Special Attorney**
Giovanni Ettore Valtorta

VALTORTA
GIOVANNI ETTORE
31/01/1959
4 1 A 1959
SOVICO MI
ITALIANA
SOVICO
VIA SAN FRANCESCO D'ASSISI 8
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DIRIGENTE

A
182
BRIZZOLATI
VERDI
NESSUNO

Firma del titolare
SOVICO 21/01/2015

IL SINDACO

SCADENZA 31/01/2025

Diritti E. 5,42

AV 0997721

REPUBBLICA ITALIANA

COMUNE DI
SOVICO (MB)

CARTA D'IDENTITÀ

N° AV 0997721

DI
VALTORTA
GIOVANNI ETTORE

FUJIFILM
Value from Innovation

**FUJIFILM Europe GmbH**

Heesenstraße 31, 40549 Düsseldorf,
PO Box 270131, 40524 Düsseldorf, Germany
Phone +49 211 5089-100, Fax +49 211 5089-344
http://www.fujifilm.eu

Willich, 23.07.2018

To Whom it may concern

Herewith we confirm, that based on the test results of the company Steelco and the submitted report from the 20.06.2018, the use of the FUJIFILM series ED-580XT in reprocessing machines made by Steelco, is basically permitted and no problems are to be expected.

Haruhiko Arai
Manager Quality & Service Support

AZIENDA OSPEDALIERA UNIVERSITARIA INTEGRATA
VERONA
(D.Lgs. n. 517/1999 - Art. 3 L.R.Veneto n. 18/2009)

*U.O. Clinica di Gastroenterologia* - *Direttore Prof. Luca Frulloni*

**U.O. Semplice Organizzata di Endoscopia Digestiva**

**Responsabile: Dr. Armando Gabbrielli**

Policlinico G.B. Rossi, P.le L.A. Scuro, 10 - 37134 Verona - Tel. 045 8124743 - Fax 045 8124898

*e-mail: endoscopia.digestiva.op@azosp.vr.it*

Date 22.6.2016

We are glad to communicate that, in our GI Departement – AOUI of Verona - Steelco S.p.A AERs Systems (EW) installed in 2012 are succesfully used with Olympus endoscopes series 140, 160 and 180.

Sincerly

Armando Gabbrielli, M.D.

AZIENDA OSPEDALIERA UNIVERSITARIA INTEGRATA DI VERONA
OSPEDALE POLICLINICO "BORGO ROMA"
U.O.C di Gastroenterologia
Unità Organizzativa Semplice
ENDOSCOPIA DIGESTIVA
DOTT. ARMANDO GABBRIELLI
ROMA 32818

**CASA DI CURA VILLA IGEA S.p.A.**
*STRADA MOIRANO 2 – 15011 ACQUI TERME (AL) ITALY tel. +39,0144-310801 fax +39,0144-310829*
*E-mail: info@villaigea.com*
*c.f. e P.IVA 02035510060 Numero REA: AL-220838 CAP. SOC. I.V. € 1.700.000,00*

Acqui Terme, June 23th, 2016

We are glad to comunicate that, in our Ambulatory Department identified as "Endoscopia Digestiva" located in Casa di Cura Villa Igea S.p.A., the Firm SO.E.M. sold and installed in 2014 and 2015 two Systems EW1 of Steelco production.
Both systems are successfully used with Olympus endoscopes series 180 and 190.

Best regards

The Legal Representative

**Casa di Cura "Villa Igea" S.p.A.**
Il Consigliere Delegato
*Poggio Dott. Giovanni*

The Bioingeenering Dept.
Maurizio La Gamba

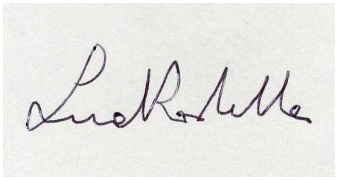
AZIENDA OSPEDALIERA DI VERONA - OSPEDALE CIVILE MAGGIORE
SERVIZIO DI CHIRURGIA ENDOSCOPICA
Responsabile: Dott. Luca Rodella

Verona, June 23, 2016

We are glad to communicate that, in our GI Department – Piastra Endoscopica / Endoscopy Dept at Polo Chirurgico "P. Confortini" - Maggiore Hospital of Verona - Steelco S.p.A AERs Systems (EW) installed in 2011 are succesfully used with Olympus endoscopes series 180 and 190.

Sincerely

Luca Rodella
Head Endoscopy Unit



Servizio Sanitario Nazionale - Regione Veneto
AZIENDA UNITA' LOCALE SOCIO-SANITARIA N. 13
DIPARTIMENTO INTERNISTICO OSPEDALE DI DOLO
**U.O.S. di GASTROENTEROLOGIA ed ENDOSCOPIA DIGESTIVA**
Resp. **Dr. Renato Marin**

Dolo, 13.07.2016

**U.O.S. di Gastroenterologia ed Endoscopia Digestiva**

**Dr. Renato Marin**
*(Responsabile)*

**Medici**

**Dr.ssa Erica Cervellin**
**Dr. ssa Sara Antoniazzi**
**Dr. ssa Adriana Sergio**

**Infermieri**

**I.P. Mara Celin**
*(con ruolo di coordinamento)*
**I.P. Silvia Bizzotto**
**I.P. Federica Carlesso**
**I.P. Federico Cipriotto**
**I.P. Samuele Marcato**
**I.P. Lisa Morelli**
**I.P. Grazia Salmaso**
**I.P. Lisa Scantamburlo**

**O.S.S.**

**Sig.ra Elisabetta Zara**

**Telefoni**

**Sala A / Segreteria**
041 5133423
**Sala B** (tel. e fax)
041 5133460

**e-mail:**

*endoscopiadigestiva.dolo@ulss13mirano.ven.it*

**Prenotazione prestazioni:**

**CUP:** tel. 041 5103520

**Prestazioni erogate**

**- EGDS e Colonscopie**
*(diagnostiche ed operative, routinarie ed in Pronta Disponibilità)*
**-Endoscopia con Videocapsula**
**- Screening Tumore Colon-Retto**
**- Visite Gastroenterologiche**

We are glad to comunicate that, in our GI department - Gastroenterology and Endoscopy Department U. O. S. D. Dolo Hospital - Steelco S.p.A. AER System (model EW2) installed in 2009 are successfully used with Olympus endoscopes series 140 – 160 – 180 – 190.

Sincerely

Renato Marin
Head Endoscopy Unit.

Regione Veneto-AZIENDA U.L.S.S. N. 13
U.O.S. DIPARTIMENTALE di GASTROENTEROLOGIA
ed ENDOSCOPIA DIGESTIVA
*Resp.: Dott. RENATO MARIN*
C.F. MRN RNT 52R25 F241H
VE 4808

James Paget University Hospitals NHS
NHS Foundation Trust

Lowestoft Road
Gorleston
Great Yarmouth
Norfolk
NR31 6LA

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E mail: judy.dron@jpaget.nhs.uk

Twitter: @jamespagetNHS

04/07/2016

To whom it may concern-

We use the Steelco AER to reprocess Olympus 240 and 260 series endoscopes. Currently we have had no issues with the process, or problems identified by our endoscope service provider that could be attributed to the Steelco. We have been very satisfied with the machine.

Yours sincerely

J Dron
Senior Sister
Endoscopy suite
James Paget University Hospital

# Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

## SECTION 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

| | |
|---|---|
| Product name | **Steelcoxide B** |
| Chemical name and synonym | **Hydrogen Peroxide Solution** |
| INDEX number | **008-003-00-9** |
| EC number | **231-765-0** |
| CAS number | **7722-84-1** |
| Registration Number | **01-2119485845-22-xxxx** |

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

| | |
|---|---|
| Intended use | **Solution "B" of the tri-component system "SteelcoXide". Concentrated sterilizing solution to be used in combination with the activator "Solution A". PROFESSIONAL USE ONLY.** |

### 1.3. Details of the supplier of the safety data sheet

| | |
|---|---|
| Name | **STEELCO S.p.A.** |
| Full address | **Via Balegante, 27** |
| District and Country | **31039 Riese Pio X (TV)**<br>**ITALY** |
| | **tel. +39 0423 7561** |
| | **fax +39 0423 755528** |
| e-mail address of the competent person responsible for the Safety Data Sheet | info@steelcogroup.com |
| Product distribution by: | **STEELCO S.p.A.** |

### 1.4. Emergency telephone number

For urgent inquiries refer to

**Centros de Orientação de Doentes Urgentes (CODU): 800250250**

## SECTION 2. Hazards identification

### 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

| | | |
|---|---|---|
| Oxidising solid, category 2 | H272 | May intensify fire; oxidiser. |
| Acute toxicity, category 4 | H302 | Harmful if swallowed. |
| Skin Irritation, category 2 | H315 | Causes skin irritation |
| Specific target organ toxicity – single exposure, category 3 | H335 | May cause respiratory irritation |
| Serious eye damage, category 1 | H318 | Causes serious eye damage. |
| Hazardous to the aquatic environment, chronic toxicity, category 3 | H412 | Harmful to aquatic life with long lasting effects. |

Classification note/notes according to Annex VI to the CLP Regulation: B

**2.2. Label elements**

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

Signal words: Danger

Hazard statements:

| | |
|---|---|
| **H272** | May intensify fire; oxidiser. |
| **H302** | Harmful if swallowed. |
| **H315** | Causes skin irritation |
| **H318** | Causes serious eye damage. |
| **H335** | May cause respiratory irritation |
| **H412** | Harmful to aquatic life with long lasting effects. |

Precautionary statements:

| | |
|---|---|
| **P305+P351+P338** | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| **P280** | Wear protective gloves/eye protection/face protection. |
| **P261** | Avoid breathing vapours/spray. |
| **P220** | Keep away from clothing and other combustible materials. |
| **P210** | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| **P310** | Immediately call a POISON CENTER. |

**Contains:** Hydrogen Peroxide Solution 35 ≤wt% <47
INDEX 008-003-00-9

**2.3. Other hazards**

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

## SECTION 3. Composition/information on ingredients

**3.1. Substances**

Contains:

| Identification | X = Conc. % | Classification 1272/2008 (CLP) |
|---|---|---|

**HYDROGEN PEROXIDE SOLUTION**

CAS 7722-84-1 | 35 ≤ x < 47 | Ox. Liq. 1 H271, Acute Tox. 4 H302, Acute Tox. 4 H332, Skin Corr. 1A H314, Eye Dam. 1 H318, Aquatic Chronic 3 H412, Classification note/notes according to Annex VI to the CLP Regulation: B

Specific concentration limit (Annex VI Legislation 1272/2008)
STOT SE 3; H335; C ≥ 35 %
Eye Dam. 1; H318: 8 % ≤ C < 50 %
Eye Irrit. 2; H319: 5 % ≤ C < 8 %
Ox. Liq. 1; H271: C ≥ 70 %
Ox. Liq. 2; H272: 50 % ≤ C < 70 %
Skin Corr. 1A; H314: C ≥ 70 %
Skin Corr. 1B; H314: 50 % ≤ C < 70 %
Skin Irrit. 2; H315: 35 % ≤ C < 50 %

EC 231-765-0

INDEX 008-003-00-9

Reg. no. 01-2119485845-22-xxxx

The full wording of hazard (H) phrases is given in section 16 of the sheet.

## SECTION 4. First aid measures

### 4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.
SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.
INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.
INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.
PROTECTION MEASURES FOR FIRST AID: for the PPE necessary for first aid interventions refer to section 8.2 of this safety data sheet.

### 4.2. Most important symptoms and effects, both acute and delayed

EYES: from painful irritation to severe chemical burns (conjunctival hyperemia, conjunctivitis, edema, blepharospasm, iritis, corneal turbidity, epithelial defects, permanent corneal damage).
SKIN: solutions starting from approx. 10%: temporary bleaching (oxygen emphysema in interstitial tissue, gas embolism in blood capillaries), erythema, pain; from a concentration of approx. 70%: chemical burns, comparable to third degree burns; contamination of large areas could lead to systemic oxygen embolism.
INHALATION: mucosal irritation, inflammatory tissue reactions, obstruction, glottic and pulmonary edema, dyspnoea up to respiratory failure; extreme cases could lead to systemic effects.
INGESTION: irritation up to corrosion of the mucous membranes in contact especially in the upper digestive tract, distension of the stomach, displacement of the upper respiratory tract due to foaming, gastritis, duodenitis, colitis, acute visceral congestion, formation of vacuoles in the submucosal gastrointestinal tract, in lymphatic channels, mesenteric lymph nodes or mucosal-associated lymphoid tissue, as well as vacuolation in other organs, systemic effects due to air embolism.
SYSTEMIC EFFECTS: shock, acute coronary insufficiency, status epilepticus, cerebrovascular collapse, respiratory failure.
The most frequent cause of death after ingestion of solutions W> 10% is the obstruction of the respiratory tract due to the formation of foam (-> mechanical asphyxia).

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.
In the event of an accident or discomfort, consult a doctor immediately (if possible show the instructions for use or the safety data sheet).

## SECTION 5. Firefighting measures

### 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

**5.2. Special hazards arising from the substance or mixture**

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Do not breathe combustion products.
By decomposition it releases oxygen. The release of oxygen can promote combustion.

**5.3. Advice for firefighters**

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

## SECTION 6. Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

*6.1.1 For those who do not intervene directly*
Do not take any action involving any personal risk or without proper training. Evacuate the surrounding areas. Do not touch or walk on the spilled material.
Wear suitable protective equipment (including personal protective equipment referred to in section 8 of this Safety Data Sheet) to prevent contamination of skin, eyes and personal clothing. Wear appropriate respirator when ventilation is inadequate.
Do not inhale the mists / vapors / fumes. Avoid the dispersion of the product into the environment. Follow the appropriate internal procedures for personnel not authorized to intervene directly in the event of accidental release.

