On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

# Sterilized Convenience Kits for Clinical and Surgical Use;

# Final Guidance for Industry

**Document issued on: January 7, 2002**

**This document does not supersede any previous document.**




**U.S. Department Of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**

**Office of Compliance**

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# Preface

## Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance for medical devices, contact Wally A. Pellerite in the Office of Compliance, Center for Devices and Radiolog ical Health at (301) 594-4692 or email WAP@cdrh.fda.gov.

For questions regarding prescription drug products, call the Division of Prescription Drug Compliance and Surveillance, in the Center for Drug Evaluation and R esearch (CDER) at (301) 594-0101. For questions regarding over the counter drugs, call the Division of Labeling & Nonprescription Drug Compliance, in CDER, at (301) 594 -0063. For questions regarding manufacturing and quality control, call the Division of Manufacturing and Product Quality at (301) 796-3191.

## Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/comp/guidance/1390.pdf , or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts -On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1390 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

# Sterilized Convenience Kits for Clinical and Surgical Use.

***This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.***

## The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that the information requested in the guidance is not relevant to the decision-making process or that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways t o contact him, can be found on the Internet at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

## Medical Device Kit Assembler / Manufacturer[1]

The Center for Devices and Radiological Health (CDRH) continues to have concerns about finished device components that are assembled into clinical or surgical convenience kits and the kit is then sterilized. In some cases, the finished device is actually being sterilized for a second time. Some components may be adversely affected by further processing i n the sterilization process. For the purposes of this guidance, a finished device component in a convenience kit is a device in finished form held for sale to an end user that is suitable for use or capable of functioning, whether

[1] For concerns regarding drug products, please review the last paragraph of this document and contact the appropriate office in the Center for Drug Evaluation and Research.

or not it is packaged, la beled or sterilized. Please ensure that your sterilization process does not adversely affect the finished components in your kits.

There are five areas that, at a minimum, you should cover to ensure that the sterilization process does not adversely affect the finished components in your convenience kits. Those areas include the following:

--Sterilization Process
- Sterilant Residuals
- Labeling
- Premarket Notification
- General Controls

A sterilization process may pose the following issues that you need to address:

1. Effects of the sterilization process -
   - Does exposure to heat during the sterilization process cause the material in a device to degrade before the labeled expiration date?

   - Does the sterilization process (e.g., vacuum effects, radiation) affect the form, fit or function of device components? The device kit repackers should ensure that the sterilization process does not adversely affect the functionality of the device components. For example, it is known that irradiation can effect certain polym ers, resulting in a loss of strength. The device component manufacturer would have information or recommendations on the effects of the sterilization processes.

   - Does the sterilization process affect the package integrity for devices? For example, the package integrity of all device components should remain in tact for any sterilization cycle that may be designated for the convenience kits.

2. Labeling -

   - The convenience kit should provide instructions for appropriate storage conditions and contain an expir ation date supported by stability data. The expiration dates for device components should be revised based on data from your process validation studies for devices. The expiration date should not be longer than the shortest expiration date of any component in the kit.

     For example, what is the impact on a kit's components when stored for one year at room temperature at 30 degrees centigrade? (See ICH, Q1A Stability Testing of New Substances and Products.) If you determine that the shortest expiration date is 3 months from the date of sterilization, that establishes the sterility expiration date for the entire kit.

- There is no specific policy in place with respect to labeling for device kits.

3. Premarket Notification -

- Is a 510(k) or PMA needed for the kit?

As a manufacturer of convenience kits, you should determine whether the sterilization of the convenience kit significantly affects the safety or effectiveness of any of the kit's components. If your sterilization process looks like it significa ntly affects the safety or effectiveness of any of the kit's medical device components, you may need to submit a premarket notification to our Office of Device Evaluation (ODE) in the Center for Devices and Radiological Health.

In making this determinatio n, we recommend that you review the interim guidance for convenience kits entitled:

> "Convenience Kits Interim Regulatory Guidance," issued by ODE. The guidance can be accessed on the Internet at http://www.fda.gov/cdrh/ode/convkit.html.

You may also need to review the procedures described in related guidance document entitled:

> "Deciding When to Submit a 510(k) for Change to an Existing Device," which may be accessed on the Internet at http://www.fda.gov/cdrh/ode/510kmod.html

Part of our premarket review of convenience kits focuses on the impact that sterilization has on individual kit components. This guidance is intended to help you address questions that can ensure that the components are not adversely affected by the reprocessing procedures and that the kit can be used for its labeled indications.

4. General Controls -

- You are required to comply with general controls, such as manuf acturing, labeling controls, and postmarket reporting of adverse events or any corrections and removals of product that present a risk to health. Because the assembly and sterilization of your convenience kit is considered a manufacturing operation subject to good manufacturing practice requirements, it is necessary for you to document that the device components are not adversely affected by further processing and that the labeling is correct. You

should be sure that expiration dates on labeling are valid. (See Title 21 Code of Federal Regulations (CFR) Part 820 for Good Manufacturing Practices (GMPs).) The agency may review those records.

Additional information regarding manufacturing regulations that apply to the sterilization of medical devices is available in the document entitled "Application of the Device Good Manufacturing Practice Regulation to the Manufacture of Sterile Devices." The document can be accessed on FDA's Internet site at: http://www.fda.gov/cdrh/ode/267.pdf. In order to receive this guidance via a fax machine, call the CDRH Facts-on-Demand (FOD) system at (800) 899-0381 or (301) 827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access the FOD option, at the second voice prompt press 2, and then enter the document number 267 followed by the pound sign. Then follow the remaining voice prompts to complete your request.

In summary, you should address the following issues related to the manufacture of your convenience kits:

1. How does your sterilization process affect the various device components in your kit?
2. What are the sterilant residuals of your sterilization process?
3. Does the labeling of the kit include validated storage instructions?
   - Is the expiration dating for the kits appropriate?
4. Is a 510(k) or PMA submission needed?
5. Do you meet the general manufacturing, labeling, and postmarket reporting requirements, i.e., adverse events and recalls (corrections and removals for devices (21 Code of Federal Regulations Parts 820, 803 and 806.))?

For questions regarding medical devices incorporated into convenience kits and their labeling requirements, please contact Wally A. Pellerite in the Center for Devices and Radiological Health, Office of Compliance at (301) 594-4692.

Drug Questions:

Contact the Center for Drug Evaluation and Research (CDER) for questions about drug products that concern labeling, new drug issues, listing and registration requirements, CGMPs, or other regulatory requirements for drugs used in convenience kits.

Prescription drugs (Rx) questions or issues should be directed to the Division of Prescription Drug Compliance and Surveillance, HFD-330 at (301) 594-0101.

Over the counter drug products questions or issues should be directed t o the Division of Labeling & Nonprescription Drug Compliance, HFD-310 at (301) 594-0063.

Current Good Manufacturing Practice (CGMP) requirement issues or questions applicable to drug products in convenience kits, should be directed to the Division of Ma nufacturing and Product Quality at (301) 594-0093.

You may also access CDER's Internet site at http://www.fda.gov/cder/directories/reference_guide.htm for information on the offices and/o r review divisions that could be contacted about the specific drug products intended for use in the sterilized kit.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radio logical Health