

Rev. 6 - 11/2019

# SPORIGERM® FAZZOLETTI\*

Disinfectant detergent

50 Wipes

with tuberculocidal, bactericidal, fungicidal, virucidal action

Medical Device Class IIb CE n° 0546

#### **INDICATIONS**

SPORIGERM FAZZOLETTI+

is a ready to use medical device with an effective disinfectant action against Gram-positive and Gram-negative bacteria, yeasts, Mycobacterium Tuberculosis (TBC), Viruses (including HIV-HBV-HCV).

A convenient solution which makes

SPORIGERM FAZZOLETTI+

a specific product for the disinfection and cleansing suitable for surfaces of non-invasive medical devices such as dental chairs,

worktops, armrests, handles, turbines,

face masks, headrests etc.,

even in the presence of organic material

(blood, saliva, exudates).

#### **INSTRUCTIONS FOR USE**

Wipe surfaces and objects to be cleaned, decontaminated and disinfected making sure these are completely dampened.

Rinsing is not necessary.

#### **CONTACT TIME**

Enveloped viruses (HIV-HBV-HCV)	5 min
Bacteria	5 min
Fungi (yeasts)	5 min
Non-enveloped viruses (Adenovirus)	5 min
Mycobacterium Tuberculosis (TBC)	.60 min

#### **PACKAGING**

Sporigerm Fazzoletti<sup>+</sup>

Code 501002......12 flow packs, 50 wipes each

Primary packaging in compliance with the technical specifications established by Farmacopea. These materials do not contain latex and are fully compatible

with all the components of the formulated.

#### **COMPOSITION** 100 grams of product

Benzalkonium Chloride	0.50 g;
O-Phenyl phenol	0.02 g;
Isopropyl alcohol, Ethyl alcohol, Co-formulants;	
Purified water, q.s. at10	00.00 g;

Bacteria
with Spores

Protozoa
with Cysts

Mycobacteria

**Non-Enveloped Viruses** 

Fungi

Vegetative Bacteria

**Enveloped Viruses** 

### INFORMATION FOR THE EXCLUSIVE USE OF HEALTHCARE PROFESSIONALS

Manufactured by:

GERMO S.p.A.

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Phone +39 02 663 01 938

www.germo.it - info@germodis.com

Distributed by:

IDS S.p.A.

Via S. Cristoforo 28/10

17100 Savona - Italy

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## SPORIGER! FA77OIFTT

Disinfectant detergent

with tuberculocidal, bactericidal, fungicidal, virucidal action

PATHOGENIC AGENTS CLASSIFIED ACCORDING TO THEIR RESISTANCE TO DISINFECTANTS

#### Wet wipes

**ACTION** 

**CHARACTERISTICS** 

The Quaternary Ammonium Salt, together with the O-Phenyl phenol, in alcohol solution, guarantees a full range of action towards Gram-positive and Gram-negative bacteria, yeasts, mycobacteria (TBC) and viruses (Adenovirus, HIV, HBV, HCV).

EN13727 - EN 13697

Bactericidal...... 5 minuti

EN13624 - EN 13697

Fungicidal ...... 5 minuti

Virucidal (Adenovirus, HIV-HCV, HBV) ...... 5 minuti

EN14348

Mycobacterium Tuberculosis (TBC) ....... 60 minuti

#### PRODUCT VALIDITY

3 years. The validity period indicated refers to a product stored in its package and correctly used and preserved.

#### **STORAGE**

To be stored in cool, dry areas, away from heat sources.

**Bacteria** with Spores

B. subtitles, C. tetani, C. difficile, C. botulinum

#### **Protozoa with Cysts**

Giardia lablia, Cryptosporidium parvum

#### **Mycobacteria**

M. tubercolosis, M. Avium intracellulare, M. chelonae

#### HIGH LEVEL **DISINFECTANTS**

CHEMICAL

**STERILISERS** 

#### **Non-Enveloped Viruses**

Coxsachievvirus, Poliovirus, Rhinovirus, Norwalk-like virus, Hepatitis A virus, Murine norovirus, Adenovirus

#### **Fungi**

Candida species, Cryptococcus species, Aspergillus species, Dermatophytes

#### **MID-LEVEL DISINFECTANTS**

#### **Vegetative Bacteria**

Staphylococcus aureus, Salmonella typhi, Pseudomonas aeruginosa, Coliforms Legionella pneumophila, MRSA, VRE, Enterococcus hirae

#### LOW LEVEL DISINFECTANTS

#### **Enveloped Viruses**

Herpex simplex, Varicella-zoster virus, Cytomegalovirus, Measles virus, Mumps virus, Rubella virus, Influenza virus, Respiratory syncytial virus, Hepatitis B & C viruses, Hantavirus, HIV, Rotavirus, Coronavirus (SARS, MERS), Herpesviridae, Filoviridae (Ebola), Rabies, Human T Cell Leukemia Virus

#### **PRECAUTIONS**

Not to be used on materials which can be damaged by alcohol.

#### **QUALITY CONTROL**

All components (raw materials, containers, labels etc.) together with the processing phases of each batch are punctually and thoroughly checked internally according to the corporate UNI EN ISO 9001 and UNI EN ISO 13485 certified Quality Management System

#### **AUTHORISATIONS**

Class IIa CE 0546 medical device complying with Directive 93/42/EEC as amended by Directive 2007/47/EE

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