



**Fabbrica Italiana Sterilizzanti  
& Dispositivi Medici**

Str. di Sabbione , 27/A 05100 TERNI  
Tel: 0744 455503  
Fax: 0744 455504  
VAT: 01493940553

## **TECHNICAL DATA SHEET**

Revisione 17 Data di revisione 12/10/2018  
First release 20/03/2007

# **ADANTIUM<sup>®</sup> PLUS**

**Concentrated Decontaminating Disinfectant-25 ml Single use**

**CE 0373**

**Adantium<sup>®</sup> Plus** is a modern, concentrated synthetic preparation for simultaneous high-level cleansing and disinfection aimed at completely decontaminating of heat termoresistant Medical Devices , according to current safety laws.

- *Powerful disinfectant, cleansing and deodorizing for the disinfection/cleansing of medical devices and surgical instruments used in direct contact with the patient;.*
  - *Effective RNA degradation through a synthetic salt having an inhibitory role on nucleases which, in a biological environment, has an important role in curbing/inactivating viral replication. (see clinical validation of Prof. Pistello )*
  - *Disinfection time: 5 minutes at a 2,5% concentration; 10 minutes at a 0,5% concentration for all micro-organisms;*
  - *Exclusive action with a total spectrum of activity (bacteria, yeasts, fungi and viruses) and **exceptionally rapid disinfection**: bacteria in 5 minutes; spores and fungi in 10 minutes; viruses within 1 minute;*
  - *No residue after rinsing;*
  - *Effective in the presence of organic substances as well. The use of hard water does not diminish its effectiveness;*
- Does not contain peroxide:** therefore ideal for the disinfection and sterilisation of more delicate and expensive devices, in that it is not corrosive for materials and is compatible with thermolabile instruments;
- *The concentrated product is stable/valid for **36 months** in its unopened and correctly stored pack;*
  - *Activation not necessary in that it is a single component and its **pH is neutral**.*



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**Classification:** Class IIa Medical Device

**Notified Body:** Istituto Superiore di Sanità - Italian

Viale Regina Elena, 299 – 00161 Rome

CE 0373

**Composition:** Diphedac<sup>®</sup>, Complex surfactant (consisting of Alkyl-dimethyl-benzyl ammonium chloride.), Solvents and Surfactants.

**Action mechanism:** **Adantium<sup>®</sup> Plus** contains a new synthetic salt which, alone or resuspended with formula, is able to effectively hinder the nucleasic activity of the RNase present in plasma, preserving the added synthetic RNA from degradation (see the study of Prof. Pistello on the clinical validation).

**Adantium<sup>®</sup> Plus**, furthermore protects the cellular RNA from degradation through RNase A.

In conclusion, on the basis of the experimental proof obtained and considering the high resistance to the physical-chemical inactivation of the RNase, **Adantium<sup>®</sup> Plus** has an effective inhibitory role on these nucleases which, in a biological environment, has an important role in curbing/inactivating viral replication.

**Particular and unique characteristics:** **Adantium<sup>®</sup> Plus**, unlike other sterilising products currently available on the market, does not have any co-carcinogenicity risk. This guarantees a totally safe use thereof, in accordance with the provisions of Safety Laws (Legislative Decree 81/08 and s. m.).

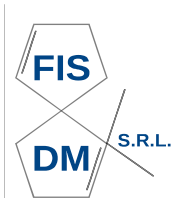
**Indications:** **Decontamination of equipment, medical surfaces and high-level**

Indicated for use on all types of surgical instruments and medical devices, equipment and medical apparatus.

**Incompatibility:** Do not mix the product with substances other than water

**Method of use:** The product can be used to perform a cleansing and a contemporary and effective decontamination of instruments and medical equipment potentially infected (a security measure, aimed at protecting the biological risk for the operators).

The solutions prepared by diluting the contents of the single-dose vial of 25 ml in 1 liter of demineralized water and kept in clean containers closed and remain active for 20 days.



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**Concentration to 2.5%:**

**-Instruments and medical equipment: Contact time 5 minutes**

**- Active solution 20 days.**

Pour Adantium® Plus- Schering-single dose of 25 ml in a container 1Lt

Place demineralized water or pure up to the volume of one liter. The solution is ready to be used with the system Hygienio.

**-Cleaning / disinfection of floors, walls and surfaces of operating theaters: Contact time 1 minutes**

Pour **Adantium® Plus-** Schering-single dose of 25 ml in a container 1Lt

Place demineralized water or pure up to the volume of one liter. The solution is ready to be used with the system Hygienio.

**IT IS NOT NECESSARY RINSING**

*Residue after rinsing:* A gas chromatography study regarding treatments on glass, PVC and stainless steel showed that 99,5% of the active ingredients was present in the water of the first rinse.

*Biodegradability:* **Over 94%** biodegradable, according to the OECD 301 BDCO norm in a concentration of 2,5%: 19,5.

DBO in a concentration of 2,5%: <5.

*Stability:* A study on the stability of the active ingredients and biological activity according to the EN 13610 norm reported a **validity of 36 months**.

