

FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices

Section VI. of FDA's *Final Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (</media/80265/download>) outlines six criterion that should be addressed in reprocessing instructions. Criterion 4 recommends that reprocessing instructions should include devices and accessories that are legally marketed. On this page is a table of FDA-cleared liquid chemical sterilants and high level disinfectants, last updated September 2015.

Manufacturer	Active Ingredient(s)	Sterilant Contact Conditions	High Level Disinfectant Contact Conditions
K091210 Acecide-C High Level Disinfectant and Sterilant			
Best Sanitizers, Inc.	3100-3400 ppm peracetic acid	<p>Indication for device sterilization</p> <p>2 hrs at 20°C</p> <p>5 days Maximum Reuse</p> <p>Contact conditions based on AOAC Sporicidal Activity Test and by simulated use testing with endoscopes.</p>	<p>7 min at 20°C</p> <p>5 days Maximum Reuse</p> <p>Contact conditions established by simulated use testing with endoscopes.</p>
K091890 Extended Use Aldahol High Level Disinfectant			
Healthpoint, Ltd.	3.4% glutaraldehyde 20.1% isopropanol	<p>Indication for device sterilization</p> <p>For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C:</p> <p>6 hrs at 25°C</p> <p>14 days Maximum Reuse</p> <p>Contact conditions based on AOAC Sporicidal Activity Test and by simulated use testing with endoscopes.</p>	<p>For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C:</p> <p>5 min at 25°C</p> <p>14 days Maximum Reuse</p> <p>Contact conditions established by simulated use testing with endoscopes.</p>

K091022 Resert XL HLD High Level Disinfectant

Steris Corporation	2.0% hydrogen peroxide	No indication for device sterilization. Passes the Modified AOAC Sporocidal Activity Test in 6 hrs at 20°C.	8 min at 20°C 21 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K090036 and K173256 Steris S40 Sterilant Concentrate

Note: Cleared for use with the Steris System 1E Liquid Chemical Sterilant Processing System

Steris Corporation	≥1820 mg/L peracetic acid	Indication for device sterilization 6 min at 46-55°C Single use – diluted by system For use in the Steris System 1E and endo Liquid Chemical Sterilant Processing Systems only Contact conditions based on AOAC Sporocidal Activity Test and simulated use testing with endoscopes.	No indication for high level disinfection
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K113015 Aldahol V High Level Disinfectant

Microchem Laboratories, Inc.	3.4% glutaraldehyde 20.1% isopropanol	Indication for device sterilization. 8 hrs at 20°C 14 days Maximum Reuse Contact conditions based on AOAC Sporocidal Activity Test and by simulated use testing with endoscopes.	10 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K120306 Rapicide OPA-28 High Level Disinfectant

Minntech Corporation	0.575% <i>ortho</i> -phthalaldehyde	No indication for device sterilization. Passes the Modified AOAC Sporidical Activity Test in 32 hrs at 20°C and 25°C.	For Manual Processing: 10 min at 20°C 28 days Maximum Reuse For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C: 5 min at 25°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K140703 OPA 30 Solution

Ciden Technologies, LLC	0.6% <i>ortho</i> -phthalaldehyde	No indication for device sterilization. Passes the Modified AOAC Sporidical Activity Test in 32 hrs at 20°C and 25°C.	For Manual Processing: 12 min at 20°C 30 days Maximum Reuse For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C: 5 min at 25°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K041984 Acecide High Level Disinfectant and Sterilant

Best Sanitizers, Inc.	3300-3800 ppm peracetic acid	No indication for device sterilization. 5 hrs at 25°C 5 days Maximum Reuse Contact conditions based on AOAC Sporidical Activity Test and by simulated use testing with endoscopes.	5 min at 25°C 5 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K051305 TD-5 High-level Disinfectant

