

SteelcoXide C€0051

SteelcoXide system is a modern and effective concentrated synthetic substance,
which is totally **hydro-soluble**,
for the chemical disinfection and sterilisation in Steelco endoscope reprocessors.
It consists of **SteelcoXide-DT** concentrated detergent used with **SteelcoXide**,
a combination of **SteelcoXide-A** and **SteelcoXide-B**.

SteelcoXide performs an exclusive synergic action combining the properties of **ADAMAVIR COMPLEX®** salt (based on Acetic Adamantane) with the properties of hydrogen peroxide.
SteelcoXide-DT performs an exclusive synergic action combining the proteolytic properties of of **ADAMAVIR COMPLEX®** with an enzymatic complex and with ionic surfactants.

- It destroys all micro-organisms without damaging the constituents or the connecting elements of the treated device (e.g. seals, rubbers, weldings, etc.).
- It does not modify the chemical and physical properties of materials, leaving the surface of the treated device totally clean, without any residual or captured chemical elements.
- **SteelcoXide-DT** prepares the materials for subsequent disinfection/sterilization, leaving the surface of the treated device totally clean **UFC=0**, without any residual or captured chemical elements. It performs a synergic action of an enzymatic complex with Adamavir Complex®, acts rapidly in the short time of 5 minutes against fungal species.
- **SteelcoXide system**, and all its components are stable/valid for **24 months** in its unopened and correctly stored pack.

Classification: Class IIb Medical Device

Notified Body: IMQ - Viale Quintiliano 43 – Milano

CE 0051

Composition: **SteelcoXide** is a bi-component solution composed by **SteelcoXide-A** and **SteelcoXide-B**.

SteelcoXide-A consists of **ADAMAVIR COMPLEX®**, a synthetic molecule and other co-formulants.

SteelcoXide-B consists of hydrogen peroxide.

The interaction between Acetic Acid and hydrogen peroxide allows the formation of an active sterilising substance.

SteelcoXide-DT contains an active formula consisting of a proteolytic ADAMAVIR COMPLEX® element, ionic surfactant and enzymatic surfactant.

Other components: basic water-soluble coformulants.

Exclusive synergetic mechanism:

Thanks to its organic synthesis element **ADAMAVIR COMPLEX®**, **SteelcoXide (SteelcoXide-A + SteelcoXide-B)** is highly stable and is chemically defined as an "ideal compound", having non-deviating, colloidal properties.

SteelcoXide (SteelcoXide-A 1% + SteelcoXide-B 1%) owes its sterilizing activity to an Exclusive Synergetic Action. It combines the specific properties of **ADAMAVIR COMPLEX®** with the oxidising properties of Hydrogen Peroxide, assuring tested efficiency in a dilution of 1:100.

SteelcoXide-DT is specifically indicated for combined use with **SteelcoXide (SteelcoXide-A + SteelcoXide-B)**, a chemical sterilant. It can be used in manual and automatic washing procedures in order to remove protein dirt from surgical instruments and accessories and to reduce microbic charge >9log according to EN ISO 15883-4:2009

It is not a common detergent for the cleaning of instruments but a product able to prepare the surface of any material for a better penetration of the following sterilising treatment. It is able to effectively

remove any impurities which may be present in the porous lamellar structure of the materials composing flexible and/or heat sensitive devices.

Instructions:

The use of **SteelcoXide SYSTEM** has been validated for high level disinfection and liquid low temperature sterilization in conformity with EN ISO 15883:2009 and EN 14937:2009 in Steelco flexible endoscope reprocessors.

Compatibility:

SteelcoXide SYSTEM has shown excellent compatibility with materials composing all the devices and systems used in medical surgical applications. It has been specifically tested on and is suitable for all optical fibre flexible devices, including new generation devices made from plastic materials.

Tested materials: metals, aluminium, brass, copper, stainless steel, carbon steel.

Plastics: polyurethane, polythene, PVC, polyacetate, polypropylene, PTFE, nylon, ABS.

Rubbers: silicon, viton, neoprene, latex, EPDM rubber.

Study:

- **University of Perugia, Perugia - Dip. Ing. Civile e Ambientale:** *Morphological study of electron microscopy SEM Spectrophotometric and FT-IR on the components of fiber optics instrument.*

Testing methods: a morphologic study with scanning electron microscopy VP SEM (CNR Department of Physical Chemistry, Rome) was carried out.

Results of the study: changes in weight or impregnation causing a variation in the initial colours were not detected.

Mode of use:

SteelcoXide (SteelcoXide-A + SteelcoXide-B) can be used for high level disinfection or low temperature sterilization in Steelco flexible endoscope reprocessors.

SteelcoXide is automatically dosed by the integrated dosing system of

the AER. **Contact time 10 minutes.**

Intended use:

- 10 mL/L (1%) for both high-level disinfection and sterilization

SteelcoXide complies with UNI EN ISO 15883:2009 for high level disinfection and has been validated at 10 mL/L (1%) dilution.

SteelcoXide complies with UNI EN ISO 14937:2009 for sterilization and has been validated at 10 mL/L (1%) dilution.

Once opened, the product lasts 30 days.