*Study:*

- Chemistry Department, "La Sapienza" University – Rome: Title of the Study: "**Study of the Stability of class IIa high-level disinfectant medical device Adantium® Plus**"

*Toxicity:* Low toxicity: (LD 50 oral rat: ~2.000 mg/kg).

*Studies:*

- *RTC – Research Toxicology Centre, Rome:*



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**Title of the Study: "Adantium Plus – Acute dermal irritation study in the rabbit – Final Report (RTC Study No: 8931-1);**

➤ *RTC – Research Toxicology Centre, Rome:*

**Title of the Study: "Adantium Plus – Single-dose oral toxicity study in the rat – Final Report (RTC Study No: 16880-1);**

➤ *A. Pavan; Department of Experimental Medicine, University of "L'Aquila":*

**Title of the Study: "Tests of acute dermal irritation and sensitisation after application of Adantium Plus (in compliance with the norms described by the ECD guidelines No. 404 and No. 410 and ISO 10993).**

### **Traceability:**

The complete traceability of batches, from raw material acceptance to the distribution of the finished product, is carried out in accordance with the procedures of internal inspection audits.

### **EN 14885**

The bibliography regarding the Adantium range was updated in accordance with EN14885 "Chemical disinfectants and antiseptics – Application of the European Standards for chemical disinfectants and antiseptics" which reports the tests to be effected on the basis of the intended application of the disinfectant.

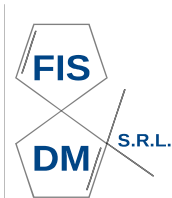
### **Clinical validation:**

*Prof. Mauro Pistello; Department of Experimental Pathology Medical Biotechnology Infectious Diseases and Epidemiology. University of Pisa:*

**Title of the Study "Testing of the inhibiting/denaturing activity of proteins and enzymes contained in biological fluids with medical devices assigned to degrade the RNA nucleic acid in cells, bacteria and the HIV and HCV viruses"**

An evaluation of the *in vitro* anti-microbial activity of **Adantium® Plus** for the prevention of infections acquired in hospitals:

the results revealed that **Adantium® Plus** showed excellent anti-microbial activity; with a reduction of > 5 logarithms in 5 minutes. This action was observed in many strains normally found in hospitals, frequently associated with nosocomial infections.



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### **Bactericidal Activity**

- Prof. Massimo Clementi; San Raffaele Life-Health University - Milan:

**Title of the Study: "Bactericidal activity of the disinfectant formula ADANTIUM® PLUS. Quantitative tests on a support/base" (EN 14561:2006)"**

#### **Results:**

*Pseudomonas aeruginosa* ATCC 15442 on a support/base: at 0,5% reduction >5 logarithms in 10 minutes;

*Pseudomonas aeruginosa* ATCC 15442 on a support/base: at 2,5% reduction >5 logarithms in 5 minutes.

- Prof. Massimo Clementi; San Raffaele Life-Health University - Milan:

**Title of the Study: "Bactericidal activity of the disinfectant formula ADANTIUM® PLUS." (EN 13727:2003)"**

#### **Results:**

*Escherichia coli* ATCC 10356: at 2,5% reduction >5 logarithms in 5 minutes;

*Pseudomonas aeruginosa* ATCC 15442: at 2,5% reduction >5 logarithms in 5 minutes;

*Enterococcus hirae* ATCC 10541: at 2,5% reduction >5 logarithms in 5 minutes;

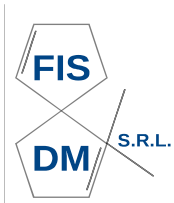
*Escherichia coli* ATCC 10356: at 0,5% reduction >5 logarithms in 10 minutes;

*Pseudomonas aeruginosa* ATCC 15442: at 0,5% reduction >5 logarithms in 10 minutes;

*Enterococcus hirae* ATCC 10541: at 0,5% reduction >5 logarithms in 10 minutes;

*U.S. Labs in collaboration with Jacaroni Diagnostic Centre:*

**Title of the Study: "DETERMINATION OF THE DECONTAMINATION PROCESS BY MEANS OF WASHING WITH HIGH-LEVEL DISINFECTANT ADANTIUM PLUS" (UNI EN ISO**



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**11737-1:2006)“.**

### **Virucidal Activity**

- Prof. Massimo Clementi; San Raffaele Life-Health University - Milan:

**Title of the Study: “Virucidal activity of the disinfectant formula ADANTIUM® PLUS.” (EN 14476:2005)“;**

#### **Results:**

*Poliovirus 1*: at 2,5% reduction >5 logarithms in 5 minutes;

*Adenovirus type 5*: at 2,5% reduction >5 logarithms in 5 minutes;

*Poliovirus 1*: at 0,5% reduction >5 logarithms in 10 minutes;

*Adenovirus type 5*: at 0,5% reduction >5 logarithms in 10 minutes;

The formula obtained with the active ingredient Diphedac® was subjected to **viral inactivation** tests at room temperature for a single time of three minutes in the presence of 5% bovine foetal serum: studies in BPL were conducted in accordance with the U.S. Environmental Protection Agency standards regarding the characterisation and the stability of the compound on the following viral cells: - *Human Coronavirus ATCC VR-740, Strain 229E* - *Herpes Simplex virus type ATCC VR734, Strain* - *Human Influenza A-type 1-Hepatitis C* - *B* - *Human Immunodeficiency virus type 1 (HIV)*.

