

CERTIFICATE OF COMPLIANCE

Part # 58782

Lot # 58782-F1108

Product Description Secure 2 Leg Gravity Fill Set with Female Screw Connector

Date of Manufacture 2026-04-08

Irradiation Date 05-25-2026

Irradiation Work Order No. 3961559

Minimum Dose Result (kGy) 23.8 kGy

Maximum Dose Result (kGy) 31.9 kGy

The above product 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.

Hoag
Quality Assurance

06-03-2026
Date

Baxter Healthcare Corporation

Certificate of Compliance

Baxter Part Number: H938901

Lot Number: 63615- A8740

EVA Dual Chamber Container 1.5L

Case Quantity: 280

GTIN Carton Label: 50085412477461

Date of Manufacture: 2026-03-24

(yyyy-mm-dd)

GTIN Dust Cover Label: 00085412477466

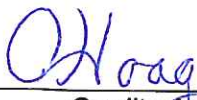
Expiration Date: 2029-03-24

(yyyy-mm-dd)

Supplier Specification: 6100-7289-33 Rev F

This is to certify that the subject item supplied to Baxter by The Metrix Company has been manufactured in accordance with the above referenced supplier specifications. Materials used in the manufacture of the subject item meet biocompatibility compliance per ISO 10993-1 Externally Communicating, Indirect Blood Contact, 30-Day. Furthermore, this product is not made with natural rubber latex or DEHP.

The subject item has been gamma sterilized to a Sterility Assurance Level of 10^{-6} . Bacterial Endotoxin Results do not exceed 20 EU per device and these results are attached.


Quality Assurance

06-03-2026
Date (mm-dd-yyyy)

Baxter Healthcare Corporation

Certificate of Compliance

Baxter Part Number:	H938905	Lot Number:	63630- <u>A8735</u>
EVA Dual Chamber Container 3L		Case Quantity:	<u>95</u>
GTIN Carton Label:	50085412477478	Date of Manufacture:	<u>2026-03-03</u>
GTIN Dust Cover Label:	00085412477473	Expiration Date:	<u>2029-03-03</u>
Supplier Specification: 6100-7288-33 Rev G			

This is to certify that the subject item supplied to Baxter by The Metrix Company has been manufactured in accordance with the above referenced supplier specifications. Materials used in the manufacture of the subject item meet biocompatibility compliance per ISO 10993-1 Externally Communicating, Indirect Blood Contact, 30-Day. Furthermore, this product is not made with natural rubber latex or DEHP.

The subject item has been gamma sterilized to a Sterility Assurance Level of 10^{-6} . Bacterial Endotoxin Results do not exceed 20 EU per device and these results are attached.

O Hoag
Quality Assurance

06-03-2026
Date

CERTIFICATE OF COMPLIANCE

Part # 64045 Lot # 64045-E1240

Product Description McKesson 250 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-03-25 Use by Date 2029-03-25
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-05-25 Irradiation Work Order No. 3961559
(yyyy-mm-dd)

Minimum Dose Result (kGy) 23.8 kGy Maximum Dose Result (kGy) 31.9 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.

Hoag
Quality Assurance

06-03-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 64050 **Lot #** 64050-E1241

Product Description McKesson 500 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-03-30 **Use by Date** 2029-03-30
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-05-25 **Irradiation Work Order No.** 3961559
(yyyy-mm-dd)

Minimum Dose Result (kGy) 23.8 kGy **Maximum Dose Result (kGy)** 31.9 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.


Quality Assurance

06-03-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 64125

Lot # 64125-E1242

Product Description McKesson 2000 mL Empty EVA Container with Detachable 3 Leg Transfer Set

Date of Manufacture 2026-03-31
(yyyy-mm-dd)

Use by Date 2029-03-31
(yyyy-mm-dd)

Irradiation Date 2026-05-25
(yyyy-mm-dd)

Irradiation Work Order No. 3961559

Minimum Dose Result (kGy) 23.8 kGy

Maximum Dose Result (kGy) 31.9 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.


Quality Assurance

06-03-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 64225

Lot # 64225-E1187

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

Date of Manufacture 2026-02-26
(yyyy-mm-dd)

Use by Date 2029-02-26
(yyyy-mm-dd)

Irradiation Date 2026-05-25
(yyyy-mm-dd)

Irradiation Work Order No. 3961559

Minimum Dose Result (kGy) 23.8 kGy

Maximum Dose Result (kGy) 31.9 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.


Quality Assurance

06-03-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 66041 Lot # 66041-E1259

Product Description Secure 100 mL Empty EVA Container with 2 Ports (Bulk Packed)

Date of Manufacture 2026-04-15 Use by Date 2029-04-15
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-05-25 Irradiation Work Order No. 3961559
(yyyy-mm-dd)

Minimum Dose Result (kGy) 23.8 kGy Maximum Dose Result (kGy) 31.9 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.

Hoag
Quality Assurance

06-03-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 66042 Lot # 66042-E1253

Product Description Secure 50 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-04-13 Use by Date 2029-04-13
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-05-25 Irradiation Work Order No. 3961559
(yyyy-mm-dd)

Minimum Dose Result (kGy) 23.8 kGy Maximum Dose Result (kGy) 31.9 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.

H. Hoag
Quality Assurance

06-03-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 66043 Lot # 66043-E1248

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

Date of Manufacture 2026-04-14 Use by Date 2029-04-14
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-05-25 Irradiation Work Order No. 3961559
(yyyy-mm-dd)

Minimum Dose Result (kGy) 23.8 kGy Maximum Dose Result (kGy) 31.9 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.

Hoag
Quality Assurance

06-03-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 66135 Lot # 66135-E1244

Product Description Secure 4000 mL Empty EVA Container with Detachable 3 Leg Transfer Set

Date of Manufacture 2026-04-07 Use by Date 2029-04-07
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-05-25 Irradiation Work Order No. 3961559
(yyyy-mm-dd)

Minimum Dose Result (kGy) 23.8 kGy Maximum Dose Result (kGy) 31.9 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

Date (mm-dd-yyyy)

06-03-2026

CERTIFICATE OF COMPLIANCE

Part # 66230 Lot # 66230-E1245

Product Description Secure 3000 mL Empty EVA Container with Female Screw Connector

Date of Manufacture 2026-04-08 Use by Date 2029-04-08
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-05-25 Irradiation Work Order No. 3961559
(yyyy-mm-dd)

Minimum Dose Result (kGy) 23.8 kGy Maximum Dose Result (kGy) 31.9 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

06-03-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE