METRIX

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 64040 **Lot #** 64040-E1468

Product Description McKesson 150 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-09-15 (yyyy-mm-dd) **Use by Date** 2029-09-15 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 kGy

The above product, supplied to McKesson Medical-Surgical Inc., has been manufactured according to *21 CFR 820 - FDA Quality System Regulations 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. Materials are traceable and have not changed without prior notice to McKesson Medical-Surgical Inc.

D Hoag
Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

METRIX
THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 64045 **Lot #** 64045-E1469

Product Description McKesson 250 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-09-16 (yyyy-mm-dd) **Use by Date** 2029-09-16 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 kGy

The above product, supplied to McKesson Medical-Surgical Inc., has been manufactured according to *21 CFR 820 - FDA Quality System Regulations 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. Materials are traceable and have not changed without prior notice to McKesson Medical-Surgical Inc.

CH Wang
Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

METRIX

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 64050 **Lot #** 64050-E1467

Product Description McKesson 500 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-09-11 (yyyy-mm-dd) **Use by Date** 2029-09-11 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 kGy

The above product, supplied to McKesson Medical-Surgical Inc., has been manufactured according to *21 CFR 820 - FDA Quality System Regulations 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. Materials are traceable and have not changed without prior notice to McKesson Medical-Surgical Inc.

C Hoag
Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 66040 **Lot #** 66040-E1473

Product Description Secure 100 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-09-16 (yyyy-mm-dd) **Use by Date** 2029-09-16 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 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.

Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 66050 **Lot #** 66050-E1474

Product Description Secure 500 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-09-18 (yyyy-mm-dd) **Use by Date** 2029-09-18 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 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.

Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

METRIX

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 66055 **Lot #** 66055-E1472

Product Description Secure 1000 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-09-18 (yyyy-mm-dd) **Use by Date** 2029-09-18 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 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.

D Hoag — Quality Assurance

10-30-2026 — Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 66225 **Lot #** 66225-E1444

Product Description Secure 2000 mL Empty EVA Container with Female Screw Connector

Date of Manufacture 2026-09-14 (yyyy-mm-dd) **Use by Date** 2029-09-14 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 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.

Quality Assurance C. Haag

Date (mm-dd-yyyy) 10-30-2026

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 66225 **Lot #** 66225-E1475

Product Description Secure 2000 mL Empty EVA Container with Female Screw Connector

Date of Manufacture 2026-09-22 (yyyy-mm-dd) **Use by Date** 2029-09-22 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 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.

OH Day
Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

METRIX
THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 66651 **Lot #** 66651-E1470

Product Description Secure 1000 mL Empty EVA Single Chamber Container with 5 Port Manifold

Date of Manufacture 2026-09-17 (yyyy-mm-dd) **Use by Date** 2029-09-17 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 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.

DH Morey
Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

METRIX

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 66653 **Lot #** 66653-E1471

Product Description Secure 3000 mL Empty EVA Single Chamber Container with 5 Port Manifold

Date of Manufacture 2026-09-21 (yyyy-mm-dd) **Use by Date** 2029-09-21 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 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.

Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

METRIX

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 68100 **Lot #** 68100-E1452

Product Description IMS 1000 mL Empty EVA Container with Detachable 2 Leg Transfer Set

Date of Manufacture 2026-09-15 (yyyy-mm-dd) **Use by Date** 2029-09-15 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 kGy

The above product, supplied to Integrated Medical Systems, Inc., has been manufactured according to *21 CFR 820 - FDA Quality System Regulations 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. Materials are traceable and have not changed without prior notice to Integrated Medical Systems, Inc.

Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

METRIX
THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 68102 **Lot #** 68102-E1453

Product Description IMS 500 mL Empty EVA Container with Detachable 2 Leg Transfer Set

Date of Manufacture 2026-09-21 (yyyy-mm-dd) **Use by Date** 2029-09-21 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 kGy

The above product, supplied to Integrated Medical Systems, Inc., has been manufactured according to *21 CFR 820 - FDA Quality System Regulations 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. Materials are traceable and have not changed without prior notice to Integrated Medical Systems, Inc.

Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic

METRIX

THE METRIX COMPANY

CERTIFICATE OF COMPLIANCE

Part # 68120 **Lot #** 68120-E1448

Product Description IMS 1000 mL Empty EVA Container with Detachable 3 Leg Transfer Set

Date of Manufacture 2026-09-22 (yyyy-mm-dd) **Use by Date** 2029-09-22 (yyyy-mm-dd)

Irradiation Date 2026-10-20 (yyyy-mm-dd) **Irradiation Work Order No.** 4056782

Minimum Dose Result (kGy) 24.6 kGy **Maximum Dose Result (kGy)** 32.3 kGy

The above product, supplied to Integrated Medical Systems, Inc., has been manufactured according to *21 CFR 820 - FDA Quality System Regulations 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. Materials are traceable and have not changed without prior notice to Integrated Medical Systems, Inc.

Quality Assurance

10-30-2026
Date (mm-dd-yyyy)

Manufacturer of SECURE™ Products

4400 Chavenelle Road • Dubuque, IA 52002-2655
Ph: 563-556-8800 • Fax: 563-556-4704 • www.metrixco.com
METRIX Dominicana • San Cristobal • Dominican Republic