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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Johnson & Johnson Medical, Inc.
2500 Arbrook Boulevard
P.O. Box 90120
Arlington, TX 76004-3130

MAY 24 1994

Attention: T. M. Wendt, Ph.D., Director
Regulatory Affairs

Paul J. Kruger, Agent
for Johnson & Johnson Medical, Inc.

Subject: CIDEX* Activated Dialdehyde Solution
EPA Registration No. 7078-1
Your Amendment Dated April 8, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to revise the product labeling to include a package insert as per FDA 510(k) labeling requirements, has been reviewed by the Agency and found to be acceptable, provided you make the following change.

Amend the submitted product label with the following statement prior to releasing the product for shipment. Immediately under "DIRECTIONS FOR USE" include: "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling." Your release for shipment of the product constitutes acceptance of this condition.

The submitted package insert is appropriate, acceptable, and complies with FDA 510(k) labeling requirements for liquid chemical germicides, as per 21 CFR Section 801.5.

A stamped copy of the product label and package insert is enclosed for your records.

If you have any questions concerning this letter, please contact Doreen Aviado at (703) 305-6554.

Sincerely,

Marshall Swindell
Acting Product Manager-31
Antimicrobial Program Branch
Registration Division (7505C)

Enclosures

	CONCURRENCES							
SYMBOL	7505C							
SURNAME	D Aviado							
DATE	5/23/94							

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

*U.S. Government Printing Office: 1992 — 620-856/40572

INDICATIONS FOR USE

STERILIZATION: This solution should be used for the sterilization of heat sensitive medical equipment for which alternative methods of sterilization are not available. Medical equipment which should always be sterilized is that which is categorized as critical (i.e., used in procedures in which contact will be made with tissues that is normally considered sterile).

HIGH LEVEL DISINFECTION: This solution should be used for the high level disinfection of heat sensitive medical equipment for which sterilization is not practical. Medical equipment which should always be subjected to high level disinfection or sterilization is that which will be used in procedures categorized as semi-critical (i.e., used in procedures in which contact will be made with intact mucous membranes or other body surfaces which are not normally considered to be sterile).

INTERMEDIATE LEVEL DISINFECTION: This solution should be used for the disinfection of medical equipment for which a risk of cross contamination exists. Medical equipment which should always be disinfected is that which is to be used in procedures categorized as non-critical (i.e., used in procedures in which contact will only be made with intact skin).

DIRECTIONS FOR USE

ACTIVATION: Activate the CIDEX Solution by adding the entire contents of the activator vial which is attached to the CIDEX Solution container. Shake well. When activated, solution changes color to green. Record the date of activation on the indicated space below, in a log book or a label affixed to any secondary container used for the activated solution. See package insert for additional instructions and information regarding activated solution.

CLEANING/DECONTAMINATION: Blood and other body fluids must be thoroughly cleaned from hard, non-porous surfaces and objects before application of the disinfectant or sterilant. For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX Solution. See package insert for additional cleaning/decontamination instructions.

STERILIZATION: Immerse medical instruments/equipment completely in CIDEX Solution for a minimum of 10 hours at 20°C. Remove equipment from the solution using aseptic technique and rinse thoroughly with sterile water. See package insert for complete instructions/information on sterilization.

HIGH LEVEL DISINFECTION: Immerse medical instruments/equipment completely in CIDEX Solution for a minimum of 45 minutes at 25°C. Remove from solution and rinse thoroughly with sterile water or with potable tap water. The quality of rinse water used is dependent upon the intended use of the instrument/equipment. See package insert for complete instructions/information on high level disinfection.

INTERMEDIATE LEVEL DISINFECTION: Immerse medical instruments/equipment completely in CIDEX Solution for a minimum of 10 minutes at 25°C - 35°C to destroy all vegetative bacteria except, for large numbers of Mycobacterium tuberculosis, but including Pseudomonas aeruginosa, pathogenic fungi and specified viruses, as indicated in the package insert.

A 10 minute immersion at 20°C will kill 97.9% Mycobacterium tuberculosis (Quantitative TB Method).

A 10 minute immersion at 25°C will kill 99.9% Mycobacterium tuberculosis (Quantitative TB Method). Remove instruments/equipment from the solution and thoroughly rinse with sterile water or potable tap water. The quality of the rinse water used is dependent upon the intended use of the instrument/equipment. See package insert for complete instructions/information on intermediate level disinfection.