SteelcoXide-DT, used together with **SteelcoXide (SteelcoXide-A + SteelcoXide-B)** is a concentrated product to be applied diluted at a 1:100 ratio, for 10 minutes contact time.

Sterilant action of **SteelcoXide (SteelcoXide-A + SteelcoXide-B)** and **SteelcoXide-DT** detergent, has been tested and validated at 1% concentration, 35°C.

Use only the original container. Any other dilution compared to the original container solution is not acceptable. Do not mix with organic materials (eg. Oil, grease, rubber, paper, ..) or rust.

Warnings:

The product must be handled by specialised staff according to appropriate safety standards and correct hygienic practices. Keep out of reach of children. Do not add bleaches or other chemical substances. Preliminary cleaning of devices with brushes is necessary. **SteelcoXide-DT** detergent must not be used as a means of preserving instruments. Keep in a dry place at room temperature and far from heat sources (a range from +5°C to +25°C). The expiry date refers to the unopened and correctly stored product.

The activated **STEELCOXIDE-A + STEELCOXIDE-B** and diluted product does not require additional specific precautionary measures for persons or the environment as the combination takes place in a closed system and highly diluted.

Precautions: The product does not require particular precautionary measures for persons or the environment as substances are at a concentration below the minimum danger threshold.

Stability and Validity: If unopened and correctly stored at room temperature, **SteelcoXide-A, SteelcoXide-B and SteelcoXide-DT** are stable for 24 months.

Study:

- **Laboratorio interno FIS&DM:** Analysis on the stability of the product according to the scheme "Tripartite ICH Guideline" and the UNI EN ISO 175:2010.

Pharmacology: The analytical method was validated by the study:

- **Dip.Pharmaceutical Clinical and Preclinical – University of Florence, Florence.** Analytical methods and bibliographic search. Prof. Chiarugi.

Toxicity: **SISTEMA SteelcoXide** at the concentrations of use is not toxic.

Biodegradability: The surfactants used in the product are biodegradable in compliance with the directive of the Detergents 648/2004/EC.

Traceability: The complete traceability of batches from raw material acceptance to the distribution of the finished product is carried out according to internal quality system procedures.

ISO 17025 certifications **SteelcoXide system**, composed by the mix of components A and B comply with EN ISO 14937:2009 standard (microbicide efficiency of the sterilising agent in terms of the selected determining organisms in compliance with Appendix A of the cited standard).

- **EN 14937:** Characterisation of a sterilising agent – **SteelcoXide**. Determination of the most resistant micro-organism – Jacaroni Centro Diagnostico;
- **EN 14937:** Characterisation of a sterilising agent – **SteelcoXide**. Microbiological test – Jacaroni Centro Diagnostico;

Bactericidal activity: SteelcoXide at room temperature, shows to possess a good bactericidal activity, since after 5 minutes of contact respectively with the bacterial suspension of the reference strain *Enterococcus faecium* ATCC 35667 and strain *Enterococcus faecium* ATCC 6057 reduces the initial bacterial load of more than 5 log ($R > 5 \log$).

This requirement is essential in order for a bactericidal disinfectant can be considered, in accordance with the procedure specified by the EN 13727/2012

Studies:

- **EN 15883:2009** Bactericidal activity of *SteelcoXide* 1% disinfectant formula. Università Cattolica "A.Gemelli" Roma.
- **EN 13727:** Bactericidal activity of *SteelcoXide* 1% disinfectant formula. (Phase 2 / Step 1). Università Cattolica "A.Gemelli" Roma.;
- **EN 14937:** Bactericidal activity of the *SteelcoXide* 1%. disinfectant formula. Quantitative test on support. Hyggen Austria Bericht B19262 III

Virucidal action: *SteelcoXide* is a powerful broad-spectrum antiviral compound which inhibits the evolution of viruses and retroviruses. Not only it destroys them but, inhibiting their RNases, it disrupts even the virus replication factor. It has lipophilic properties and through fluorescent excitation causes irreversible damage of the cellular membrane. ***SteelcoXide*** solution is effective on viruses in **1 minute** – The study demonstrated the capability of denaturing and completely inactivating viral RNase **ufp=0**

Studies:

- M. Pistello; Retrovirus Centre, Department for Experimental Pathology and Virology, Microbiology Institute, "Sant'Anna University of Pisa, Pisa: **"Inhibition of the HIV, HCV viral RNase" by the synthetic ADAMAVIR COMPLEX.**

SteelcoXide at room temperature, shows to possess a good bactericidal activity, since after 5 minutes of contact respectively with the viral suspension reduces the initial charge of more than 5 log ($R > 5 \log$).

- **EN 14937:** Virucidal activity of STEELCOXIDE-1% disinfectant.
Quantitative test on support. Hygcn Austria Bericht B19262 III

*Mycobactericidal and
sporicidal activity:*

The combined use of **SteelcoXIDE-A + SteelcoXIDE-B** and of the **SteelcoXIDE-DT** detergent, at 1% concentration and 35°C temperature, in a standard flexible endoscope reprocessing cycle (washing + chemical sterilization) results in sporicidal activity greater than 7.3 log units on *B. Atropheus* and more than 6.3 log units on *G. Stearothermophilus*.