*6.1.2 For those who intervene directly*
Stop the leak if there is no danger.
Evacuate unauthorized personnel. Wear suitable protective equipment. (see section 8 of this Safety Data Sheet). Follow the appropriate internal procedures for authorized personnel. Isolate the danger area and deny entry. Ventilate enclosed spaces before entering.

**6.2. Environmental precautions**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

**6.3. Methods and material for containment and cleaning up**

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

**6.4. Reference to other sections**

Any information on personal protection and disposal is given in sections 8 and 13.

## SECTION 7. Handling and storage

**7.1. Precautions for safe handling**

Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapours

or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

**7.2. Conditions for safe storage, including any incompatibilities**

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. Keep containers away from any incompatible materials, see section 10 for details.

**7.3. Specific end use(s)**

No use other than that indicated in section 1.2 of this safety data sheet

## SECTION 8. Exposure controls/personal protection

**8.1. Control parameters**

Regulatory References:

| | | |
|---|---|---|
| DEU | Deutschland | Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56 |
| ESP | España | Límites de exposición profesional para agentes químicos en España 2019 |
| FRA | France | Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS |
| GBR | United Kingdom | EH40/2005 Workplace exposure limits (Fourth Edition 2020) |
| | TLV-ACGIH | ACGIH 2020 |

**HYDROGEN PEROXIDE SOLUTION**

**Threshold Limit Value**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| MAK | DEU | 0,71 | 0,5 | 0,71 | 0,5 | |
| VLA | ESP | 1,4 | 1 | | | |
| VLEP | FRA | 1,5 | 1 | | | |
| WEL | GBR | 1,4 | 1 | 2,8 | 2 | |
| TLV-ACGIH | | 1,4 | 1 | | | |

| Predicted no-effect concentration - PNEC | | |
|---|---|---|
| Normal value in fresh water | 12,6 | µg/L |
| Normal value in marine water | 12,6 | µg/L |
| Normal value for fresh water sediment | 47 | µg/kg |
| Normal value for marine water sediment | 47 | µg/kg |
| Normal value for water, intermittent release | 19,8 | µg/L |
| Normal value of STP microorganisms | 4,66 | mg/l |
| Normal value for the terrestrial compartment | 2,3 | µg/kg |

**Health - Derived no-effect level - DNEL / DMEL**

| | Effects on consumers | | | | Effects on workers | | | |
|---|---|---|---|---|---|---|---|---|
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | | | | | VND | VND | VND | VND |
| Inhalation | 1,93 mg/m3 | VND | 210 µg/m³ | VND | 3 mg/m3 | VND | 1,4 mg/m3 | VND |
| Skin | | | | | VND | VND | VND | VND |

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

**8.2. Exposure controls**

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.
Provide an emergency shower with face and eye wash station.

HAND PROTECTION
Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION
Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).
In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.
Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.
If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.
Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

## SECTION 9. Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

| | | |
|---|---|---|
| Appearance | liquid | |
| Colour | transparent | |
| Odour | pungent | |
| Odour threshold | Not determined | |
| pH | 3 | |
| Melting point / freezing point | -33 °C | Concentration:30% |
| Initial boiling point | 108 °C | Concentration:35% |
| Boiling range | Not determined | |
| Flash point | > 60 °C | |

| | | |
|---|---|---|
| Evaporation rate | Not determined | |
| Flammability (solid, gas) | Sulla base dello stato fisico | |
| Lower inflammability limit | Not applicable | |
| Upper inflammability limit | Not applicable | |
| Lower explosive limit | Not applicable | |
| Upper explosive limit | Not applicable | |
| Vapour pressure | 13,33 20 °C | Concentration:35%<br>Temperature:20 °C |
| Vapour density | 1,2 | |
| Relative density | 1,05 | |
| Solubility | soluble in water | |
| Partition coefficient: n-octanol/water | -1,57 Log Pow | Concentration:60%<br>Temperature:20 °C |
| Auto-ignition temperature | Not applicable | |
| Decomposition temperature | >60 °C | |
| Viscosity | 1,249 mPa s | Concentration:60%<br>Temperature:20 °C |
| Explosive properties | Non esplosivo | |
| Oxidising properties | Ossidante con cat.2 | |

**9.2. Other information**

| | |
|---|---|
| Molecular weight | 24,400 |

## SECTION 10. Stability and reactivity

**10.1. Reactivity**

Decomposes if exposed to: light,heat.
Decomposes on contact with: alkaline metals.Possibility of explosion.
The product is a strong oxidizing and reactive agent.

**10.2. Chemical stability**

In contact with impurities, decomposition catalysts, incompatible substances, and combustible substances, the substance can give rise to a self-accelerated exothermic decomposition reaction with formation of oxygen.

**10.3. Possibility of hazardous reactions**

The product may react violently with water. Danger of decomposition if exposed to heat.
The product is a strong oxidizing and reactive agent.
Impurities, decomposition catalysts, incompatible substances, combustible substances, can cause self-accelerated, exothermic decomposition and oxygen formation.
Risk of overpressure and bursting due to decomposition in confined spaces and pipes.
The release of oxygen can promote combustion.

**10.4. Conditions to avoid**

Avoid overheating. Prevent moisture or water from penetrating inside the containers.
Avoid exposure to: light,heat. Avoid contact with: alkaline substances.

**10.5. Incompatible materials**

Incompatible with: flammable substances, acetone, ethanol, glycerol, organic sulphides, hydrated bases, oxidising substances, iron,copper,bronze, chromium, zinc,l ead, silver, manganese, acetic acid.

Impurities, decomposition catalysts, metal salts, alkalis, hydrochloric acid, reducing agents (Risk of decomposition.).
Flammable substances (Fire hazard).
Organic solvents (Explosion hazard)

**10.6. Hazardous decomposition products**

Oxygen.

## SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

**11.1. Information on toxicological effects**

Metabolism, toxicokinetics, mechanism of action and other information

It is an endogenous product formed in the cells of the organism. It penetrates through the skin and mucous membranes and decomposes in the underlying tissues. This causes diffuse infiltration of the released oxygen and the formation of emboli.
In the mammalian organism, the enzymes that mostly work for the metabolism of the substance are glutathione peroxidase and catalase (INRS, 2007).

Information on likely routes of exposure

The primary route of exposure for hydrogen peroxide solution is through the respiratory tract and skin. (GESTIS Substance Database)

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Acute Effects:
Depending on the concentration: irritating to corrosive effects on the skin and mucous membranes, especially those of the eyes;
Inflammatory changes of the respiratory tract, in extreme cases lung damage due to higher vapor / aerosol concentrations.

Chronic Effects:
Irritation of the mucous membranes (mainly of the eyes and throat) and gradual discoloration of the hair; possible skin changes. (GESTIS Substance Database)

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:> 20 mg/l
ATE (Oral) of the mixture: 1043,88 mg/kg
ATE (Dermal) of the mixture: Not classified (no significant component)

LD50 (Oral) 1193 mg/kg Rat at the concentration of 35%
LD50 (Dermal) 2000 mg/kg bw Rabbit

Method: equivalent or similar to OECD 401
Reliability (Klimisch score): 1
Species: Rat (Male / Female)

Routes of exposure: oral
Results: LD50 = 1026 mg / kg bw
Details of the tested material: 70% Hydrogen Peroxide

Method: equivalent or similar to OECD 403
Reliability (Klimisch score): 1
Species: Rat (Sprague-Dawley; Male / Female)
Routes of exposure: inhalation (vapors)
Results: LD50 not determinable at concentrations of 170 mg / m3
Details of the tested material: 50% Hydrogen Peroxide

Method: equivalent or similar to OECD 402
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White, male / female)
Routes of exposure: cutaneous
Results: LC50 = not determinable at a concentration of 2000 mg / kg bw
Details of the tested material: Hydrogen Peroxide 35%

SKIN CORROSION / IRRITATION

Corrosive for the skin

Method: equivalent or similar to OECD 404
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White, male / female)
Routes of exposure: cutaneous
Results: Category 2 Irritant (EC1272 / 2008)
Details of the tested material: Hydrogen Peroxide 49.2%

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

Method: equivalent or similar to OECD 405
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White, male / female)
Routes of exposure: ocular
Results: Category 2 Irritant (GHS Criteria)
Details of the tested material: Hydrogen Peroxide 10%

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

Method: equivalent or similar to OECD 474
Reliability (Klimisch score): 1
In vivo test
Species: Mouse (Swiss OF1 / ICO: OF1, male / female)
Routes of exposure: intraperitoneal
Results: negative with and without metabolic activation
Details of the tested material: Hydrogen Peroxide 35%

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

Reference: publication (1996)
Species: hamster (Syrian; Male / Female)
Routes of exposure: oral mucosa
Results: negative. NOAEL (carcinogenicity): not detected
Details of the tested material: Hydrogen Peroxide 3%
Bibliographic reference: J Am Coll Toxicol 15 (1), 45-61

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Reference: publication (1958)
Species: Rat (Osborne-Mendel; Male / Female)
Routes of exposure: Oral
Results: no effect observed
Details of the tested material: 0.45% Hydrogen Peroxide
Bibliographic reference: Nature 181, 1453

Adverse effects on sexual function and fertility

Female rats that received 0.45% hydrogen peroxide with water to drink for 5 weeks gave birth to normal litters after mating with untreated males. The fertility of male mice was not changed 3 months after administering a 1% product to drinking water for 4 weeks (INRS, 2007).

Adverse effects on development of the offspring

Reference: publication (1958)
Species: Rat (Wistar)
Routes of exposure: Oral
Results: no effect observed
Details of the tested material: Hydrogen Peroxide 10%
Bibliographic reference: Acta Obst Gynaec Japan 34, 2149-2154

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Based on available data, the substance has no specific target organ toxicity effects for single exposure and is not classified under the relevant CLP hazard class.

Target organ

Respiratory trait.

Route of exposure

Inalation (vapour).

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Method: OECD 40
Reliability (Klimisch score): 1
Species: Mouse (C57BL / 6NCrlBR; males / females)
Routes of exposure: oral
Results: negative. NOAEL = 100 ppm

Method: OECD 412

Reliability (Klimisch score): 1
Species: Rat (Alpk: ApfSD; males / females)
Routes of exposure: inhalation (aerosol)
Results: negative. NOAEL = 2.9 mg / m³ air

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

No data are available on the hazard in case of aspiration.

## SECTION 12. Ecological information

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

**12.1. Toxicity**

Activated sludge:

EC50 (30 min) = 466 mg/l (OECD 209)
EC50 (3 h) >1000 mg/l (OECD 209)

HYDROGEN PEROXIDE SOLUTION

| | |
|---|---|
| LC50 - for Fish | 16,4 mg/l/96h Pimephales promelas (USEPA Toxic Substances Control Act Test Guideline) |
| EC50 - for Crustacea | 2,4 mg/l/48h Daphnia pulex (USEPA Toxic Substances Control Act Test Guidelines) |
| EC50 - for Algae / Aquatic Plants | 1,38 mg/l/72h Skeletonema costatum, soluzione al 35% |
| Chronic NOEC for Fish | 5 mg/L/96 h Pimephales promelas (USEPA Toxic Substances Control Act Test Guideline) |
| Chronic NOEC for Crustacea | 1 mg/l Daphnia pulex (USEPA Toxic Substances Control Act Test Guidelines) |
| Chronic NOEC for Algae / Aquatic Plants | 0,63 mg/l Skeletonema costatum, soluzione al 35% |

**12.2. Persistence and degradability**

Quickly biodegradable, 99% in 30 min. (OECD 209)

| | |
|---|---|
| Solubility in water | 100000 mg/l |

**12.3. Bioaccumulative potential**

| | |
|---|---|
| Partition coefficient: n-octanol/water | -1,57 |

**12.4. Mobility in soil**

Soil / sediment: Log KOC = 0.2 evaporation and adsorption not significant.
Air, volatility, Henrym's constant = 0.75 kPa.m3 / mol. At 20 ° C

**12.5. Results of PBT and vPvB assessment**

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

**12.6. Other adverse effects**

Information not available

## SECTION 13. Disposal considerations

**13.1. Waste treatment methods**

Reuse if possible. Product residues are to be considered special hazardous waste. The dangerousness of the waste that partially contains this product must be evaluated according to the laws in force. (Ref. Annex D - Part IV of Legislative Decree n. 152/2006 and subsequent amendments and adjustments).
Disposal must be entrusted to an authorized waste management company, in compliance with national and possibly local regulations.
The legal responsibility for disposal lies with the producer / holder of the waste.
Different CER (European Refusal Code) codes could be applied to this product according to the specific circumstances that generated the waste, any alterations and contaminations.
The product as it is, out of specification in the original packaging, or poured into a suitable container for disposal as waste, or the product in specification but no longer usable (for example following an accidental spill), it is to be classified with a CER code compatible with the description of use indicated in section 1.2.
The suitable final destination of the waste will be evaluated by the manufacturer according to the chemical-physical characteristics of the waste itself, compatible with the plant authorized to which it will be conferred for recovery, treatment or final disposal according to the procedures provided for by the regulations in force.
Disposal via the wastewater drain is not permitted.

CONTAMINATED PACKAGING
Contaminated packaging must be sent, properly labeled, for recovery or disposal in compliance with national regulations on the management of waste and is to be classified with the following CER code:
15 01 10 *: packaging containing residues of dangerous substances or contaminated by these substances.

