THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 66043 **Lot #** 66043-A8706

Product Description Secure 50 mL Empty EVA Container with 2 Ports (Bulk Packed)

Date of Manufacture 2025-04-03 **Use by Date** 2028-04-03

Irradiation Date 4/25/25 **Irradiation Work Order No.** 3738543

Minimum Dose Result (kGy) 23.7 kGy **Maximum Dose Result (kGy)** 32.1 kGy

The above product has been manufactured according to *21 CFR 820 - FDA Quality System Regulations, Canadian Medical Devices Regulations Part 1- SOR 98/282, and ISO 13485 Medical Devices - Quality Management System* and complies with the relevant requirements. The product has been manufactured and assembled in accordance with internal specifications, with component traceability and lot number control in an ISO Class 8 cleanroom (*ISO 14644 Cleanrooms and associated controlled environments*).

The fluid pathway materials of this product have been tested and qualified to conform with *ISO 10993-1 Biological evaluation of medical devices* for biocompatibility test requirements. Incoming materials are inspected upon arrival to confirm compliance to specification and are assigned control numbers for traceability.

The product has been processed with Gamma Radiation to achieve a 10^{-6} sterility assurance level (SAL) in accordance with *ISO 11137 Sterilization of health care products – Radiation* according to a validated gamma irradiation procedure to yield a sterile fluid path. The certificate of processing is on file and has been reviewed to verify the minimum and maximum doses meet the validated dose range requirements. Sterilization dose audit and a determination of bioburden is completed quarterly on representative product to monitor the sterilization dose effectiveness as required by *ISO 11137 Sterilization of health care products – Radiation*.

The pyrogenicity of this product's fluid pathway has been tested for bacterial endotoxin content and meets the endotoxin criteria in accordance with established manufacturing operating procedures. The test method is in compliance with *ANSI/AAMI ST72 "Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing.* The laboratory test report is on file and has been reviewed to verify the test result is less than or equal to 20 EU/device (USP <161>).

Product testing and inspections have been completed to ensure conformity to the specifications and records are maintained on file as part of the device history record.

JH Gray
Quality Assurance

5-5-25
Date

Manufacturer of SECURE™ Products

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