# Microbiological Methods for Testing the Sterility of Tattoo Inks

## Sterility Testing

Tattoo inks contaminated with microorganisms can cause infections and lead to serious health injuries when introduced into the skin during a tattooing procedure, since there is an increased risk of infection any time the skin barrier is broken. Manufacturer testing of the final formulated tattoo ink products to ensure the inks are free of any microorganisms can help protect consumer safety. Testing methods that can help determine whether inks are free of microorganisms include USP <71> “Sterility Tests” (the principal source used for sterility testing methods for the drug industry in the United States). Other sources of methods are European Pharmacopoeia 2.6.1 and Japanese Pharmacopoeia 4.06 (which are also used for sterility testing worldwide). For detailed information on the methods, please refer to the FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice: https:/www.fda.gov/regulatory-information/search-fda-guidance-documents/sterile-drug-products-produced-aseptic-processing-current-good-manufacturing-practice