CS Medical, L.L.C.	2.65% glutaraldehyde	No indication for device sterilization. Passes the AOAC Sporidical Activity Test in 10 hrs at 22 °C.	5 min at 37.8°C Single use to be used exclusively with the TD-100 Transesophageal Probe Disinfectant. Contact conditions established by simulated use testing with endoscopes.
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K041360 Aldahol III High Level Disinfectant

Healthpoint LTD	3.4% glutaraldehyde 26% isopropanol	Indication for device sterilization. 10 hrs at 20° C Contact conditions based on AOAC Sporicidal Activity Test only.	10 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K012889 Banicide Advanced for Sterilization and High Level Disinfection			
Pascal Company, Inc.	3.5% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C 30 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 25°C 30 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K032959 Cidex® OPA Concentrate			
Advanced Sterilization Products	5.75% <i>ortho</i> -phthaldehyde (OPA)	No indication for device sterilization. In-Use solution (0.05% OPA) passes the AOAC Sporicidal Activity Test in 32 hrs at 50°C.	5 min at 50°C Single use – diluted by system For use in the EvoTech Integrated Endoscope Disinfection System only. Contact conditions established by simulated use testing with endoscopes.
K030004 Cidex OPA Solution			
Advanced Sterilization Products	0.55% <i>ortho</i> -phthaldehyde	No indication for device sterilization. Passes the AOAC Sporicidal Activity Test in 32 hrs at 20°C and 25°C.	Manual Processing 12 min at 20°C 14 days Maximum Reuse Automated Endoscope Reprocessor (AER) 5 min at 25°C 14 days Maximum Reuse (For processing in an AER only with FDA-cleared capability to maintain solution temperature at 25°C.) Contact conditions established by simulated use testing with endoscopes.
K013280 Sterilox Liquid High Level Disinfectant System			
Sterilox, Technologies, Inc.	Hypochlorite and Hypochlorous acid 650-675 ppm Active	No indication for device sterilization. Passes the Modified AOAC Sporicidal Activity Test in 24 hrs at 25°C.	10 min at 25°C Single use - generated on site Contact conditions established by simulated use testing with endoscopes.
K003087 Sporicidin Sterilizing and Disinfecting Solution			

Sporicidin International	1.12% glutaraldehyde 1.93% phenol/phenate	Indication for device sterilization. 12 hrs at 25°C 14 days Maximum Reuse Contact conditions based on AOAC Sporocidal Activity Test only.	20 min at 25°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K993042 Rapicide High Level Disinfectant and Sterilant

MediVators, Inc.	2.5% glutaraldehyde	Indication for device sterilization. 7 hrs 40 min at 35°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes and additional supporting information.	Automated Endoscope Reprocessor 5.0 min at 35°C 28 days Maximum Reuse (For processing in an AER only with FDA-cleared capability to maintain the solution temperature at 35°C.) Contact conditions established by simulated use testing with endoscopes.
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K991487 °Cidex®OPA Solution High Level Disinfectant

Advanced Sterilization Products	0.55% <i>ortho</i> -phthaldehyde	No indication for device sterilization. Passes the AOAC Sporocidal Activity Test in 32 hrs at 20°C.	12 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K974188 °Cetylce-G Concentrate and Diluent Concentrate

Cetylite Industries, Inc.	3.2% glutaraldehyde	Indication for device sterilization. 10 hrs at 20°C 28 days Maximum Reuse Contact conditions based on AOAC Sporocidal Activity Test only.	40 min at 20°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K974062 MedSci 3% Glutaraldehyde

MedSci, Inc.	3% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporocidal Activity Test only.	25 min at 25°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K972708 EndoSpore Plus Sterilizing and Disinfecting Solution

Note: Due to the lack of test strips for monitoring the concentrations of the active ingredients, the reuse period is limited to 14 days.