Reorder No.

2245

REUSABLE

Sterilizing and Disinfecting Solution

Sporicidal Fungicidal Bactericidal
Virucidal Tuberculocidal Pseudomonacidal

Cidex*

activated dialdehyde solution

Active Ingredient	
Glutaraldehyde	2.4%
Inert Ingredients	97.6%
Total	100.0%

NOTE — Contents of attached vial *must* be added to solution before this product is effective. *See Directions for Use - Activation.*

EPA REG. No. 7078-1
EPA EST. No. 36125 PR-1

Keep out of reach of children.

DANGER: See right side panel for additional precautionary statements.

*TRADEMARK

CONTENTS: 0.946 L (ONE QT.)

Johnson & Johnson MEDICAL INC.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMEST

DANGER: Keep Out of Reach of Chil

Direct contact is corrosive to exposed into eyes, on skin or on clothing. pouring. Avoid contamination of food

STATEMENT OF PRACTICAL TREATM of water for at least 15 minutes. Fo quantities of water and call a physicia

NOTE TO PHYSICIAN: Probable muco

STORAGE AND DISPOSAL: Store at c

Pesticide Disposal: Discard residual

Container Disposal: Do not reuse em

Refer to package insert for warranted

CONTROL NUMBER AND EXPIRATION DA

NOTE TO USER: ACTIVATION DATE: _
Do not use beyond 14
CIDEX Solution Test

EXPIRATION DATE FO

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For technical safety TRADE

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 2 4 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

7078-1

SCALE: 100%

or intermediate level disinfectant, when used according to the **Directions for Use.**

Sterilant: CIDEX Solution is a sterilant when used or reused, according to Directions for Use, at full strength for a maximum of 14 days at **25°C** with an immersion time of at least **10 hours.**

High Level Disinfectant: CIDEX Solution is a high level disinfectant when used or reused, according to Directions for Use, at full strength for a maximum of 14 days at **25°C** with an immersion time of at least **45 minutes.**

Intermediate Level Disinfectant: CIDEX Solution is an intermediate level disinfectant when used or reused, according to Directions for Use, at full strength for a maximum of 14 days.

A **10 minute** immersion at **20°C to 25°C** will destroy all vegetative bacteria, except for large numbers of **Mycobacterium tuberculosis**, but including **Pseudomonas aeruginosa**, pathenogenic fungi and specified viruses, as indicated in Section E - Directions for Use - Item 3(c).

A **10 minute** immersion at **20°C** will kill **87.9% Mycobacterium tuberculosis** (Quantitative TB Method).

A **10 minute** immersion at **25°C** will kill **99.8% Mycobacterium tuberculosis** (Quantitative TB Method).

2) **Reuse Period**

CIDEX Solution has also demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse. CIDEX Solution can be reused for a period not to exceed 14 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in **Directions for Use. DO NOT** rely solely on days in use. **Efficacy of this product during its use-life must be verified by the CIDEX* Solution Test Strip to determine that at least the minimum effective concentration (MEC) of 1.5% glutaraldehyde is present.**

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAY 24 1994
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 7078-1

*Trademark

3) **General Information on Selection and Use of Germicides for MedicalDevice Reprocessing**

Choose a germicide with the level of microbial activity that is appropriate for the reusable medical device or equipment surface. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process.

First, for patient contacting devices, determine whether the reusable device to be reprocessed is a critical, semi-critical, or noncritical device.

- A **critical device** presents a high risk of infection if not sterile. Critical devices routinely penetrate the skin or mucous membranes during use or are otherwise used in normally sterile tissue of the body.
- A **semi-critical device** makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body.
- A **noncritical device** contacts only intact skin during routine use.

Second, determine the level of germicidal activity that is needed or the reusable device.

Critical Device	Sterilization required (e.g.: products that enter sterile tissue or the vascular system, such as laparoscopes and microsurgical instruments)
Semi-critical Device	Sterilization recommended whenever practical, otherwise High Level Disinfection acceptable (e.g.: GI endoscopes, anesthesia equipment for the airway, diaphragm-fitting rings, etc.)
Noncritical Device	Intermediate Level Disinfection recommended when there is a risk of cross-contamination, otherwise Low Level Disinfection acceptable (e.g.: bed pans, blood pressure cuffs, linens, etc.)
Medical Equipment Surface	Same as for noncritical device (e.g.: crutches, oxygen cylinders, etc.)

Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.

*Trademark

4) Microbial Activity

The following table indicates the spectrum of activity as demonstrated by testing of CIDEX Solution**:

BACTERIA		FUNGI	VIRUSES	
SPORES	VEGETATIVE ORGANISMS		NON-ENVELOPED	ENVELOPED
Bacillus subtilis	Staphylococcus aureus	Trichophyton mentagrophytes	Poliovirus Type 1	Coronavirus
Clostridium sporogenes	Salmonella choleraesuis		Rhinovirus Type 14	Cytomegalovirus
	Pseudomonas aeruginosa		Adenovirus Type 2	Influenza virus Type A [WS/33]
	Mycobacterium tuberculosis		Vaccinia	HIV-1 (AIDS Virus)
				Herpes simplex Type 1, 2

** Testing was done after 14 days of simulated resue using prescribed testing methods.

*Trademark

5) **Material Compatibility**

CIDEX Solution is recommended for use with medical devices made from the materials shown below. Care must be taken with medical and dental equipment such as anesthesia and respiratory therapy tubing, dental mirrors and burs. These devices may be damaged when cleaned with a highly alkaline detergent, poorly rinsed after disinfection, stored wet or dried at temperatures exceeding 105°F.

METALS

Chrome plate[1]
Copper[1]
Monel[1]
Nickel plate[1]
Nickel silver alloy[1]
Platinum[1]
Silver Solder[1]
Tungsten[1]
70-30 Solder[1]
Aluminum[2]
Gold plate[2]
Silver plate[2]
Anodized aluminum[5]
Brass[5]
Carbon steel[7]
Stainless steel[7]

PLASTICS

Polysulfone[1]
Teflon[1]
Polyethylene terephthalate (Polyester)[3]
Polymethylmethacrylate (Acrylic)[3]
Polystyrene[3]
Polyvinylchloride (PVC)[3]
Polycarbonate[4]
Acrylonitrile-butadiene-styrene (ABS)[7]
Nylon[7]
Polyethylene[7]
Polypropylene[7]

ELASTOMERS

Polychloroprene (Neoprene)[1]
Polyurethane[1]
Black natural rubber[7]
Red natural rubber[7]
Silicone rubber (Silastic)[7]

NOTE:

1 Represents 8 hours of continuous contact with CIDEX Solution.
2 Represents 10 hours of total contact with CIDEX Solution over 20 disinfection cycles.
3 Represents 20 hours of total contact with CIDEX Solution over 20 disinfection cycles.
4 Represents 40 hours of total contact with CIDEX Solution over 40 disinfection cycles.
5 Represents 144 hours of continuous contact with CIDEX Solution.
6 Represents 283 hours of total contact with CIDEX Solution over 20 sterilization cycles.
7 Represents 336 hours or greater of continuous contact with CIDEX Solution.

*Trademark

6) **Precleaning Agent Compatibility**

CIDEX Solution is compatible with enzymatic detergents (e.g.: ENZOL* Enzymatic Detergent) which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acidic or alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the CIDEX Solution by altering its pH.

B) **Contraindications**

1) **Sterilant Usage**

Routine biological monitoring is not feasible with CIDEX Solution, and therefore, CIDEX Solution should **NOT** be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g.: heat, ethylene oxide, or peroxide gas plasma.

CIDEX Solution should not be used for sterilization of critical devices intended for single use (e.g.: catheters).

2) **High Level Disinfectant Usage**

CIDEX Solution should **NOT** be used to high level disinfect a semi-critical device when sterilization is practical.

3) **Endoscope Usage**

CIDEX Activated Dialdehyde Solution is not the method of choice for sterilization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization. In general, glutaraldehyde solutions that do not contain surfactants (e.g.: CIDEX Solution) are more appropriate for flexible endoscopes, since glutaraldehyde solutions containing surfactants (e.g.: CIDEX FORMULA 7* Solution or CIDEX PLUS* 28 Day Solution) are more difficult to rinse from the devices. However, these surfactant containing disinfectants may be used for reprocessing of flexible endoscopes **if a validated protocol for rinsing and leak testing is employed.**

*Trademark

C) **Warnings**

CIDEX ACTIVATED DIALDEHYDE SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Keep Out of Reach of Children
Contains Glutaraldehyde

1) **Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing.**
2) **Avoid contamination of food.**
3) **Use in well ventilated area in closed containers.**

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, get medical attention.