## SECTION 14. Transport information

**14.1. UN number**

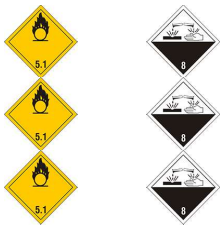
ADR / RID, IMDG, IATA: 2014

**14.2. UN proper shipping name**

| | |
|---|---|
| ADR / RID: | HYDROGEN PEROXIDE, AQUEOUS SOLUTION |
| IMDG: | HYDROGEN PEROXIDE, AQUEOUS SOLUTION |
| IATA: | HYDROGEN PEROXIDE, AQUEOUS SOLUTION |

**14.3. Transport hazard class(es)**

| | | |
|---|---|---|
| ADR / RID: | Class: 5.1 | Label: 5.1 (8) |
| IMDG: | Class: 5.1 | Label: 5.1 (8) |
| IATA: | Class: 5.1 | Label: 5.1 (8) |




**14.4. Packing group**

ADR / RID, IMDG, IATA: II

**14.5. Environmental hazards**

ADR / RID: NO

IMDG: NO
IATA: NO

**14.6. Special precautions for user**

| | | | |
|---|---|---|---|
| ADR / RID: | HIN - Kemler: 58 | Limited Quantities: 1 L | Tunnel restriction code: (E) |
| | Special provision: - | | |
| IMDG: | EMS: F-H, S-Q | Limited Quantities: 1 L | |
| IATA: | Cargo: | Maximum quantity: 5 L | Packaging instructions: 554 |
| | Pass.: | Maximum quantity: 1 L | Packaging instructions: 550 |
| | Special provision: | - | |

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Information not relevant

## SECTION 15. Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: P8

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Product

Point 3

*Liquid substances or mixtures that correspond to the criteria relating to one of the following hazard classes or categories referred to Annex I of Regulation (EC) No. 1272/2008:*
*a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types from A to F;*
*b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or development, 3.8 effects other than narcotic effects, 3.9 and 3.10;*
*c) hazard class 4.1;*
*d) hazard class 5.1.*

Contained substance

Point 75

HYDROGEN PEROXIDE SOLUTION
Reg. no.: 01-2119485845-22-xxxx

*Substances included in one or more of the following:*
*a) substances classified in one of the following classes in Annex VI, part 3, of Regulation (EC) no. 1272/2008:*
*- category 1A, 1B or 2 carcinogenicity, category 1A, 1B or 2 germ cell mutagenicity, but excluding substances classified due to effects following exposure by inhalation only;*
*- Reproductive toxicity of category 1A, 1B or 2, but excluding substances classified due to effects following exposure by inhalation only;*
*- skin sensitization of category 1, 1A or 1B;*
*- skin corrosion of category 1, 1A, 1B or 1C or skin irritation of category 2;*
*- serious category 1 eye damage or category 2 eye irritation;*
*b) substances listed in Annex II of Regulation (EC) no. 1223/2009 of the European Parliament and of the Council (*);*
*c) substances listed in Annex IV of Regulation (EC) no. 1223/2009 for which a condition is indicated in at least one of the columns g, h or i of the table of that annex;*
*d) substances listed in Appendix 13 of this annex. The ancillary requirements referred to in points 7 and 8 of*

*the column*
*2 of this item apply to all mixtures intended for tattooing practices, regardless of whether contain one of the substances referred to in points a) to d) of this column and entry.*

Regulation (EC) No. 2019/1148 - on the marketing and use of explosives precursors

HYDROGEN PEROXIDE (CAS 7722-84-1) - Restricted explosives precursor
The acquisition, introduction, possession or use of that restricted explosives precursor by members of the general public is subject to a restriction as set out in Article 5(1) and (3). Restricted explosives precursors shall not be made available to, or introduced, possessed or used by members of the general public.
The acquisition, introduction, possession or use of that regulated explosives precursor by members of the general public is subject to reporting obligations as set out in Article 9.
All suspicious transactions and significant disappearances and thefts must be reported to the relevant national contact point.

Italian Ministry of the Interior
Tel.: +390646542182
E-Mail: precursori@dcpc.interno.it

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

*Class IIb medical device according to the 93/42 regulation.*

**15.2. Chemical safety assessment**

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

## SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

| | |
|---|---|
| **Ox. Liq. 1** | Oxidising liquid, category 1 |
| **Ox. Sol. 2** | Oxidising solid, category 2 |

| | |
|---|---|
| **Acute Tox. 4** | Acute toxicity, category 4 |
| **Skin Corr. 1A** | Skin corrosion, category 1A |
| **Skin Corr. 1C** | Skin corrosion, category 1C |
| **Eye Dam. 1** | Serious eye damage, category 1 |
| **Aquatic Chronic 3** | Hazardous to the aquatic environment, chronic toxicity, category 3 |
| **H271** | May cause fire or explosion; strong oxidiser. |
| **H272** | May intensify fire; oxidiser. |
| **H302** | Harmful if swallowed. |
| **H332** | Harmful if inhaled. |
| **H314** | Causes severe skin burns and eye damage. |
| **H318** | Causes serious eye damage. |
| **H412** | Harmful to aquatic life with long lasting effects. |

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)

14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2018/1480 (XIII Atp. CLP)
16. Regulation (EU) 2019/521 (XII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Regulation (EU) 2020/217 (XIV Atp. CLP)
- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) – Italy

TRAINING FOR WORKERS:
The training of workers must include contents, updates and duration according to the risk profiles assigned to the working sectors of membership, according to the procedures provided for by Legislative Decree 81/2008.

**NOTE FOR THE RECIPIENT OF THE SAFETY DATA SHEET (SDS):**

It is the recipient of this SDS who must ensure that the information contained is read and understood by all persons who manipulate, store, use, or in any case come into contact in any way with the substance or mixture to which this sheet refers. In particular the recipient must provide adequate training to personnel assigned to the use of hazardous substances or mixtures. The recipient must make sure of the suitability and completeness of the information in relation to the specific use of the substance or mixture.
However, the substance or mixture to which this SDS refers must not be used for uses other than those specified in section 1. Do not assume responsibility for improper use. Since the use of the product does not fall under the direct control of the Supplier, it is the user's obligation observe, under their own responsibility, the laws and regulations in force regarding national and community hygiene and safety.
The information contained in this SDS is provided in good faith and is based on the current state of scientific and technical knowledge as of the date revision indicated, available from the Supplier indicated in section 1 of this sheet. The SDS should not be construed as a guarantee of any specific property of the substance or mixture. The information refers only to the substance or mixture specifically designated for section 1 and may not be valid for the substance or mixture used in combination with other materials or in other processes not specifically indicated in the text.
This version of the SDS supersedes all previous versions.

CALCULATION METHODS FOR CLASSIFICATION:

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.
Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.
Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Classification of the mixture according to Regulation (EC) n. 1272/2008 Classification procedure

| | | |
|---|---|---|
| May intensify fire; oxidiser. | H272 | Based on experimental data |
| Harmful if swallowed. | H302 | Based on literature data |
| Causes skin irritation | H315 | Based on literature data |
| May cause respiratory irritation | H335 | Based on literature data |
| Causes serious eye damage. | H318 | Based on literature data |
| Harmful to aquatic life with long lasting effects. | H412 | Based on literature data |

Changes to previous review
The following sections were modified:
01/ 02 / 03 / 04 / 05 / 06 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16.

Room 201 & 202, 12th Building,
Shenzhen Software Park Phase II,
1 Keji Middle 2nd Road, Yuehai Subdistrict,
Nanshan District, Shenzhen,
518057, Guangdong, China.
Tel:86-755-26722890
Fax:86-755- 2652 6612
E-mail:
sonoscape@sonoscape.net

SonoScape

Sept. 6th, 2019

Elisa Basso
STEELCO SPA
Via Balegante, 27 - 31039 Riese Pio X (TV) – ITALY

Dear Ms. Basso,

This is to claim that the following Sonoscape gastroscopes and colonoscopes are able to be reprocessed in Steelco's automated endoscope reprocessor(AER) and also be stored in Steelco's endoscopy drying cabinet, which are both listed here below.

Sonoscape's gastroscope & colonoscope models:

- Gastroscope: EG-550, EG-550L, EG-500, EG-500L
- Colonoscope: EC-550, EC-550T, EC-550L, EC-550L/T, EC-500, EC-500T, EC-500L, EC-500L/T

Steelco's AER & Drying Cabinet model:

- AER: Endoscope Washer EW1
- Drying Cabinet ED 200

Also, Steelco shall provide the scope reprocessing connectors for their AER to reprocess above mentioned Sonoscape endoscopes.

Sincerely

6/9/2019

Ronan Lao
Global Marketing Director
Endoscopy Division
Sonoscape Medical Corp.
www.sonoscape.com

# Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

## SECTION 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product name **Steelcoxide A**

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended Use: **Soluzione "A" of tricomponent system "SteelcoXide". Alcohol based activator of concetrated sterilizing solution "SteelcoXide B".**

Uses advised against: Uses other than those indicated.

### 1.3 Details of the supplier of the safety data sheet

Name **STEELCO S.p.A.**
Full address **Via Balegante, 27**
District and Country **31039 Riese Pio X (TV)**
**ITALY**

**tel. +39 0423 7561**

**fax +39 0423 755528**

e-mail address of the competent person responsible for the Safety Data Sheet **info@steelcogroup.com**

### 1.4. Emergency telephone number

For urgent inquiries refer to **Centros de Orientação de Doentes Urgentes (CODU): 800250250**

## SECTION 2. Hazards identification

### 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

| | | |
|---|---|---|
| Flammable liquid, category 2 | H225 | Highly flammable liquid and vapour. |
| Skin corrosion, category 1 | H314 | Causes severe skin burns and eye damage |
| Specific target organ toxicity - single exposure, category 3 | H336 | May cause drowsiness or dizziness. |

### 2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

Signal words: Danger

Hazard statements:

| | |
|---|---|
| **H225** | Highly flammable liquid and vapour. |
| **H314** | Causes severe skin burns and eye damage |
| **H336** | May cause drowsiness or dizziness. |

Precautionary statements:

| | |
|---|---|
| **P210** | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| **P312** | Call a POISON CENTRE if you feel unwell. |
| **P261** | Avoid breathing vapours / spray. |
| **P280** | Wear eye protection / face protection. |
| **P305+P351+P338** | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| **P337+P313** | If eye irritation persists: Get medical advice. |

**Contains:** PROPAN-2-OL

**2.3. Other hazards**

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

## SECTION 3. Composition/information on ingredients

**3.2. Mixtures**

Contains:

| **Identification** | **x = Conc. %** | **Classification 1272/2008 (CLP)** |
|---|---|---|
| **PROPAN-2-OL** | | |
| CAS 67-63-0<br>EC 200-661-7<br>INDEX 603-117-00-0<br>Reg. no. 01-2119457558-25-XXXX | 15 ≤ x < 35 | Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336 |
| **ACETIC ACID** | | |
| CAS 64-19-7<br>EC 200-580-7 | 3 ≤ x < 10 | Flam. Liq. 3 H226, Skin Corr. 1A H314, Eye Dam. 1 H318, Classification note/notes according to Annex VI to the CLP Regulation: B<br><br>Specific concentration limits (Annex VI of Reg. 1272/2008)<br>Skin Corr. 1A; H314: C ≥90 % Skin Corr. 1B; H314: 25 %≤ C <90 % Skin Irrit. 2; H315: 10 % ≤C <25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 % |

INDEX 607-002-00-6
Reg. no. 01-2119475328-30-xxxx

**ETHANOL**

| | | |
|---|---|---|
| CAS 64-17-5 | 3 ≤ x < 8 | Flam. Liq. 2 H225, Eye Irrit. 2 H319 |

EC 200-578-6
INDEX 603-002-00-5
Reg. no. 01-2119457610-43-XXXX

The full wording of hazard (H) phrases is given in section 16 of the sheet.

## SECTION 4. First aid measures

### 4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.
SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.
INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.
INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.
PROTECTION MEASURES FOR FIRST AID: for the PPE necessary for first aid interventions refer to section 8.2 of this safety data sheet.

### 4.2. Most important symptoms and effects, both acute and delayed

Specific information on symptoms and effects caused by the product are unknown.

### 4.3. Indication of any immediate medical attention and special treatment needed

Information not available

## SECTION 5. Firefighting measures

### 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.
UNSUITABLE EXTINGUISHING EQUIPMENT
Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

### 5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

PROPAN-2-OL
Carbon oxides.

### 5.3. Advice for firefighters

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always

wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

## SECTION 6. Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

*6.1.1 For those who do not intervene directly*
Do not take any action involving any personal risk or without proper training. Evacuate the surrounding areas. Do not touch or walk on the spilled material.
Wear suitable protective equipment (including personal protective equipment referred to in section 8 of this Safety Data Sheet) to prevent contamination of skin, eyes and personal clothing. Wear appropriate respirator when ventilation is inadequate.
Do not inhale the mists / vapors / fumes. Avoid the dispersion of the product into the environment. Follow the appropriate internal procedures for personnel not authorized to intervene directly in the event of accidental release.

*6.1.2 For those who intervene directly*
Stop the leak if there is no danger.
Evacuate unauthorized personnel. Wear suitable protective equipment. (see section 8 of this Safety Data Sheet). Follow the appropriate internal procedures for authorized personnel. Isolate the danger area and deny entry. Ventilate enclosed spaces before entering.

**6.2. Environmental precautions**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

**6.3. Methods and material for containment and cleaning up**

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

**6.4. Reference to other sections**

Any information on personal protection and disposal is given in sections 8 and 13.