Cottrell Limited	7.35% hydrogen peroxide 0.23% peracetic acid	Indication for device sterilization. 180 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.	15 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K970230 Sporox™ Sterilizing & Disinfection Solution			
Reckitt & Colman Inc.	7.5% hydrogen peroxide	Indication for device sterilization. 6 hrs at 20°C 21 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	30 min at 20°C 21 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K960513 Peract™ 20 Liquid Sterilant/Disinfectant			
Minntech Corporation	1.0% hydrogen peroxide 0.08% peracetic acid	Indication for device sterilization. 8 hrs at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.	25 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K932922 Procide 14 N.S.			
Cottrell Limited	2.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 20°C 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K932922 Omnicide™ Long Life Activated Dialdehyde Solution			
Cottrell Limited	2.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 20°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 20°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K932922 Omnicide™ Plus			

Cottrell Limited	3.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 20°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 20°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K931592 Metricide Plus 30 Long-Life Activated Dialdehyde Solution			
Metrex Research, Inc.	3.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only. FDA accepted Metricide Plus as identical to Cidex Plus.	90 min at 25°C 28 days Maximum Reuse FDA accepted Metricide Plus as identical to Cidex Plus.
K931052 Metricide 28 Long-Life Activated Dialdehyde Solution			
Metrex Research, Inc.	2.5% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only. FDA accepted Metricide 28 as identical to Cidex Formula 7.	90 min at 25°C 28 days Maximum Reuse FDA accepted Metricide 28 as identical to Cidex Formula 7.
K930284 Metricide Activated Dialdehyde Solution			
Metrex Research, Inc.	2.6% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only. FDA accepted Metricide as identical to Cidex.	45 min at 25°C 14 days Maximum Reuse FDA accepted Metricide as identical to Cidex.
K924434 Cidex™ Activated Dialdehyde Solution			
Johnson & Johnson Medical Products	2.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 25°C 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 25°C 14 days Maximum Reuse Contact conditions based on literature references.

K924334 Cidex Formula 7™ Long-Life Activated Dialdehyde Solution

Johnson & Johnson Medical Products	2.5% glutaraldehyde	Indication for device sterilization. 10 hrs at 20-25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	90 min at 25°C 28 days Maximum Reuse Contact conditions based on literature references.
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K923744 Cidex Plus™ 28 Day Solution

Johnson & Johnson Medical Products	3.4% glutaraldehyde	Indication for device sterilization. 10 hrs at 20-25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	20 min at 25°C 28 days Maximum Reuse Contact conditions based on literature references.
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K914749 Wavicide - 01

Wave Energy Systems	2.5% glutaraldehyde	Indication for device sterilization. 10 hrs at 22°C 30 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 22°C 30 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K080420 Resert XL HLD High Level Disinfectant

Steris Corporation	2.0% Hydrogen peroxide	No indication for device sterilization. <i>In-Use solution passes the AOAC Sporicidal Activity Test in 6 hrs at 20 °C</i>	8 min at 20°C 21 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K070627 Opaciden Solution

Ciden Technologies, LLC	0.60% <i>ortho</i> -phthalaldehyde (OPA)	No indication for device sterilization. <i>In-Use solution passes the AOAC Sporicidal Activity Test in 32 hrs at 21 °C and 32 hrs at 25-27°C.</i>	For Manual Processing: 12 min at 20°C 14 days Maximum Reuse For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C: 5 min at 25°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
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K063159 Sterilox High Level Disinfectant System

Sterilox, Technologies, Inc.	Hypochlorous acid/hypochlorite 400-450 ppm Active	No indication for device sterilization. <i>Passes the Modified AOAC Sporicidal Activity Test in 32 hrs at 30 ° C.</i>	10 min at 30°C Single use - generated on site <i>Contact conditions established by simulated use testing with endoscopes.</i>
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K060618 Cidex Activated Dialdehyde Solution

Advanced Sterilization Products	2.4% glutaraldehyde	10 hrs at 25 °C 14 days Maximum Reuse <i>Contact conditions based on AOAC Sporocidal Activity Test and by simulated use testing with endoscopes.</i>	45 min at 25 °C 14 days Maximum Reuse <i>Contact conditions established by simulated use testing with endoscopes.</i>
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