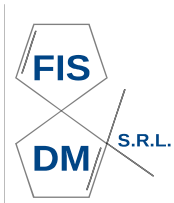
*Study Directory: Mary J. Miller – Douglas G. Anderson – Karen M. Ramm – Jennifer Palmen – Tonia Bevers* **ATS LABS** – Saint. Paul, MN 55120 – USA.

All the formulas have complete viral inactivation properties within 3 minutes.

### **Fungicidal Activity:**

- Prof. Massimo Clementi; San Raffaele Life-Health University - Milan:

**Title of the Study: “Fungicidal activity of the disinfectant formula**



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### ***ADANTIUM® PLUS.™ (EN 13624:2005)™;***

#### **Results in dirty conditions:**

*Candida albicans* ATCC 10231 on a support/base: at 0,5% reduction >5 logarithms in 10 minutes;

*Aspergillus niger* ATCC 16404 on a support/base: at 0,5% reduction >5 logarithms in 10 minutes;

*Candida albicans* ATCC 10231 on a support/base: at 2,5% reduction >5 logarithms in 5 minutes;

*Aspergillus niger* ATCC 16404 on a support/base: at 2,5% reduction >5 logarithms in 5 minutes;

- Prof. Massimo Clementi; San Raffaele Life-Health University - Milan:

***Title of the Study: "Fungicidal activity of the disinfectant formula ADANTIUM® PLUS. Quantitative Tests on a support/base" (EN 14562:2006)™;***

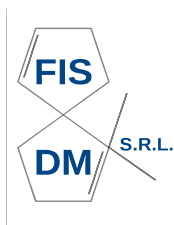
#### **Results in dirty conditions:**

*Candida albicans* ATCC 10231: at 0,5% reduction >4 logarithms in 10 minutes;

*Aspergillus niger* ATCC 16404: at 0,5% reduction >4 logarithms in 10 minutes;

*Candida albicans* ATCC 10231: at 2,5% reduction >4 logarithms in 5 minutes;

*Aspergillus niger* ATCC 16404: at 2,5% reduction >4 logarithms in 5 minutes.



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**Mycobactericidal  
Activity:**

- Prof. Massimo Clementi; San Raffaele Life-Health University - Milan:  
**Title of the Study: "Mycobactericidal activity of the disinfectant formula ADANTIUM® PLUS." (EN 14348:2005);**

**Tests performer in dirty and clean conditions:**

*Mycobacterium avium* ATCC 15769: at 2,5% reduction >5 logarithms in 5 minutes;

*Mycobacterium terrae* ATCC 15755: at 2,5% reduction >5 logarithms in 5 minutes;

*Mycobacterium avium* ATCC 15769: at 0,5% reduction >5 logarithms in 10 minutes;

*Mycobacterium terrae* ATCC 15755: at 0,5% reduction >5 logarithms in 10 minutes.

**Sporicidal Activity:**

- Prof. Massimo Clementi; San Raffaele Life-Health University - Milan:  
**Title of the Study: "Sporicidal activity of the disinfectant formula ADANTIUM® PLUS." (EN 14347:2005)";**

On the basis of the experimental conditions and criteria of interpretation provided by the European Standard EN 14347:2005, **Adantium® Plus** showed sporicidal activity in 10 minutes at 2,5% dilution and an elimination/a reduction of 3log<sub>10</sub> spores already at 0,5% dilution.

**Warnings:**

The European guideline of CE 88/379 regarding dangerous preparations and the Italian Ministry of Health require certain precautions when handling the product according to the following.

**(H) Risk phrases:**

Eye Dam. 2: H319- Causes serious eye irritation  
Flam. Liq. 3: H226 - Flammable liquid and vapour.  
Skin Irrit. 2: H315 - Causes skin irritation.  
Skin Sens. 1A: H317 - May cause an allergic skin reaction.  
Aquatic Acute 1: H400: Very toxic to aquatic life.

**(P) Precautionary  
advice:**

P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.





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P332+313: If skin irritation occurs: Get medical advice/attention P362:  
Take off contaminated clothing and wash before reuse.  
P370+P378: In case of fire: Use ABC powder extinguisher to put it out.  
P501: Dispose of contents/container to the collection points for  
hazardous waste

**Formats and packaging:**

**Vials Schering**

**25 ML Single use - Codice ADP25**

**MEDIVAL DEVICES CLASS IIa**

**CE 0373**

**CND:** D99-DISINFETTANTI E ANTISETTICI-ALTRI

**N° Repertorio:** 1247699/R

**Industrial property rights**

Manufactured by: **FIS & DM Ltd.** - Str. di Sabbione , 27/A - 05100 TERNI

[Telephone +39 \(0\)744 455503 - Fax: +39 \(0\)744 455504 - e mail: info@fisindustry.it](mailto:info@fisindustry.it)

*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.*