## SECTION 7. Handling and storage

**7.1. Precautions for safe handling**

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

**7.2. Conditions for safe storage, including any incompatibilities**

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a cool and well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

**7.3. Specific end use(s)**

Information not available

## SECTION 8. Exposure controls/personal protection

### 8.1. Control parameters

Regulatory References:

| | | |
|---|---|---|
| DEU | Deutschland | Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56 |
| ESP | España | Límites de exposición profesional para agentes químicos en España 2019 |
| FRA | France | Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS |
| GBR | United Kingdom | EH40/2005 Workplace exposure limits (Fourth Edition 2020) |
| EU | OEL EU | Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC. |
| | TLV-ACGIH | ACGIH 2020 |

**PROPAN-2-OL**

**Threshold Limit Value**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| AGW | DEU | 500 | 200 | 1000 | 400 | |
| MAK | DEU | 500 | 200 | 1000 | 400 | |
| VLA | ESP | 500 | 200 | 1000 | 400 | |
| VLEP | FRA | | | 980 | 400 | |
| WEL | GBR | 999 | 400 | 1250 | 500 | |
| TLV-ACGIH | | 492 | 200 | 983 | 400 | |

| Predicted no-effect concentration - PNEC | | |
|---|---|---|
| Normal value in fresh water | 140,9 | mg/l |
| Normal value in marine water | 140,9 | mg/l |
| Normal value for fresh water sediment | 552 | mg/kg |
| Normal value for marine water sediment | 552 | mg/kg |
| Normal value for water, intermittent release | 140,9 | mg/l |
| Normal value of STP microorganisms | 2,251 | g/l |
| Normal value for the food chain (secondary poisoning) | 160 | mg/kg |
| Normal value for the terrestrial compartment | 28 | mg/kg |

**Health - Derived no-effect level - DNEL / DMEL**

| | Effects on consumers | | | | Effects on workers | | | |
|---|---|---|---|---|---|---|---|---|
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | | | | | VND | VND | VND | 26 mg/kg bw/d |
| Inhalation | VND | VND | VND | 89 mg/m3 | VND | VND | VND | 500 mg/m3 |
| Skin | VND | VND | VND | 319 mg/kg bw/d | VND | VND | VND | 888 mg/kg bw/d |

**ACETIC ACID**

**Threshold Limit Value**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| AGW | DEU | 25 | 10 | 50 (C) | 20 (C) | |
| MAK | DEU | 25 | 10 | 50 | 20 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| VLA | ESP | 25 | 10 | 50 | 20 | |
| VLEP | FRA | 25 | 10 | 50 | 20 | |
| WEL | GBR | 25 | 10 | 50 | 20 | |
| OEL | EU | 25 | 10 | 50 | 20 | |
| TLV-ACGIH | | 25 | 10 | 37 | 15 | |

| Predicted no-effect concentration - PNEC | | |
|---|---|---|
| Normal value in fresh water | 3,058 | mg/l |
| Normal value in marine water | 305,8 | µg/L |
| Normal value for fresh water sediment | 11,36 | mg/kg |
| Normal value for marine water sediment | 1,136 | mg/kg |
| Normal value for water, intermittent release | 30,58 | mg/l |
| Normal value of STP microorganisms | 85 | mg/l |
| Normal value for the terrestrial compartment | 470 | µg/kg soil dw |

**Health - Derived no-effect level - DNEL / DMEL**

| | Effects on consumers | | | | Effects on workers | | | |
|---|---|---|---|---|---|---|---|---|
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | NPI | | NPI | | | | | |
| Inhalation | 25 mg/m3 | NPI | 25 mg/m3 | NPI | 25 mg/m3 | NPI | 25 mg/m3 | NPI |
| Skin | VND | NPI | VND | NPI | VND | NPI | VND | NPI |

**ETHANOL**

**Threshold Limit Value**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| AGW | DEU | 380 | 200 | 1520 | 800 | |
| MAK | DEU | 380 | 200 | 1520 | 800 | |
| VLA | ESP | | | 1910 | 1000 | |
| VLEP | FRA | 1900 | 1000 | 9500 | 5000 | |
| WEL | GBR | 1920 | 1000 | | | |
| TLV-ACGIH | | | | 1884 | 1000 | |

| Predicted no-effect concentration - PNEC | | |
|---|---|---|
| Normal value in fresh water | 960 | µg/L |
| Normal value in marine water | 790 | mg/l |
| Normal value for fresh water sediment | 3,6 | mg/kg |
| Normal value for marine water sediment | 2,9 | mg/kg |
| Normal value for water, intermittent release | 2,75 | mg/l |
| Normal value of STP microorganisms | 580 | mg/l |
| Normal value for the food chain (secondary poisoning) | 380 | mg/kg food |
| Normal value for the terrestrial compartment | 630 | µg/kg soil dw |

**Health - Derived no-effect level - DNEL / DMEL**

| | Effects on consumers | | | | Effects on workers | | | |
|---|---|---|---|---|---|---|---|---|
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | | | | | | NPI | | 87 mg/kg bw/d |
| Inhalation | 950 mg/m3 | NPI | NPI | 114 mg/m3 | 1900 mg/m3 | NPI | NPI | 950 mg/m3 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Skin | NPI | NPI | NPI | 206 mg/kg bw/d | NPI | NPI | NPI | 343 mg/kg bw/d |

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

**8.2. Exposure controls**

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION
Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION
Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, wear a mask with a type AX filter, whose limit of use will be defined by the manufacturer (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.
Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.
If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

PROPAN-2-OL
IBE (Biological Indicators of Exposure - ACGIH 2020): acetone in urine = 40 mg / L (end of shift)

## SECTION 9. Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

| | |
|---|---|
| Appearance | liquid |
| Colour | colourless |

| | | |
|---|---|---|
| Odour | pungent | |
| Odour threshold | Not determined | |
| pH | 1,6 | |
| Melting point / freezing point | Not available | |
| Initial boiling point | 105 °C | |
| Boiling range | Not available | |
| Flash point | 15 °C | |
| Evaporation rate | Not determined | |
| Flammability (solid, gas) | not applicable | Reason for missing data:Sulla base dello stato fisico |
| Lower inflammability limit | Not determined | |
| Upper inflammability limit | Not determined | |
| Lower explosive limit | Not determined | |
| Upper explosive limit | Not determined | |
| Vapour pressure | Not available | |
| Vapour density | Not determined | |
| Relative density | 0,986 g/L | |
| Solubility | soluble in water | |
| Partition coefficient: n-octanol/water | 0,05 (Propan-2-olo) | |
| Auto-ignition temperature | Not available | |
| Decomposition temperature | Not determined | |
| Viscosity | Not determined | |
| Explosive properties | Not Explosive | |
| Oxidising properties | Not Oxydante | |

**9.2. Other information**

VOC (Directive 2010/75/EC) : 25,21 % - 240,23 g/litre

## SECTION 10. Stability and reactivity

**10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

ACETIC ACID
It is highly corrosive: it attacks the most common metals with the development of hydrogen.

**10.2. Chemical stability**

The product is stable in normal conditions of use and storage.

ACETIC ACID
Hygroscopic. Polymerises in contact with acetic aldehyde.

**10.3. Possibility of hazardous reactions**

The vapours may also form explosive mixtures with the air.

ACETIC ACID
Risk of explosion on contact with: chromium (VI) oxide,potassium permanganate,sodium peroxide,perchloric acid,phosphorus chloride,hydrogen peroxide.May react dangerously with: alcohols,bromine pentafluoride,chlorosulphuric acid,dichromate-sulphuric acid,ethane diamine,ethylene glycol,potassiun hydroxide,strong bases,sodium hydroxide,strong oxidising agents,nitric acid,ammonium nitrate,potassium tert-butoxide,oleum.Forms explosive mixtures with: air.
Violent reactions in case of contact with strong bases, oxidants and other reactive compounds.
Formation of hydrogen in case of contact with carbon steel and non-noble metals.

ETHANOL

Risk of explosion on contact with: alkaline metals,alkaline oxides,calcium hypochlorite,sulphur monofluoride,acetic anhydride,acids,concentrated hydrogen peroxide,perchlorates,perchloric acid,perchloronitrile,mercury nitrate,nitric acid,silver,silver nitrate,ammonia,silver oxide,ammonia,strong oxidising agents,nitrogen dioxide.May react dangerously with: bromoacetylene,chlorine acetylene,bromine trifluoride,chromium trioxide,chromyl chloride,fluorine,potassium tert-butoxide,lithium hydride,phosphorus trioxide,black platinum,zirconium (IV) chloride,zirconium (IV) iodide.Forms explosive mixtures with: air.

**10.4. Conditions to avoid**

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

PROPAN-2-OL
Heat, flames and sparks. Extreme temperatures and direct sunlight.

ACETIC ACID
Avoid exposure to: sources of heat,naked flames.
No ventilation. Open flames, heating and sparks. Humidity.

ETHANOL
Avoid exposure to: sources of heat,naked flames.
Avoid high temperatures and proximity to ignition sources

**10.5. Incompatible materials**

PROPAN-2-OL
Oxidizing agents, acid anhydrides, aluminum, halogenated compounds, acids.

ACETIC ACID
Incompatible with: carbonates,hydroxides,phosphates,oxidising substances,bases.
Bases, acetic anhydride, nitric acid, alcohol, halogens, halogen compounds and oxidizing materials.

ETHANOL
Strong mineral acids, oxidizing agents. High temperature aluminum.

**10.6. Hazardous decomposition products**

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

ACETIC ACID
When heated to decomposition, it develops irritating fumes. Carbon monoxide, carbon dioxide ($CO_2$)

## SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

**11.1. Information on toxicological effects**

Metabolism, toxicokinetics, mechanism of action and other information

PROPAN-2-OL
It is readily absorbed following inhalation exposure and rapidly spreads to tissues. However, it is also readily excreted in the urine, essentially in the form of the 2-methoxyacetic acid metabolite. (Arch Toxicol, 68, -588-94 - Johanson G, 1994)

ACETIC ACID
The substance is absorbed from the gastrointestinal tract and the lungs. It is rapidly distributed throughout the body. It is almost completely metabolized at the cellular level. After reaction with acetyl coenzyme A, the acetic acid is transformed by the Krebs cycle and is incorporated into the lipids and proteins, part of it is transformed into formic acid. Only a small part is found in the urine in unchanged form

Information on likely routes of exposure

ACETIC ACID
The main routes of potential exposure are expected to be inhalation and skin contact in workers exposed to the manufacture and use of the substance.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture: Not classified (no significant component)
ATE (Oral) of the mixture: Not classified (no significant component)
ATE (Dermal) of the mixture: Not classified (no significant component)

ETHANOL
LD50 (Oral) 1187 mg/kg Ratto
LC50 (Inhalation) 115,9 mg/l/4h

ACETIC ACID
LD50 (Oral) 3310 mg/kg Ratto
LD50 (Dermal) 1060 mg/kg Coniglio
LC50 (Inhalation) 11,4 mg/l/4h Ratto

PROPAN-2-OL
LD50 (Oral) 4710 mg/kg Rat
LD50 (Dermal) 12800 mg/kg Rat
LC50 (Inhalation) 72,6 mg/l/4h Rat

PROPAN-2-OL

Method: equivalent or similar to OECD 401
Reliability (Klimisch score): 2
Species: Rat (Sherman)
Routes of exposure: oral
Results: LD50 = 5840 mg / kg

Method: equivalent or similar to OECD 402
Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: cutaneous

Results: LC50 = 16.4 ml / kg

Method: equivalent or similar to OECD 403
Reliability (Klimisch score): 1
Species: Rat (Fischer 344; Male / Female)
Routes of exposure: inhalation (vapors)
Results: LD50> 10000 ppm / 6h

ACETIC ACID

Bibliographic reference: "The acute oral toxicity of acetic, chloroacetic, dichloroacetic and trichloroacetic acids (J Ind Hyg Toxicol, Vol 23, PP 78-82 (1941))"
Reliability (Klimisch score): 2
Species: rat (Male / Female)
Routes of exposure: oral
Results: LD50: 3310 mg / kg

Method: equivalent or similar to OECD 403
Reliability (Klimisch score): 2
Species: rat (Sprague-Dawley Male / Female)
Routes of exposure: inhalation (vapors)
Results: LC50: 11.4 mg / l 4h

Reference: [Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 16]
Species: Rabbit
Routes of exposure: cutaneous
Results: LD50: 1060 mg / kg

ETHANOL

Method: OECD 401
Reliability (Klimish score): 1
Species: rat (Cox CD; Male / Female)
Route of exposure: oral
Results: LD50: 10470 mg / kg

Method: OECD 403
Reliability (Klimish score): 2
Species: rat (Sprague-Dawley; Male / Female)
Route of Exposure: inhalation (vapors)
LC50 results (male): 116.9 mg / l 4h

Reference: Schechter, M. et al, Pharmacol Biochem Behav 52 (1): 245-248, 1995
Reliability (Klimisch score): 2
Species: Mouse (HS; male / female)
Routes of exposure: intraperitoneal
Results: LD50 = 9450 mg / kg body weight

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: cutaneous
Results: Not irritating
Reference: Nixon G et al, Toxicology and Applied Pharmacology 31, 481-490 (1975)

ACETIC ACID

Method: equivalent or similar to OECD 404
Reliability (Klimisch score: 2
Species: rabbit
Routes of exposure: cutaneous
Results: Based on the strength of evidence of the available data as determined by expert judgment, the substance is classified as corrosive to the skin.

ETHANOL

Method: OECD 404
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White)
Routes of exposure: cutaneous
Results: non-irritating.

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

PROPAN-2-OL

Method: equivalent or similar to OECD 405
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White)
Routes of exposure: ocular
Results: irritating

ACETIC ACID

Method: equivalent or similar to OECD 405
Reliability (Klimisch score): 2
Species: rabbit (Rsk: NZW)
Routes of exposure: ocular
Results: Based on the strength of evidence of the available data as determined by expert judgment, the substance is classified as corrosive to eyes.

ETHANOL

Method: OECD 405
Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: ocular
Results: irritating.

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

Method: OECD 406
Reliability (Klimisch score): 1
Species: Guinea pig (Dunkin-Hurtley; Male / Female)
Routes of exposure: cutaneous
Results: not sensitizing

ACETIC ACID

Based on the strength of evidence of the available data as determined by expert judgment, the substance is not classified for the respiratory or skin sensitization hazard class.

