

TATTOO INK STERILIZATION



Background

Tattoo ink and tattoo ink-based products may carry microorganism contaminants, increasing the risk of infection once introduced into the skin during the tattooing process. Microorganisms can be presented through a variety of sources such as raw materials or components used to manufacture the product, or the people, equipment, and environments to which the product is exposed. With numerous potential sources of contamination, the bioburden of a product can fluctuate between batches. A routine testing plan is recommended to ensure a consistent microbiological challenge is presented to the validated sterilization process.

Tattoo ink sterilization process

STERIS AST assists tattoo ink manufacturers and distributors in reducing or eliminating bioburden on finished product through radiation sterilization processing.

Radiation sterilization technologies, including [gamma](#), [electron beam](#), and [X-ray](#), are used to reduce or eliminate bioburden on tattoo ink and tattoo ink-based products, ensuring final products are free of any viable microorganisms.

If the manufacturer of the product is making a sterile claim, routine control of a sterilization process through a validation must be performed to ensure that any sterilization method used achieved the sterility assurance level.

Commonly processed tattoo products:

- Permanent tattoos
- Henna
- Black henna
- Decal temporary tattoos
- Permanent makeup

Note: Radiation sterilization can also be used as contamination control to salvage products or lots.

The importance of sterility testing

Sterility testing demonstrates whether a product is free of microorganisms and confirms the requirements for sterility of a product following exposure to a sterilization process or aseptic manufacture.

STERIS completes sterility testing to USP 71/EP 2.6.1 to evaluate the sterility of a finished product in its final packaging, ensuring consumer safety.

STERIS AST maintains cosmetic registrations as required under Section 607 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies

Web: steris-ast.com
Email: ast_info@steris.com
(EMEA-APAC) +44 330 236 8344
(Americas) 877.783.7479

