

☒ CERTIFICATE OF CONFORMITY

Part Number	Description	Quantity	Expiry Date	Lot #
P180010TU	SOL-M 10ml Luer Lock Syringe Sterile Convenience Tray	300,000	2029-03-31	04402115

REGULATORY COMPLIANCE AND QUALITY SYSTEM

Sol-M Products comply with the regulatory requirements of the region which these are sold and manufactured.

Sol-M Products sold in the US comply with the current FDA Quality System Regulation 21 CFR 820. Medical devices are listed with FDA per 21 CFR 807. Manufacturing sites are registered with FDA per 21 CFR 807. The devices satisfy FDA pre-market notification requirements per 21 CFR 807.

Sol-M Products which are CE marked comply with Medical Devices Regulation 2017/745 and are manufactured within product facilities that comply with international standard ISO 13485: Quality Systems- Medical Devices- Requirements for regulatory purposes.

STERILITY

All products which are labeled as “sterile” and released for sale by Sol-M are certified to be sterile as long as the package is unopened and undamaged.

The product(s) indicated above were sterilized per ANSI/AAMI/ISO 11135:2014, Sterilization of health care products, Ethylene oxide: Requirements for development, validation and routine control of a sterilization process for medical devices and in compliance with FDA 21CFR 820.75 Process Validation. Each sterilization cycle is accompanied by strategically placed biological indicators (SAL 10^{-6}) that monitors the sterilization cycle effectiveness and are tested in accordance with established validation parameters.

BIOCOMPATABILITY

This product has been evaluated in accordance with ISO 10993 “Biological Evaluation of Medical Devices” and complies with all relevant sections.

PYROGENICITY

All products which are labeled as non-pyrogenic and released for sale by Sol-M have been tested per European Pharmacopeia (EP) 10th Edition, Section 5.1.10 (Guidelines for using the test for bacterial endotoxins) and meets limits as specified in Sol-M product specifications.

QUALITY CONTROL TESTING AND RELEASE

Sol-Millennium Medical, Inc. hereby certifies that the materials, processes, and procedures used to manufacture the product indicated above are in compliance with the specifications listed in the product's Device Master Record Index.

Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and signed off by qualified personnel for product release.

Inspector:	Huadong Tang	Date:	2024-04-18
Reviewer:	Felix Zhang	Date:	2024-04-18