ETHANOL

Method: equivalent or similar OECD 406
Reliability (Klimisch score): 2
Species: Guinea pig (Pirbright White; Female)
Routes of exposure: cutaneous
Results: not sensitizing.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

Based on available data, the substance has no mutagenic effects and is not classified under the relevant hazard class CLP.

ACETIC ACID

Method: equivalent or similar to OECD 471 - In vitro test
Reliability (Klimisch score): 2
Species: Salmonella Typhimurium
Results: negative with and without metabolic activation.

Method: equivalent or similar to EU B.12 - live test
Reliability (Klimisch score): 1
Species: rat (CD (Sprague-Dawley) Male / Female)
Routes of exposure: inhalation (vapors)
Results: negative.

ETHANOL

Method: equivalent or similar to OECD 471 - In vitro test
Reliability (Klimisch score): 1
Species: S. typhimurium
Results: negative with and without metabolic activation
Method: equivalent or similar to OECD 474 - In vivo test
Species: mouse (NMRI; Male / Female)
Routes of exposure: intraperitoneal
Results: negative.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

PROPAN-2-OL
Based on available data, the substance has no carcinogenic effects and is not classified under the relevant hazard class CLP.

ACETIC ACID

Bibliographic reference: "The stimulating effect of acetic acid, alcohol and thermal burn injury on oesophagus and forestomach carcinogenesis induced by n-nitrososarcosin ethyl ester in rats" (Cancer Letters Vol 47, pp179-185 (1989))
Reliability (Klimisch score): 2
Species: rat (outbred white; male)
Routes of exposure: oral
Results: negative. LOAEL: 64 mg / kg body weight / day

ETHANOL

Method: equivalent or similar to OECD 453
Reliability (Klimisch score): 1
Species: rat (Fischer 344 / DuCrj; Male / Female)
Routes of exposure: inhalation (vapors)
Results: negative.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

Method: equivalent or similar to OECD 416
Reliability (Klimisch score): 1
Species: Rat (Sprague-Dawley; Male / Female)
Routes of exposure: Oral
Results: negative. NOAEL = 1000 mg / kg bw / day.

Adverse effects on sexual function and fertility

PROPAN-2-OL

Method: equivalent or similar to OECD 416
Reliability (Klimsch score): 1
Species: rat (Sprague-Dawley Male / Female)
Routes of exposure: oral
Results: negative.

ETHANOL

Method: equivalent or similar to OECD 416
Reliability (Klimisch score): 1
Species: mouse (CD-1; Male / Female)
Routes of exposure: oral
Results: No effect on fertility at doses equivalent to 20.7 g / kg / day

Adverse effects on development of the offspring

PROPAN-2-OL

Method: equivalent or similar to OECD 414
Reliability (Klimsch score): 1
Species: rat (Sprague-Dawley)
Routes of exposure: oral
Results: negative.

ACETIC ACID

Method: equivalent or similar to EU B.31
Reliability (Klimisch score): 2
Species: rat (Wistar)
Routes of exposure: oral
Results: negative.
NOAEL (developmental toxicity): 1 600 mg / kg body weight / day.

ETHANOL

Method: equivalent or similar to OECD 414
Reliability (Klimisch score): 2
Species: rat (Sprague-Dawley)
Routes of exposure: inhalation
Results: negative. NOAEL (maternal) = 16000 ppm.
NOAEL (fetus)> = 20,000 ppm

STOT - SINGLE EXPOSURE

May cause drowsiness or dizziness

PROPAN-2-OL

Metodo: OECD 426
Affidabilità (Klimisch score): 1
Specie: Ratto (Sprague-Dawley; Femmina)
Vie d'esposizione: orale.
Risultati: Può provocare sonnolenza o vertigini.
In base ai dati disponibili, la sostanza presenta effetti di tossicità specifica per organi bersaglio per esposizione singola ed è classificata sotto la relativa classe di pericolo CLP.

ACETIC ACID

In humans, serious effects are reported following accidental single exposures by any route, mainly due to the local corrosive action of the substance with consequent systemic effects (INRS, 2011). Inhalation exposure to vapors or aerosols immediately causes irritation symptoms.

ETHANOL

Based on available data, the substance has no specific target organ toxicity effects for single exposure and is not classified under the relevant CLP hazard class.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

Accordi to available data, this substance does not present specific organ toxicity for repeated exposition and it is not classified under the relevant CLP hazard class.

ACETIC ACID

Based on available data, the substance has no specific target organ toxicity effects on repeated exposure and is not classified under the relevant CLP hazard class
Bibliographic reference: Antihypertensive effects of acetic acid and vinegar on spontaneously hypertensive rats (Biosci. Biotechnol. Biochem Vol 65, (12), pp 2690-2694 (2001))
Reliability (Klimisch score): 2
Species: rat (Male)
Routes of exposure: oral
Results: negative. NOAEL: 290 mg / kg body weight / day

Bibliographic reference: Acetic acid, a potent stimulator of mouse epidermal macromolecular synthesis and hyperplasia but with weak tumor-promoting ability (Nat. Cancer Inst., Vol 55, pp 983-987 (1975))
Reliability (Klimisch score): 2
Species: mouse (CD-1 Female)
Routes of exposure: cutaneous
Results: negative. NOAEL: 30 mg / animal

ETHANOL

Method: equivalent or similar OECD 408
Reliability (Klimisch score): 2
Species: Rat (Sprague-Dawley; Male / Female)
Routes of exposure: oral
Results: negative. NOAEL: 1730 mg / kg body weight / day

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

PROPAN-2-OL

No data are available on the hazard in case of aspiration.

ACETIC ACID

No data are available on the hazard in case of aspiration.

ETHANOL

No data are available on the hazard in case of aspiration.

## SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

**12.1. Toxicity**

| | |
|---|---|
| ETHANOL | |
| LC50 - for Fish | 14,2 g/l/96h Pimephales promelas (US EPA E03-05) |
| EC50 - for Crustacea | 5012 mg/l/48h Ceriodaphnia dubia (ASTM E729-80) |
| EC50 - for Algae / Aquatic Plants | 275 mg/l/72h Chlorella vulgaris (OECD 201) |
| Chronic NOEC for Fish | 250 mg/L/5 d |
| | |
| ACETIC ACID | |
| LC50 - for Fish | > 300,82 mg/l/96h Oncorhynchus mykiss (equivalent or similar to OECD 203) |
| EC50 - for Crustacea | > 300,82 mg/l/48h Daphnia magna (OECD 202) |
| EC50 - for Algae / Aquatic Plants | > 300,82 mg/l/72h Skeletonema costatum (equivalent or similar to ISO 10253) |
| Chronic NOEC for Algae / Aquatic Plants | > 300,82 mg/l/72h Skeletonema costatum (equivalent or similar to ISO 10253) |
| | |
| PROPAN-2-OL | |
| LC50 - for Fish | 9640 mg/l/96h Pimephales promelas (equivalent or similar to OECD 203) |
| EC50 - for Crustacea | > 10000 mg/l/48h Daphnia magna (equivalent or similar to OECD 202) |

**12.2. Persistence and degradability**

PROPAN-2-OL
Easily biodegradable, 53% in 5 giorni (equivalent or similar to EU C.5)

ACETIC ACID
Easily biodegradable, 96% in 20 days (Price, K.S., Waggy, G.T. And Conway, R.A. 1974, J. Water pollut. Contr. Fed. Vol 46 PP 46-77)

Solubility in water > 10000 mg/l

ETHANOL
Readily biodegradable, 60% in 10 days (BOD - Standard methods for the examination of water and waste water 1971. 13th ed, American Public Health Assoc, NY)

**12.3. Bioaccumulative potential**

ETHANOL

| | |
|---|---|
| Partition coefficient: n-octanol/water | -0,35 Log Kow 24°C (OECD 107) |

ACETIC ACID

| | |
|---|---|
| Partition coefficient: n-octanol/water | -0,17 Log Kow (CRC Press Inc. Boca Raton. USA.) |
| BCF | 3,16 (Q)sar (Meylan,WM, Howard,PH, Boethling,RS et al. 1999) |

PROPAN-2-OL

| | |
|---|---|
| Partition coefficient: n-octanol/water | 0,05 |

**12.4. Mobility in soil**

ACETIC ACID
Based on an estimated Koc value of approx. 1, very high mobility in soil is expected.
Acetic acid volatilizes from the dry soil surface according to the vapor pressure value. Based on the pKa value of 4.76, it mainly exists in anionic form in water. The anionic form adsorbs less than the corresponding neutral form in soils containing organic carbon and clay (HSDB, 2018).

ACETIC ACID

| | |
|---|---|
| Partition coefficient: soil/water | 1,153 |

**12.5. Results of PBT and vPvB assessment**

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

**12.6. Other adverse effects**

Information not available

## SECTION 13. Disposal considerations

**13.1. Waste treatment methods**

Reuse if possible. Product residues are to be considered special hazardous waste. The dangerousness of the waste that partially contains this product must be evaluated according to the laws in force. (Ref. Annex D - Part IV of Legislative Decree no. 152/2006 and subsequent amendments and adjustments).
Disposal must be entrusted to an authorized waste management company, in compliance with national and possibly local regulations.
The legal responsibility for disposal lies with the producer / holder of the waste.
Different CER (European Waste Code) codes could be applied to this mixture according to the specific circumstances that generated the waste, any alterations and contaminations.

The product as it is, out of specification in the original packaging, or poured into a suitable container for disposal as waste, or the product in specification but no longer usable (for example following an accidental spill), is to be classified with a code CER compatible with the description of use indicated in section 1.2.

The appropriate final destination of the waste will be assessed by the manufacturer according to the chemical-physical characteristics of the waste itself compatible with the authorized plant to which it will be conferred for recovery, treatment or final disposal in the manner prescribed by current regulations.
Disposal via the wastewater drain is not permitted.
For hazardous substances registered according to EC Regulation 1907/2006 (REACH) for which a chemical safety report has been prepared, refer to the specific information contained in the exposure scenarios attached to this SDS.

CONTAMINATED PACKAGING
Contaminated packaging must be sent, properly labeled, for recovery or disposal in compliance with national regulations on waste management and must be classified with the following EWC code:

15 01 10 *: packaging containing residues of dangerous substances or contaminated by these substances

## SECTION 14. Transport information

**14.1. UN number**

ADR / RID, IMDG, IATA: 1987

**14.2. UN proper shipping name**

| | |
|---|---|
| ADR / RID: | ALCOHOLS, N.O.S. MIXTURE (Propan-2-OI, Ethanol) |
| IMDG: | ALCOHOLS, N.O.S. MIXTURE (Propan-2-OI, Ethanol) |
| IATA: | ALCOHOLS, N.O.S. MIXTURE (Propan-2-OI, Ethanol) |

**14.3. Transport hazard class(es)**

| | | |
|---|---|---|
| ADR / RID: | Class: 3 | Label: 3 |
| IMDG: | Class: 3 | Label: 3 |
| IATA: | Class: 3 | Label: 3 |

**14.4. Packing group**

ADR / RID, IMDG, IATA: II

**14.5. Environmental hazards**

| | |
|---|---|
| ADR / RID: | NO |
| IMDG: | NO |
| IATA: | NO |

For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

**14.6. Special precautions for user**

| | | | |
|---|---|---|---|
| ADR / RID: | HIN - Kemler: 33<br>Special provision: 640D | Limited Quantities: 1 L | Tunnel restriction code: (D/E) |
| IMDG: | EMS: F-E, S-E | Limited Quantities: 1 L | |

| | | | |
|---|---|---|---|
| IATA: | Cargo: | Maximum quantity: 60 L | Packaging instructions: 364 |
| | Pass.: | Maximum quantity: 5 L | Packaging instructions: 353 |
| | Special provision: | A3 | |

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Information not relevant

## SECTION 15. Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: P5c

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Product

Point 3

*Liquid substances or mixtures that meet the criteria relating to one of the following hazard classes or categories as set out in Annex I of Regulation (EC) No. 1272/2008:*
*a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;*
*b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or development, 3.8 effects other than narcotic effects, 3.9 and 3.10;*
*c) hazard class 4.1;*
*d) hazard class 5.1.*

Point 40

*Substances classified as flammable gases of category 1 or 2, flammable liquids of category 1, 2 or 3, flammable solids of category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases of categories 1, 2 or 3, category 1 pyrophoric liquids or category 1 pyrophoric solids, even if not listed in Part 3 of Annex VI to Regulation (EC) No. 1272/2008Contained substance*

Point 75 ACETIC ACID
Reg. no.: 01-2119475328-30-xxxx

*Substances included in one or more of the following:*
*a) substances classified in one of the following classes in Annex VI, part 3, of Regulation (EC) no. 1272/2008:*
*- category 1A, 1B or 2 carcinogenicity, category 1A, 1B or 2 germ cell mutagenicity, but excluding substances classified due to effects following exposure by inhalation only;*
*- Reproductive toxicity of category 1A, 1B or 2, but excluding substances classified due to effects following exposure by inhalation only;*
*- skin sensitization of category 1, 1A or 1B;*
*- skin corrosion of category 1, 1A, 1B or 1C or skin irritation of category 2;*
*- serious category 1 eye damage or category 2 eye irritation;*
*b) substances listed in Annex II of Regulation (EC) no. 1223/2009 of the European Parliament and of the Council (*);*
*c) substances listed in Annex IV of Regulation (EC) no. 1223/2009 for which a condition is indicated in at least one of the columns g, h or i of the table of this annex;*
*d) substances listed in Appendix 13 of this annex. The ancillary requirements referred to in points 7 and 8 of column 2 of this entry apply to all mixtures intended for tattooing practices, regardless of whether they contain one of the substances referred to in points a) to d) of this column and entry.*

Regulation (EC) No. 2019/1148 - on the marketing and use of explosives precursors

Not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

Medical device, class IIb according to legislation 93/42.