The studies have been made by the European Laboratory certified and accredited HYGCEN attesting the compliance and conformity of the sterilizing agent **SteelcoXIDE-A + SteelcoXIDE-B** to **EN ISO 14937**.

Studies:

- **EN 15883:2009** Sporicidal activity of the *SteelcoXide* 1% disinfectant formula. Università Cattolica "A.Gemelli" Roma.
- **EN 14937:** Sporicidal activity of the *SteelcoXide* 1% disinfectant formula. Quantitative test on support. Hygcn Austria Bericht B19262 III

Proteolytic activity:

The proteolytic activity of **ADAMAVIR COMPLEX** was determined through the studies carried out at Pisa University.

- **Pisa University, Department for Experimental Pathology, Medical Biotechnologies, Infectious Diseases and Epidemiology - Retrovirus Centre – Director: Prof. Mauro Pistello – 27 October 2006-** *Studies on microbiologic efficiency and viral activity. Test of Exjum's capacity to denature viral RNasi.*

The study demonstrated the ability of Adamavir Complex to denature proteins either as a single substance or in combination with the co-formulants of the product.

The efficacy of the washing has been widely evaluated. The results have shown that when the product is used according to its instructions, the cleaning action is effective. The percentage of removal of organic residual is equal to 98,5% with rinses at 30° and equal to 85,5% with rinses at room temperature (drying test at room temperature).

Fungicidal activity:

The fungicidal activity was evaluated by studies:

- At the University Vita-Salute San Raffaele, Milan, study coordinator Prof. M.Clementi: "Activities of the fungicide formulation disinfectant SteelcoXide 1%".
- **EN 13624:2003: Activities of the fungicide solution SteelcoXide-A 1% solution SteelcoXide-B (1%).**

Studies show that the synergistic action of the two solutions **SteelcoXide-A** e **SteelcoXide-B** results in a reduction of more than 5Log10 (*Aspergillus niger*, *Candida albicans*)

Physical and chemical properties:

	SteelcoXide-A	SteelcoXide-B
colour	transparent	transparent
odour	orange/winegar	pungent
physical status	liquid	liquid
pH	3.7 ± 0,5	min 0,5 - max 3
properties	At ambient pressure and temperature	
Boiling point and vaporization range	N/A	N/A

(H) Risk phrases:

The risk phrases mentioned below are to be referred exclusively to the product as is. Are not considered valid by the percentages of use to which the product is intended as the substances are present at a concentration below the minimum danger threshold

SteelcoXide:

SteelcoXide-A:

Eye Irrit. 2: H319 Causes serious eye irritation
H314 Causes severe skin burns and eye damage
Flam. Liq. 3: H225 Highly flammable liquid and vapour
STOT SE 3: H336 May cause drowsiness or dizziness.

SteelcoXide-B:

Eye Irr. 2: H314 Causes severe skin burns and eye damage.
H272 May cause a fire, combustion
H302 Harmful if swallowed H332 Harmful if inhaled
H335 May cause respiratory irritation.

SteelcoXide-DT

Acute Tox.4: H302 - Harmful if swallowed
Flam Liq 3: H226 - Flammable liquid and vapour
Skin Irrit. 2: H315 - Causes skin irritation
Eye Dam. 2: H320 - Causes eye irritation
STOT SE 3: H335 - Causes eye irritation
Aquatic Acute 4: H413 - May cause long lasting harmful effects to aquatic life

(P) Precautionary advice:

The precautionary advice phrases mentioned below are to be referred exclusively to the product as is. Are not considered valid by the percentages of use to which the product is intended as the substances are present at a concentration that does not require any precautionary advice

SteelcoXide

SteelcoXide-A:

P210 Keep away from heat/sparks/open flames/hot surfaces - No smoking
P260 Do not breathe fume/gas/vapours
P280 Wear protective gloves/protective clothing/eye protection/face

protection

P301+330+331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting

P303+361+353 IF ON SKIN (or hair): Remove/Take off immediately all. contaminated clothing. Rinse skin with water/shower

P305+351+338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing

P501 Dispose of contents/container to accordance with local regulations regional national international

SteelcoXide-B:

P210 Keep away from heat/sparks/open flames/hot surfaces – No smoking

P233 Keep container tightly closed

P260 Do not breathe fume/gas/vapours

P264 Wash hands thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection

P301+330+331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting

P303+361+353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

P305+351+338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing

P403 Store in a well ventilated place

P501 Dispose of contents/container to accordance with local regulations regional national international.

SteelcoXide-DT

P261 – Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 – Wear protective gloves/protective clothing/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 P342 + P311 – If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician



Technical Data Sheet

Revision nr. 5 date of revision 10/05/2016

Issue date 06/12/2013

Packaging

Code 9992069 - Kit composed by one 5 liter tank per each of the 3 chemicals

SteelcoXide-A + SteelcoXide-B + SteelcoXide-DT

N.B. Further information, literature and safety sheets are available from the company only upon request. The company reserves the right to modify or update the information at any time.