Sterility Issues with Medical Devices Processed at Steril Milano Facilities - Letter to Industry

June 2, 2021

Dear Medical Device Manufacturers:

The U.S. Food and Drug Administration (FDA) is aware of sterility issues with medical devices processed at the Steril Milano (http://www.sterilmilano.it/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) S.R.L. Reggiolo and Monza ethylene oxide sterilization facilities, in Italy. The FDA became aware that Steril Milano falsified graphs and parameters of sterilization certificates for a variety of FDA-regulated products, dating back to 2016.

The FDA is working with medical device manufacturers, international partners, and U.S. federal partners to investigate the scope of medical devices that may be impacted and intends to contact potentially impacted firms that are known to have contracted medical device sterilization services with these Steril Milano facilities. The FDA believes that 97 medical device manufacturers may be affected. The types of medical devices that may be affected include biopsy needles, catheters, intravascular administration sets, arthroscopes, syringes, and other medical devices. The Steril Milano S.R.L. Reggiolo and Monza ethylene oxide sterilization facilities were closed in March 2021 and are no longer sterilizing medical devices.

Several recalls are associated with the sterility concerns at the Steril Milano S.R.L. Reggiolo and Monza facilities. As of June 1, 2021, 10 firms have voluntarily recalled their affected medical devices.

At this time, the FDA is not aware of reports of patient harm associated with impacted products.

Recommendations for manufacturers:

- Determine if any of your medical devices currently in distribution were processed at the Steril Milano S.R.L. Reggiolo and Monza facilities. Possible questions to assess your inventory include:
    - Have you used Steril Milano to sterilize medical devices?
    - Have you sold products to others that were sterilized by Steril Milano?
    - Have you purchased products from other manufacturers or distributors that used Steril Milano sterilizer?

- Quarantine any existing inventory that may be affected and notify customers of any distributed medical devices.
- Evaluate the risk and develop corrective actions to address the sterility issues.
- Contact the FDA Center for Devices and Radiological Health (CDRH) at DICE@fda.hhs.gov (mailto:DICE@fda.hhs.gov), 800-638-2041, or 301-796-7100 if:
    - Your medical devices were processed at Steril Milano facilities and
    - You become aware of information related to patient safety, higher infection rates, or non-sterile products in distribution.
- Report any device-related events (/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems) involving patient injury, death, or a device malfunction.
- Proactively assess potential disruption in distributing your medical device, including the potential for shortage, and contact the FDA about a medical device supply chain issue (/medical-devices/medical-device-safety/contact-fda-about-medical-device-supply-chain-issue).
- Report a recall for medical devices to the FDA Office of Regulatory Affairs (ORA):
    - ORAdevices1recalls@fda.hhs.gov (mailto:ORAdevices1recalls@fda.hhs.gov): CT, DE, IN, KY, MA, MD, ME, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV, and the District of Columbia
    - ORAdevices2recalls@fda.hhs.gov (mailto:ORAdevices2recalls@fda.hhs.gov): AL, FL, GA, IA, IL, KS, LA, MN, MO, MS, NC, NE, PR, SC, SD, TN, WI, and U.S. Virgin Islands
    - ORAdevices3recalls@fda.hhs.gov (mailto:ORAdevices3recalls@fda.hhs.gov): AK, AR, AZ, CA, CO, HI, ID, MT, NM, NV, OK, OR, TX, UT, WA, WY

FDA Actions

The FDA issued an import alert 89-04 (https://www.accessdata.fda.gov/cms_ia/importalert_241.html) on May 24, 2021, to prevent medical devices processed at the Steril Milano S.R.L. Reggiolo and Monza facilities from entering the United States. The FDA is notifying manufacturers, companies, and health care organizations who may have used Steril Milano for medical devices or product sterilization.

The FDA is working to provide imports information to device manufacturers and health care delivery organizations to ensure they are aware of the issues and preparing to reduce patient impact if medical devices sterilized at these sterilization facilities become unavailable. In addition, the FDA continues to monitor imported products and increase screening activity for impacted firms and products.

The FDA continues to actively work with sterilization experts, medical device manufacturers, and other government agencies to advance innovative ways to sterilize medical devices while maintaining device safety and effectiveness.

The FDA appreciates your attention to this matter. If you have questions, contact the Center for Devices and Radiological Health's Division of Industry Communication and Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041, or 301-796-7100.

Sincerely,

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