D.Lgs. 152/2006 and following modifications

Emissions according to Chapter V, Annex I:

TAB. D Class 3 04,97 %
TAB. D Class 4 21,22 %
TAB. D Class 5 03,73 %

**15.2. Chemical safety assessment**

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

## SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

| | |
|---|---|
| **Flam. Liq. 2** | Flammable liquid, category 2 |
| **Flam. Liq. 3** | Flammable liquid, category 3 |
| **Skin Corr. 1A** | Skin corrosion, category 1A |
| **Eye Irrit. 2** | Eye irritation, category 2 |
| **STOT SE 3** | Specific target organ toxicity - single exposure, category 3 |
| **H225** | Highly flammable liquid and vapour. |
| **H226** | Flammable liquid and vapour. |
| **H314** | Causes severe skin burns and eye damage. |
| **H319** | Causes serious eye irritation. |
| **H336** | May cause drowsiness or dizziness. |

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2018/1480 (XIII Atp. CLP)
16. Regulation (EU) 2019/521 (XII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Regulation (EU) 2020/217 (XIV Atp. CLP)
- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) – Italy

**Training for workers:**
The training of workers must include contents, updates and duration according to the risk profiles assigned to the working sectors of membership, according to the procedures provided for by Legislative Decree 81/2008.

**Procedure used to derive the classification according to Regulation (EC) 1272/2008 (CLP) in relation to mixtures:**

| Classification of the mixture according to Regulation (EC) n. 1272/2008 | | Classification procedure |
|---|---|---|
| Flammable liquid, category 2 | H225 | Based on experimental data. |
| Skin corrosion, category 1 | H314 | Based on experimental data. |
| Specific target organ toxicity - single exposure, category 3 | H336 | Based on literature data. |

**Note for the recipient of the Safety Data Sheet (SDS):**

It is the recipient of this SDS who must ensure that the information contained is read and understood by all persons who handle, store, use, or otherwise come into contact in any way with the substance or mixture to which this sheet refers. In particular, the recipient must provide adequate training to personnel assigned to the use of dangerous substances or mixtures. The recipient must ensure the suitability and completeness of the information in relation to the specific use of the substance or mixture.
However, the substance or mixture to which this SDS refers must not be used for uses other than those specified in section 1. No responsibility is assumed for improper uses. Since the use of the product does not fall under the direct control of the Supplier, it is the user's obligation to observe, under his own responsibility, the laws and regulations in force regarding national and Community hygiene and safety.
The information contained in this SDS is provided in good faith and is based on the current state of scientific and technical knowledge, at the revision date indicated, available from the Supplier indicated in section 1 of this sheet. The SDS should not be interpreted as a guarantee of any specific property of the substance or mixture. The information refers only to the substance or mixture specifically designated in section 1 and may not be valid for the substance or mixture used in combination with other materials or in other processes not specifically indicated in the text.

This version of the SDS supersedes all previous versions.

Changes from the previous revision.

Changes have been made to the following sections:
01/02/03/04/05/06/07/08/09/10/11/12/13/14/15/16.

# Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

## SECTION 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product name **Steelcoxide-DT**

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use **Concentrated decontaminating disinfectant product. Compatible with thermolabile medical devices and latest generation optical fibers. FOR PROFESSIONAL USE ONLY.**

Uses advised against: Uses other than those indicated.

### 1.3 Details of the supplier of the safety data sheet

Name **STEELCO S.p.A.**
Full address **Via Balegante, 27**
District and Country **31039 Riese Pio X (TV)**
**ITALY**

**tel. +39 0423 7561**

**fax +39 0423 755528**

e-mail address of the competent person
responsible for the Safety Data Sheet **info@steelcogroup.com**

### 1.4. Emergency telephone number

For urgent inquiries refer to **Centros de Orientação de Doentes Urgentes (CODU): 800250250**

## SECTION 2. Hazards identification

### 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

| | | |
|---|---|---|
| Flammable liquid, category 2 | H225 | Highly flammable liquid and vapour. |

### 2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

Signal words: **Danger**

Hazard statements:

**H225** Highly flammable liquid and vapour.
**EUH208** Contains: SUBTILISINE
May produce an allergic reaction.

Precautionary statements:

**P210** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
**P233** Keep container tightly closed.

**2.3. Other hazards**

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

## SECTION 3. Composition/information on ingredients

**3.2. Mixtures**

Contains:

| Identification | x = Conc. % | Classification 1272/2008 (CLP) |
|---|---|---|
| **ETHANEDIOL**<br>CAS 107-21-1<br>EC 203-473-3<br>INDEX 603-027-00-1<br>Reg. no. 01-2119456816-28-xxxx | 6 ≤ x < 10 | Acute Tox. 4 H302, STOT RE 2 H373 |
| **PROPAN-2-OL**<br>CAS 67-63-0<br>EC 200-661-7<br>INDEX 603-117-00-0<br>Reg. no. 01-2119457558-25-XXXX | 6≤ x < 10 | Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336 |
| **ETHANOL**<br>CAS 64-17-5<br>EC 200-578-6<br>INDEX 603-002-00-5 | 1 ≤ x < 3 | Flam. Liq. 2 H225, Eye Irrit. 2 H319 |

Reg. no. 01-2119457610-43-XXXX

**SUBTILISINE**

CAS 9014-01-1 | 0,2 ≤ x < 0,6 | Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Resp. Sens. 1 H334, Aquatic Acute 1 H400 M=1, Aquatic Chronic 2 H411

EC 232-752-2

INDEX 647-012-00-8

Reg. no. 01-2119480434-38-xxxx

The full wording of hazard (H) phrases is given in section 16 of the sheet.

## SECTION 4. First aid measures

### 4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.
PROTECTION MEASURES FOR FIRST AID: for the PPE necessary for first aid interventions refer to section 8.2 of the present safety data sheet.

### 4.2. Most important symptoms and effects, both acute and delayed

Specific information on symptoms and effects caused by the product are unknown.

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.
In the event of an accident or discomfort, consult a doctor immediately (if possible show the instructions for use or the safety data sheet).

## SECTION 5. Firefighting measures

### 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.
UNSUITABLE EXTINGUISHING EQUIPMENT
Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

### 5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

PROPAN-2-OL
Carbon oxides.

### 5.3. Advice for firefighters

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

## SECTION 6. Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

Block the leakage if there is no hazard.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.
Send away individuals who are not suitably equipped. Use explosion-proof equipment. Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site.

*6.1.1 For those who do not intervene directly*
Do not take any action involving any personal risk or without proper training. Evacuate the surrounding areas. Don't touch either
walk on the spilled material.
Wear suitable protective equipment (including personal protective equipment referred to in section 8 of this Safety Data Sheet)
to prevent contamination of skin, eyes and personal clothing. Wear an appropriate respirator when ventilation is inadequate.
Do not inhale the mists / vapors / fumes. Avoid the dispersion of the product into the environment. Follow the appropriate internal procedures provided for non-personnel authorized to intervene directly in the event of accidental release.

*6.1.2 For those who intervene directly*
Stop the leak if there is no danger.
Evacuate unauthorized personnel. Wear suitable protective equipment (see section 8 of this Safety Data Sheet).
Follow the appropriate internal procedures for authorized personnel. Isolate the danger area and deny entry. Ventilate enclosed spaces before
to come in.

**6.2. Environmental precautions**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

**6.3. Methods and material for containment and cleaning up**

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

**6.4. Reference to other sections**

Any information on personal protection and disposal is given in sections 8 and 13.

## SECTION 7. Handling and storage

**7.1. Precautions for safe handling**

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

### 7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a cool and well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

### 7.3. Specific end use(s)

No use other than that indicated in section 1.2 of this safety data sheet.

## SECTION 8. Exposure controls/personal protection

### 8.1. Control parameters

Regulatory References:

| | | |
|---|---|---|
| DEU | Deutschland | Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56 |
| ESP | España | Límites de exposición profesional para agentes químicos en España 2019 |
| FRA | France | Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS |
| ITA | Italia | Decreto Legislativo 9 Aprile 2008, n.81 |
| GBR | United Kingdom | EH40/2005 Workplace exposure limits (Fourth Edition 2020) |
| EU | OEL EU | Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC. |
| | TLV-ACGIH | ACGIH 2020 |

**ETHANEDIOL**

**Threshold Limit Value**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| AGW | DEU | 26 | 10 | 52 | 20 | SKIN |
| MAK | DEU | 26 | 10 | 52 | 20 | SKIN |
| VLA | ESP | 52 | 20 | 104 | 40 | SKIN |
| VLEP | FRA | 52 | 20 | 104 | 40 | SKIN |
| VLEP | ITA | 52 | 20 | 104 | 40 | SKIN |
| WEL | GBR | 52 | 20 | 104 | 40 | SKIN |
| OEL | EU | 52 | 20 | 104 | 40 | SKIN |
| TLV-ACGIH | | | 25 | | 50 | |
| TLV-ACGIH | | | | 10 | | INHAL |

| Predicted no-effect concentration - PNEC | | |
|---|---|---|
| Normal value in fresh water | 10 | mg/l |
| Normal value in marine water | 1 | mg/l |
| Normal value for water, intermittent release | 10 | mg/l |
| Normal value of STP microorganisms | 199,5 | mg/l |
| Normal value for the terrestrial compartment | 1,53 | mg/kg |

| Health - Derived no-effect level - DNEL / DMEL | Effects on consumers | Effects on workers |
|---|---|---|

| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
|---|---|---|---|---|---|---|---|---|
| Oral | | NPI | | NPI | | | | |
| Inhalation | NPI | NPI | 7 mg/m3 | NPI | NPI | NPI | 35 mg/m3 | NPI |
| Skin | NPI | NPI | NPI | 53 mg/kg bw/d | NPI | NPI | NPI | 106 mg/kg bw/d |

**PROPAN-2-OL**

**Threshold Limit Value**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| AGW | DEU | 500 | 200 | 1000 | 400 | |
| MAK | DEU | 500 | 200 | 1000 | 400 | |
| VLA | ESP | 500 | 200 | 1000 | 400 | |
| VLEP | FRA | | | 980 | 400 | |
| WEL | GBR | 999 | 400 | 1250 | 500 | |
| TLV-ACGIH | | 492 | 200 | 983 | 400 | |

| Predicted no-effect concentration - PNEC | | |
|---|---|---|
| Normal value in fresh water | 140,9 | mg/l |
| Normal value in marine water | 140,9 | mg/l |
| Normal value for fresh water sediment | 552 | mg/kg |
| Normal value for marine water sediment | 552 | mg/kg |
| Normal value for water, intermittent release | 140,9 | mg/l |
| Normal value of STP microorganisms | 2,251 | g/l |
| Normal value for the food chain (secondary poisoning) | 160 | mg/kg |
| Normal value for the terrestrial compartment | 28 | mg/kg |

**Health - Derived no-effect level - DNEL / DMEL**

| | Effects on consumers | | | | Effects on workers | | | |
|---|---|---|---|---|---|---|---|---|
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | | | | | VND | VND | VND | 26 mg/kg bw/d |
| Inhalation | VND | VND | VND | 89 mg/m3 | VND | VND | VND | 500 mg/m3 |
| Skin | VND | VND | VND | 319 mg/kg bw/d | VND | VND | VND | 888 mg/kg bw/d |

**ETHANOL**

**Threshold Limit Value**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| AGW | DEU | 380 | 200 | 1520 | 800 | |
| MAK | DEU | 380 | 200 | 1520 | 800 | |
| VLA | ESP | | | 1910 | 1000 | |
| VLEP | FRA | 1900 | 1000 | 9500 | 5000 | |
| WEL | GBR | 1920 | 1000 | | | |
| TLV-ACGIH | | | | 1884 | 1000 | |

| Predicted no-effect concentration - PNEC |
|---|

| | | |
|---|---|---|
| Normal value in fresh water | 960 | µg/L |
| Normal value in marine water | 790 | mg/l |
| Normal value for fresh water sediment | 3,6 | mg/kg |
| Normal value for marine water sediment | 2,9 | mg/kg |
| Normal value for water, intermittent release | 2,75 | mg/l |
| Normal value of STP microorganisms | 580 | mg/l |
| Normal value for the food chain (secondary poisoning) | 380 | mg/kg food |
| Normal value for the terrestrial compartment | 630 | µg/kg soil dw |

**Health - Derived no-effect level - DNEL / DMEL**

| | Effects on consumers | | | | Effects on workers | | | |
|---|---|---|---|---|---|---|---|---|
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | | | | | | NPI | | 87 mg/kg bw/d |
| Inhalation | 950 mg/m3 | NPI | NPI | 114 mg/m3 | 1900 mg/m3 | NPI | NPI | 950 mg/m3 |
| Skin | NPI | NPI | NPI | 206 mg/kg bw/d | NPI | NPI | NPI | 343 mg/kg bw/d |

**SUBTILISINE**

**Threshold Limit Value**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | mg/m3 | ppm | mg/m3 | ppm | |
| VLA | ESP | | | 6E-05 | | |
| WEL | GBR | 4E-05 | | | | |

Predicted no-effect concentration - PNEC

| | | |
|---|---|---|
| Normal value in fresh water | 1,7 | µg/L |
| Normal value in marine water | 170 | ng/L |
| Normal value for water, intermittent release | 900 | ng/L |
| Normal value of STP microorganisms | 65 | mg/l |
| Normal value for the terrestrial compartment | 568 | µg/kg soil |

