**註2:**

**2015年3月美國FDA**公告核准次氯酸為高階殺菌劑

# FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices - March 2015

Section VI. of FDA’s [Final Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf) 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** |
| --- | --- | --- | --- |
| **K930284 Metricide Activated Dialdehyde Solution** | | | |
| Sterilox, Technologies, Inc. | **Hypochlorous acid/hypochlorite** 400-450 ppm Active free chlorine | **No indication for device sterilization.** Passes the Modified AOAC Sporicidal Activity Test in 32 hrs at 30 ° C. | 10 min at 30ºC Single use - generated on site Contact conditions established by simulated use testing with endoscopes. |
| **K060618 Cidex Activated Dialdehyde Solution** | | | |
| Advanced Sterilization Products | 2.4% glutaraldehyde | 10 hrs at 25 °C 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test and by simulated use testing with endoscopes. | 45 min at 25 °C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes. |

**資料來源: FDA網頁**<https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and>