Harmful if swallowed. Drink large quantities of water and call a physician immediately.

Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

Emergency, safety, or technical information about CIDEX Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

*Trademark

D) **Precautions**

1) Disposable latex gloves, eye protection, face masks, and liquid-proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.

2) Contaminated, reusable devices **MUST BE THOROUGHLY CLEANED** prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the germicide.

3) The user **MUST** adhere to the **Directions for Use** since any modification will affect the safety and effectiveness of the germicide.

4) The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using CIDEX Solution.

5) The use of CIDEX Solution in automated endoscope washers must be part of a validated reprocessing procedure provided by the washer manufacturer. Contact the manufacturer of the endoscope washer for instructions on the maximum number of reprocessing cycles which may be used before refilling with fresh CIDEX Solution. Use CIDEX Solution Test Strips to monitor glutaraldehyde concentration before each cycle to detect unexpected dilution.

*Trademark

E) Directions for Use

1) Activation

Activate the CIDEX Solution by adding the entire contents of the Activator Vial which is attached to the CIDEX Solution container. Shake well. Activated solution immediately changes color to green, thereby indicating solution is ready to use. CIDEX Solution is intended for use in manual (bucket and tray) systems made from polypropylene, ABS, polyethylene, glass-filled polypropylene or specially molded polycarbonate plastics. Record the date of activation (mixing date) and expiration date on the CIDEX Solution container label in the space provided, in a log book or a label affixed to any secondary container used for the activated solution.

2) Cleaning/Decontamination

Blood and other body fluids must be thoroughly cleaned from surfaces, lumens, and objects before application of the disinfectant or sterilant. Blood and other body fluids should be autoclaved and disposed of according to all applicable federal, state and local regulations for infectious waste disposal.

For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in CIDEX Solution. Cleanse and rinse the lumens of hollow instruments before filling with CIDEX Solution. **Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.**

*Trademark

3) **Usage**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

a) **Sterilization (Bucket/Tray Manual System)**

Immerse medical equipment/device completely in CIDEX Solution for a minimum of **10 hours at 25°C** to eliminate all microorganisms including **Clostridium sporogenes** and **Bacillus subtilis** spores. Remove equipment from the solution using sterile technique and **rinse thoroughly** with **sterile water** following the rinsing instructions below.

b) **High Level Disinfection (Bucket/Tray Manual System)**

Immerse medical equipment/device completely in CIDEX Solution for a minimum of **45 minutes at 25°C** to destroy all pathenogenic microorganisms, except for large numbers of bacterial endospores, but including **Mycobacterium tuberculosis** (Quantitative TB Method). Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

c) **Intermediate Level Disinfection (Bucket/Tray Manual System)**

Immerse medical equipment/device completely in CIDEX Solution for a minimum of **10 minutes** at **20°C to 25°C** to destroy all vegetative bacteria, except for large numbers of **Mycobacterium tuberculosis**, but including **Pseudomonas aeruginosa**, pathogenic fungi, and viruses **(Poliovirus Type 1; Adenovirus Type 2; Herpes simplex Type 1,2; HIV-1 (AIDS virus); Influenza Type A [WS/33]; Vaccinia; Coronavirus; Cytomegalovirus; Rhinovirus Type 14)** on inanimate surfaces.

A **10 minute** immersion at **20°C** will kill 87.9% **Mycobacterium tuberculosis** (Quantitative TB Method).

A **10 minute** immersion at **25°C** will kill 99.8% **Mycobacterium tuberculosis** (Quantitative TB Method).

Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

*Trademark

d) Rinsing Instructions

Following immersion in CIDEX Solution, thoroughly rinse the equipment or medical device by immersing it completely in three separate copious volumes of water. Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device or equipment manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose as it will be contaminated with glutaraldehyde.

Refer to the reusable device/equipment manufacturer's labeling for additional rinsing instructions.