**Health - Derived no-effect level - DNEL / DMEL**

| | Effects on consumers | | | | Effects on workers | | | |
|---|---|---|---|---|---|---|---|---|
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | | 3,6 mg/kg bw/d | | 1,8 mg/kg bw/d | | | | |
| Inhalation | NPI | NPI | 15 ng/m3 | NPI | NPI | NPI | 60 ng/m3 | NPI |
| Skin | | | | | VND | NPI | VND | NPI |

Substances that could be released in case of decomposition:

**FORMALDHEYDE**

| Type | Country | TWA/8h | | STEL/15min | | Remarks / Observations |
|---|---|---|---|---|---|---|
| | | Mg/m3 | ppm | mg/m3 | ppm | |
| VLEP | ITA | 0,37 | 0,3 | 0,74 | 0,6 | |
| OEL | EU | 0,37 | 0,3 | 0,74 | 0,6 | |
| TLV-ACGIH | | | 0,1 | 0,74 | 0,3 (C) | |

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

### 8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION
Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION
Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.
Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, wear a mask with a type AX filter, whose limit of use will be defined by the manufacturer (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.
Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.
If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

PROPAN-2-OL
IBE (Biological Indicators of Exposure - ACGIH 2020): acetone in urine = 40 mg / L (end of shift)

## SECTION 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| Appearance | liquid |
| Colour | straw yellow |
| Odour | mild |
| Odour threshold | Not determined |
| pH | 9,5 |
| Melting point / freezing point | Not available |
| Initial boiling point | 106 °C |

| | | |
|---|---|---|
| Boiling range | Not available | |
| Flash point | 35 °C | |
| Evaporation rate | Not determined | |
| Flammability (solid, gas) | not applicable | Reason for missing data: Based on the physical state |
| Lower inflammability limit | Not available | |
| Upper inflammability limit | Not available | |
| Lower explosive limit | Not available | |
| Upper explosive limit | Not available | |
| Vapour pressure | Not available | |
| Vapour density | Not determined | |
| Relative density | 1,022 g/cm$^3$ | |
| Solubility | soluble in water | |
| Partition coefficient: n-octanol/water | Not determined | |
| Auto-ignition temperature | Not available | |
| Decomposition temperature | Not determined | |
| Viscosity | Not determined | |
| Explosive properties | Not Explosive | |
| Oxidising properties | Not Oxidizing | |

**9.2. Other information**

Information not available

## SECTION 10. Stability and reactivity

**10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

ETHANEDIOL
In the air absorbs moisture.Decomposes at temperatures above 200°C/392°F.
It can absorb atmospheric moisture up to twice its own weight. It decomposes at temperatures above 200 ° C.

**10.2. Chemical stability**

The product is stable in normal conditions of use and storage.

**10.3. Possibility of hazardous reactions**

The vapours may also form explosive mixtures with the air.

ETHANEDIOL
Risk of explosion on contact with: perchloric acid.May react dangerously with: chlorosulphuric acid,sodium hydroxide,sulphuric acid,phosphorus pentasulphide,chromium (III) oxide,chromyl chloride,potassium perchlorate,potassium dichromate,sodium peroxide,aluminium.Forms explosive mixtures with: air.

Risk of explosion on contact with: perchloric acid. It can react dangerously with: chlorosulfuric acid, sodium hydroxide, sulfuric acid, phosphorus pentasulfide, chromium (III) oxide, chromyl chloride, potassium perchlorate, potassium dichromate, sodium peroxide, aluminum. Forms explosive mixtures with air.

ETHANOL
Risk of explosion on contact with: alkaline metals,alkaline oxides,calcium hypochlorite,sulphur monofluoride,acetic anhydride,acids,concentrated hydrogen peroxide,perchlorates,perchloric acid,perchloronitrile,mercury nitrate,nitric acid,silver,silver nitrate,ammonia,silver oxide,ammonia,strong oxidising agents,nitrogen dioxide.May react dangerously with: bromoacetylene,chlorine acetylene,bromine trifluoride,chromium trioxide,chromyl chloride,fluorine,potassium tert-butoxide,lithium hydride,phosphorus trioxide,black platinum,zirconium (IV) chloride,zirconium (IV) iodide.Forms explosive mixtures with: air.

**10.4. Conditions to avoid**

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

ETHANEDIOL
Avoid exposure to: sources of heat,naked flames.
Avoid exposure to heat sources and naked flames.

PROPAN-2-OL
Heat, flames and sparks. Extreme temperatures and direct sunlight.

ETHANOL
Avoid exposure to: sources of heat,naked flames.
Avoid high temperatures and proximity to ignition sources

**10.5. Incompatible materials**

PROPAN-2-OL
Oxidizing agents, acid anhydrides, aluminum, halogenated compounds, acids.

ETHANOL
Strong mineral acids, oxidizing agents. High temperature aluminum.

**10.6. Hazardous decomposition products**

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

ETHANEDIOL
May develop: hydroxyacetaldehyde, glyoxal, acetaldehyde, methane, carbon monoxide, hydrogen.
Due to thermal decomposition or in the event of fire, gases and vapors potentially harmful to health can be released.

## SECTION 11. Toxicological information

**11.1. Information on toxicological effects**

In the absence of experimental toxicological data on the product itself, the possible health hazards of the product have been assessed on the basis of the properties
of the substances contained, according to the criteria established by the reference legislation for classification.
Therefore, consider the concentration of the individual dangerous substances possibly mentioned in sect. 3, to evaluate the resulting toxicological effects from exposure to the product.

Metabolism, toxicokinetics, mechanism of action and other information

PROPAN-2-OL
It is readily absorbed following inhalation exposure and rapidly spreads to tissues. However, it is also readily excreted in the urine, essentially in the form of the 2-methoxyacetic acid metabolite. (Arch Toxicol, 68, -588-94 - Johanson G, 1994)

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

ETHANEDIOL
Ingestion initially stimulates the central nervous system; later replaced by a phase of depression. There may be kidney damage, with anuria and uremia. Over-exposure symptoms are: vomiting, drowsiness, difficulty in breathing, convulsions. The lethal dose for humans is approx. 1.4 ml/kg.

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture: Not classified (no significant component)
ATE (Oral) of the mixture:>2000 mg/kg
ATE (Dermal) of the mixture: Not classified (no significant component)

ETHANEDIOL
LD50 (Oral): 7712 mg/kg Ratto
LD50 (Dermal): 9530 mg/kg Coniglio
LC50 (Inhalation): 2,5 mg/l/6h Ratto

ETHANOL
LD50 (Oral): 1187 mg/kg Ratto
LC50 (Inhalation): 115,9 mg/l/4h

PROPAN-2-OL
LD50 (Oral): 4710 mg/kg Rat
LD50 (Dermal): 12800 mg/kg Rat
LC50 (Inhalation): 72,6 mg/l/4h Rat

SUBTILISINE
LD50 (Oral): 1800 mg/kg Rat

ETHANEDIOL
Harmful if swallowed (Harmonized classification, Annex VI, CLP Reg.)

Reference: Evaluation of the Developmental Toxicity of Ethylene Glycol Aerosol in the CD Rat and CD-1 Mouse by Whole-Body Exposure. (Fundamental and Applied Toxicology 24: 57-75 (1995))
Reliability (Klimisch score): 2
Species: rat (Sprague-Dawley; Male/Female)
Routes of exposure: inhalation (aerosol)
Results: LC50> 2.5 mg / L

Reference: Assessment of the Developmental Toxicity of Ethylene Glycol Applied Cutaneously to CD-1 Mice. (Fundamental and Applied Toxicology 27: 155-166 (1995)) "
Reliability (Klimisch score): 2
Species: mouse (CD-1; Male/Female)
Routes of exposure: cutaneous
Results: LD50> 3500 mg / kg.

PROPAN-2-OL
Method: equivalent or similar to OECD 401
Reliability (Klimisch score): 2
Species: Rat (Sherman)

Routes of exposure: oral
Results: LD50 = 5840 mg / kg

Method: equivalent or similar to OECD 402
Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: cutaneous
Results: LC50 = 16.4 ml / kg

Method: equivalent or similar to OECD 403
Reliability (Klimisch score): 1
Species: Rat (Fischer 344; Male/Female)
Routes of exposure: inhalation (vapors)
Results: LD50> 10000 ppm / 6h

ETHANOL
Method: OECD 401
Reliability (Klimish score): 1
Species: rat (Cox CD; Male/Female)
Route of exposure: oral
Results: LD50: 10470 mg / kg

Method: OECD 403
Reliability (Klimish score): 2
Species: rat (Sprague-Dawley; Male/Female)
Route of Exposure: inhalation (vapors)
LC50 results (male): 116.9 mg / l 4h

Reference: Schechter, M. et al, Pharmacol Biochem Behav 52 (1): 245-248, 1995
Reliability (Klimisch score): 2
Species: Mouse (HS; Male/Female)
Routes of exposure: intraperitoneal
Results: LD50 = 9450 mg / kg body weight

SUBTILISINE
Method: OECD 401
Reliability (Klimisch score): 1
Species: rat (Wistar; Male/Female)
Routes of exposure: oral
Results LD50: 1800 mg / kg body weight / day
The substance is classified as harmful by inhalation.

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Method: BASF-internal standards
Reliability (Klimisch score): 2
Species: rabbit (Vienna White)
Routes of exposure: cutaneous
Results: non-irritating

PROPAN-2-OL
Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: cutaneous
Results: Not irritating
Reference: Nixon G et al, Toxicology and Applied Pharmacology 31, 481-490 (1975)

ETHANOL

Method: OECD 404
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White)
Routes of exposure: cutaneous
Results: non-irritating.

SUBTILISINE
The substance causes skin irritation Harmonized classification, Annex VI, CLP Reg.)

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Method: BASF-internal standards
Reliability (Klimisch score): 2
Species: rabbit (Vienna White)
Routes of exposure: ocular
Results: non-irritating

PROPAN-2-OL
Method: equivalent or similar to OECD 405
Reliability (Klimisch score): 1
Species: Rabbit (New Zealand White)
Routes of exposure: ocular
Results: irritating

ETHANOL
Method: OECD 405
Reliability (Klimisch score): 2
Species: Rabbit
Routes of exposure: ocular
Results: irritating.

SUBTILISINE
The substance causes serious eye damage (Harmonized Classification, Annex VI, CLP Reg.)

RESPIRATORY OR SKIN SENSITISATION

May produce an allergic reaction.Contains:SUBTILISINE

ETHANEDIOL
Reference: Evaluation of Skin Irritation and Sensitization of Two Diol Solutions used as Experimental Dentin Primers in Humans and Guinea Pigs. (Dental Materials Journal 15 (2): 226-232 (1996))
Reliability (Klimisch score): 2
Species: Guinea Pig (Dunkin-Hartley; Female)
Routes of exposure: cutaneous
Results: not sensitizing.

PROPAN-2-OL
Method: OECD 406
Reliability (Klimisch score): 1
Species: Guinea pig (Dunkin-Hurtley; Male/Female)
Routes of exposure: cutaneous
Results: not sensitizing

ETHANOL
Method: equivalent or similar OECD 406
Reliability (Klimisch score): 2

Species: Guinea pig (Pirbright White; Female)
Routes of exposure: cutaneous
Results: not sensitizing.

SUBTILISINE
The substance causes respiratory sensitization (Harmonized Classification, Annex VI, CLP Reg.)

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Method: OECD 471 - In vitro test
Reliability (Klimisch score): 1
Species: S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2
Results: negative

Method: Publication 1986 - In vivo testing
Reliability (Klimisch score): 2
Species: rat (Fischer 344; Male/Female)
Routes of exposure: oral
Results: negative.

PROPAN-2-OL
Based on available data, the substance has no mutagenic effects and is not classified under the relevant hazard class CLP.

ETHANOL
Method: equivalent or similar to OECD 471 - In vitro test
Reliability (Klimisch score): 1
Species: S. typhimurium
Results: negative with and without metabolic activation

Method: equivalent or similar to OECD 474 - In vivo test
Species: mouse (NMRI; Male/Female)
Routes of exposure: intraperitoneal
Results: negative.

SUBTILISINE
Method: OECD 473 - Test in vitro
Reliability (Klimisch score): 1
Species: human (lymphocytes)
Results: negative with and without metabolic activation

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Available studies have shown no carcinogenic potential. In a carcinogenicity study lasting two years, carried out by the US National Toxicology Program (NTP), in which ethylene glycol was administered in the feed, "no evidence of carcinogenic activity" in male and female B6C3F1 mice was observed (NTP, 1993).

PROPAN-2-OL
Based on available data, the substance has no carcinogenic effects and is not classified under the relevant hazard class CLP.

ETHANOL
Method: equivalent or similar to OECD 453
Reliability (Klimisch score): 1
Species: rat (Fischer 344 / DuCrj; Male/Female)

Routes of exposure: inhalation (vapors)
Results: negative.

SUBTILISINE
No data available.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Reference: Chronic Toxicity and Oncogenicity Studies of Ethylene Glycol in Rats and Mice. (Fundamental and Applied Toxicology 7: 547-565 (1986))
Reliability (Klimisch score): 2
Species: mouse (CD-1; Male/Female)
Routes of exposure: oral
Results: negative.

PROPAN-2-OL
Method: equivalent or similar to OECD 416
Reliability (Klimisch score): 1
Species: Rat (Sprague-Dawley; Male/Female)
Routes of exposure: Oral
Results: negative. NOAEL = 1000 mg / kg bw / day.

SUBTILISINE
No data available.

Adverse effects on sexual function and fertility

PROPAN-2-OL
Method: equivalent or similar to OECD 416
Reliability (Klimsch score): 1
Species: rat (Sprague-Dawley Male/Female)
Routes of exposure: oral
Results: negative.

ETHANOL
Method: equivalent or similar to OECD 416
Reliability (Klimisch score): 1
Species: mouse (CD-1; Male/Female)
Routes of exposure: oral
Results: No effect on fertility at doses equivalent to 20.7 g / kg / day

Adverse effects on development of the offspring

PROPAN-2-OL
Method: equivalent or similar to OECD 414
Reliability (Klimsch score): 1
Species: rat (Sprague-Dawley)
Routes of exposure: oral
Results: negative.

ETHANOL
Method: equivalent or similar to OECD 414
Reliability (Klimisch score): 2
Species: rat (Sprague-Dawley)
Routes of exposure: inhalation
Results: negative. NOAEL (maternal) = 16000 ppm. NOAEL (fetus)> = 20,000 ppm

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Based on available data, the substance has no specific target organ toxicity effects for single exposure and is not classified under the relevant CLP hazard class.

PROPAN-2-OL
Method: OECD 426
Reliability (Klimisch score): 1
Species: Rat (Sprague-Dawley; Female)
Routes of exposure: oral.
Results: May cause drowsiness or dizziness.
Based on available data, the substance exhibits specific target organ toxicity effects from single exposure and is classified under the relevant CLP hazard class.

ETHANOL
Based on available data, the substance has no specific target organ toxicity effects for single exposure and is not classified under the relevant CLP hazard class.

SUBTILISINE
Based on available data, the substance exhibits specific target organ toxicity effects from single exposure and is classified under the relevant CLP hazard class. (Harmonized classification, Annex VI, CLP Reg.)

Target organ

SUBTILISINE
Lungs.

Route of exposure

SUBTILISINE
Inalation.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ETHANEDIOL
Method: equivalent or similar to OECD 452
Reliability (Klimisch score): 2
Species: Rat (Wistar; Male)
Routes of exposure: oral
Results: observed toxicity towards the kidneys and bladder. NOAEL = 150 mg / kg bw / day

PROPAN-2-OL
Based on available data, the substance has no specific target organ toxicity effects on repeated exposure and is not classified under the relevant CLP hazard class.

ETHANOL
Method: equivalent or similar OECD 408
Reliability (Klimisch score): 2
Species: Rat (Sprague-Dawley; Male/Female)
Routes of exposure: oral
Results: negative. NOAEL: 1730 mg / kg body weight / day

SUBTILISINE
Based on available data, the substance has no specific target organ toxicity effects on repeated exposure and is not classified under the relevant CLP hazard class.

Target organ

ETHANEDIOL
Kidneys

Route of exposure

ETHANEDIOL
Oral

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

ETHANEDIOL
No data on aspiration hazard are available

PROPAN-2-OL
No data on aspiration hazard are available

ETHANOL
No data are available on the hazard in case of aspiration.

SUBTILISINE
No data on aspiration hazard are available

## SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

**12.1. Toxicity**

| | |
|---|---|
| ETHANEDIOL | |
| LC50 - for Fish | > 72,86 g/l/96h Pimephales promelas (EPA 600/4-90/027) |
| EC50 - for Crustacea | > 100 mg/l/48h Daphnia magna (OECD 202) |
| EC50 - for Algae / Aquatic Plants | > 10940 mg/l/72h Pseudokirchneriella subcapitata (EPA/600/4-89/001) |
| Chronic NOEC for Fish | > 15,38 g/l/7 d |
| Chronic NOEC for Crustacea | > 8,59 g/l/7 d |
| Chronic NOEC for Algae / Aquatic Plants | 100 mg/l/72h |

| | |
|---|---|
| ETHANOL | |
| LC50 - for Fish | 14,2 g/l/96h Pimephales promelas (US EPA E03-05) |
| EC50 - for Crustacea | 5012 mg/l/48h Ceriodaphnia dubia (ASTM E729-80) |
| EC50 - for Algae / Aquatic Plants | 275 mg/l/72h Chlorella vulgaris (OECD 201) |
| Chronic NOEC for Fish | 250 mg/L/5 d |

| | |
|---|---|
| PROPAN-2-OL | |
| LC50 - for Fish | 9640 mg/l/96h Pimephales promelas (equivalent or similar to OECD 203) |
| EC50 - for Crustacea | > 10000 mg/l/48h Daphnia magna (equivalent or similar to OECD 202) |
| | |
| SUBTILISINE | |
| LC50 - for Fish | 8,2 mg/l/96h Oncorhynchus mykiss; (OECD 203( |
| EC50 - for Crustacea | 0,17 mg/l/48h Daphnia Magna; OECD 202 |
| EC50 - for Algae / Aquatic Plants | 0,29 mg/l/72h Pseudokirchnerella subcapitata (OECD 201) |
| Chronic NOEC for Fish | 0,042 mg/l/34d Pimphales promelas; (OECD 210) |
| Chronic NOEC for Crustacea | 0,019 mg/l/14d Daphnia magna; (OECD 211) |
| Chronic NOEC for Algae / Aquatic Plants | 0,041 mg/l/72h Pseudokirchnerella subcapitata; (OECD 201) |

**12.2. Persistence and degradability**

ETHANEDIOL
Rapidly degradable, 90-100% in 10 days (OECD 301 A)
Solubility in water 1000 - 10000 mg/l

PROPAN-2-OL
Rapidly degradable, 53% in 5 days (equivalent or similar to EU C.5)

ETHANOL
Readily biodegradable, 60% in 10 days (BOD - Standard methods for the examination of water and waste water 1971. 13th ed, American Public Health Assoc, NY)

SUBTILISINE
Rapidly degradable, 79% in 28 days (OECD 301 B).

**12.3. Bioaccumulative potential**

| | |
|---|---|
| ETHANEDIOL | |
| Partition coefficient: n-octanol/water | -1,36 Log Kow ( ACS Professional Reference Book, 1995) |
| | |
| ETHANOL | |
| Partition coefficient: n-octanol/water | -0,35 Log Kow 24°C (OECD 107) |
| | |
| PROPAN-2-OL | |
| Partition coefficient: n-octanol/water | 0,05 |

**12.4. Mobility in soil**

Information not available

**12.5. Results of PBT and vPvB assessment**

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

**12.6. Other adverse effects**

Information not available

## SECTION 13. Disposal considerations

**13.1. Waste treatment methods**

Reuse if possible. Product residues are to be considered special hazardous waste. The dangerousness of the waste that partially contains this product must be evaluated according to the laws in force. (Ref. Annex D - Part IV of Legislative Decree no. 152/2006 and subsequent amendments and adjustments).
Disposal must be entrusted to an authorized waste management company, in compliance with national and possibly local regulations.
The legal responsibility for disposal lies with the producer / holder of the waste.
Different CER (European Waste Code) codes could be applied to this mixture according to the specific circumstances that generated the waste, any alterations and contaminations.

The product as it is, out of specification in the original packaging, or poured into a suitable container for disposal as waste, or the product in specification but no longer usable (for example following an accidental spill), is to be classified with a code CER compatible with the description of use indicated in section 1.2.
The appropriate final destination of the waste will be assessed by the manufacturer according to the chemical-physical characteristics of the waste itself compatible with the authorized plant to which it will be conferred for recovery, treatment or final disposal in the manner prescribed by current regulations.
Disposal via the wastewater drain is not permitted.
For hazardous substances registered according to EC Regulation 1907/2006 (REACH) for which a chemical safety report has been prepared, refer to the specific information contained in the exposure scenarios attached to this SDS.

CONTAMINATED PACKAGING
Contaminated packaging must be sent, properly labeled, for recovery or disposal in compliance with national regulations on waste management and must be classified with the following EWC code:

15 01 10 *: packaging containing residues of dangerous substances or contaminated by these substances

## SECTION 14. Transport information

**14.1. UN number**

| | |
|---|---|
| ADR / RID, IMDG, IATA: | 1993 |

**14.2. UN proper shipping name**

| | |
|---|---|
| ADR / RID: | FLAMMABLE LIQUID, N.O.S. (Propan-2-ol; Ethanol) MIXTURE |
| IMDG: | FLAMMABLE LIQUID, N.O.S. (Propan-2-ol; Ethanol) MIXTURE |
| IATA: | FLAMMABLE LIQUID, N.O.S. (Propan-2-ol; Ethanol) MIXTURE |

**14.3. Transport hazard class(es)**

| | | |
|---|---|---|
| ADR / RID: | Class: 3 | Label: 3 |
| IMDG: | Class: 3 | Label: 3 |
| IATA: | Class: 3 | Label: 3 |


**14.4. Packing group**

| | |
|---|---|
| ADR / RID, IMDG, IATA: | III |

**14.5. Environmental hazards**

| | |
|---|---|
| ADR / RID: | NO |
| IMDG: | NO |
| IATA: | NO |

**14.6. Special precautions for user**

| | | | |
|---|---|---|---|
| ADR / RID: | HIN - Kemler: 30 | Limited Quantities: 5 L | Tunnel restriction code: (D/E) |
| | Special provision: - | | |
| IMDG: | EMS: F-E, S-E | Limited Quantities: 5 L | |
| IATA: | Cargo: | Maximum quantity: 220 L | Packaging instructions: 366 |
| | Pass.: | Maximum quantity: 60 L | Packaging instructions: 355 |
| | Special provision: | A3 | |

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Information not relevant

## SECTION 15. Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: P5c

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Product

Point 3

*Liquid substances or mixtures that meet the criteria relating to one of the following hazard classes or categories as set out in Annex I of Regulation (EC) No. 1272/2008:*
*a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;*
*b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or development, 3.8 effects other than narcotic effects, 3.9 and 3.10;*
*c) hazard class 4.1;*
*d) hazard class 5.1.*

Point 40

*Substances classified as flammable gases of category 1 or 2, flammable liquids of category 1, 2 or 3, flammable solids of category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases of categories 1, 2 or 3, category 1 pyrophoric liquids or category 1 pyrophoric solids, even if not listed in Part 3 of Annex VI to Regulation (EC) No. 1272/2008Contained substance*

Point 75 SUBTILISINE
Reg. No. 01-2119480434-38-xxxx

*Substances included in one or more of the following:*

*a) substances classified in one of the following classes in Annex VI, part 3, of Regulation (EC) no. 1272/2008:*
*- category 1A, 1B or 2 carcinogenicity, category 1A, 1B or 2 germ cell mutagenicity, but excluding substances classified due to effects following exposure by inhalation only;*
*- Reproductive toxicity of category 1A, 1B or 2, but excluding substances classified due to effects following exposure by inhalation only;*
*- skin sensitization of category 1, 1A or 1B;*
*- skin corrosion of category 1, 1A, 1B or 1C or skin irritation of category 2;*
*- serious category 1 eye damage or category 2 eye irritation;*
*b) substances listed in Annex II of Regulation (EC) no. 1223/2009 of the European Parliament and of the Council (*);*
*c) substances listed in Annex IV of Regulation (EC) no. 1223/2009 for which a condition is indicated in at least one of the columns g, h or i of the table of this annex;*
*d) substances listed in Appendix 13 of this annex. The ancillary requirements referred to in points 7 and 8 of column 2 of this entry apply to all mixtures intended for tattooing practices, regardless of whether they contain one of the substances referred to in points a) to d) of this column and entry.*

Regulation (EC) No. 2019/1148 - on the marketing and use of explosives precursors

Not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

Medical device, class IIb according to legislation 93/42.

**15.2. Chemical safety assessment**

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

## SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

| | |
|---|---|
| **Flam. Liq. 2** | Flammable liquid, category 2 |

| | |
|---|---|
| **Flam. Liq. 3** | Flammable liquid, category 3 |
| **Skin Corr. 1A** | Skin corrosion, category 1A |
| **Eye Irrit. 2** | Eye irritation, category 2 |
| **STOT SE 3** | Specific target organ toxicity - single exposure, category 3 |
| **H225** | Highly flammable liquid and vapour. |
| **H226** | Flammable liquid and vapour. |
| **H314** | Causes severe skin burns and eye damage. |
| **H319** | Causes serious eye irritation. |
| **H336** | May cause drowsiness or dizziness. |

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2018/1480 (XIII Atp. CLP)

16. Regulation (EU) 2019/521 (XII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Regulation (EU) 2020/217 (XIV Atp. CLP)
- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) – Italy

**Training for workers:**
The training of workers must include contents, updates and duration according to the risk profiles assigned to the working sectors of membership, according to the procedures provided for by Legislative Decree 81/2008.

**Procedure used to derive the classification according to Regulation (EC) 1272/2008 (CLP) in relation to mixtures:**

| Classification of the mixture according to Regulation (EC) n. 1272/2008 | | Classification procedure |
|---|---|---|
| Flammable liquid, category 2 | H225 | Based on experimental data. |

**Note for the recipient of the Safety Data Sheet (SDS):**

It is the recipient of this SDS who must ensure that the information contained is read and understood by all persons who handle, store, use, or otherwise come into contact in any way with the substance or mixture to which this sheet refers. In particular, the recipient must provide adequate training to personnel assigned to the use of dangerous substances or mixtures. The recipient must ensure the suitability and completeness of the information in relation to the specific use of the substance or mixture.
However, the substance or mixture to which this SDS refers must not be used for uses other than those specified in section 1. No responsibility is assumed for improper uses. Since the use of the product does not fall under the direct control of the Supplier, it is the user's obligation to observe, under his own responsibility, the laws and regulations in force regarding national and Community hygiene and safety.
The information contained in this SDS is provided in good faith and is based on the current state of scientific and technical knowledge, at the revision date indicated, available from the Supplier indicated in section 1 of this sheet. The SDS should not be interpreted as a guarantee of any specific property of the substance or mixture. The information refers only to the substance or mixture specifically designated in section 1 and may not be valid for the substance or mixture used in combination with other materials or in other processes not specifically indicated in the text.

This version of the SDS supersedes all previous versions.

Changes from the previous revision.

Changes have been made to the following sections:
01/02/03/04/05/06/07/08/09/10/11/12/13/14/15/16.