STERILE WATER RINSE

The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

1. Devices intended for use in normally sterile areas of the body;

2. Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g., high risk population served) and;

3. When practicable, bronchoscopes, due to a risk of **atypical Mycobacteria** contamination from potable water supply.

POTABLE WATER RINSE

For all other devices a sterile water rinse is recommended when practicable, otherwise a high quality potable tap water rinse is acceptable. A high quality potable water is one that meets Federal Clean Water Standards at the point of use.

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with **Pseudomonads** and **atypical** (fast growing) **Mycobacteria** often present in potable water supplies. A device (e.g.: colonoscope) that is not completely dried provides an ideal situation for rapid colonization of bacteria. Additionally, **Mycobacteria** are highly resistant to drying, therefore, rapid drying will avoid possible colonization but may not result in a device free from **atypical Mycobacteria**. Although these bacteria are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

*Trademark

e) **Reusage**

CIDEX Solution has also demonstrated efficacy in the presence of 4% organic soil contamination and a simulated amount of microbiological burden during reuse. This solution **may be used and reused** within the limitations indicated above for up to **14 days** after activation. **Do not use activated solution beyond 14 days. Efficacy of this product during its use-life must be verified by the CIDEX Solution Test Strip to determine that the minimum effective concentration (MEC) of 1.5% is present.**

4) **Monitoring of Germicide to Ensure Specifications are Met**

During the usage of CIDEX Solution, as a high or intermediate level disinfectant and/or sterilant, it is recommended that a thermometer and timer be utilized to ensure that the optimum usage conditions are met. In addition, it is recommended that the CIDEX Solution be tested with the CIDEX Solution Test Strip prior to each usage. This is to insure that the appropriate concentration of glutaraldehyde is present and to guard against a dilution which may lower the effectiveness of the solution below its MEC. The pH of the activated solution may also be periodically checked to verify that the pH of the solution is between 8.2 and 8.9.

5) **Post-Processing Handling and Storage of Reusable Devices**

Sterilized or disinfected reusable devices are either to be immediately used or stored in a manner to minimize recontamination. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against recontamination. Refer to the reusable device-equipment manufacturer's labeling for additional storage and/or handling instructions.

*Trademark

F) **Storage Conditions and Expiration Date**

1) Prior to activation, CIDEX Solution should be stored in its original sealed container at controlled room temperature 15°-30°C (59°-86°F).

Once the CIDEX Solution has been activated, it should be stored in the original container until transferred to the containers in which the immersion for disinfection or sterilization is to take place. Containers should be stored in a well ventilated, low traffic area at controlled room temperature.

2) The expiration dates of the unactivated CIDEX Solution and activator will be found on the bottom of the immediate containers.

3) The use period for activated CIDEX Solution is for no longer than 14 days following activation or as indicated by the CIDEX Solution Test Strip. Once activated, the solution requires no further dilution prior to its usage.

G) **Emergency and Technical Product Information**

Emergency, safety, or technical information about CIDEX Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

H) **User Proficiency**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and the handling of toxic substances such as liquid chemical germicides. Additional information about CIDEX Solution can be obtained from Johnson & Johnson Medical, Inc. Customer Relations at 1-800-423-5850, or by contacting your local Johnson & Johnson Medical, Inc. sales representative.

*Trademark

I) Disposal Information

Germicide Disposal

Discard residual solution in drain. Flush thoroughly with water.

Container Disposal

- **0.946 L (One Quart) and 3.785 L (One Gallon) Size Containers**
  Do not reuse empty container. Wrap container and put in trash.

- **9.462 L (2 1/2 Gallon) Size Container**
  Triple rinse empty container with water and dispose of in an incinerator or landfill approved for pesticide containers.

J) How Supplied

Reorder	Description	Case Contains
2245	0.946 L (One Quart) Container	4 x 0.946 L (4 qts)/box; 4 boxes/case; i6 x 0.946 L (16 qts)/case
2250	3.785 L (One Gallon) Container	4 x 3.785 L (4 gals)/case
2253	9.462 L (2 1/2 Gallon) Container	2 x 9.462 L (2 x 2 1/2 gals) /case
2920	CIDEX Solution Test Strips	60 strips/btl; 2 btls/case
2921	CIDEX Solution Test Strips	60 strips/btl; 12 btls/case
2927	CIDEX Solution Test Strips	15 strips/btl; 2 btls/case

References supplied upon request.

*Trademark