

Baxter Healthcare Corporation

Certificate of Compliance

Baxter Part Number: H938905

Lot Number: 63630- A8745

EVA Dual Chamber Container 3L

Case Quantity: 480

GTIN Carton Label: 50085412477478

Date of Manufacture: 2026-05-26

GTIN Dust Cover Label: 00085412477473

Expiration Date: 2029-05-26

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.

C. Hoag
Quality Assurance

07-15-2026
Date

CERTIFICATE OF COMPLIANCE

Part # 64210 Lot # 64210-E1315

Product Description McKesson 500 mL Empty EVA Container with Female Screw Connector

Date of Manufacture 2026-05-25 Use by Date 2029-05-25
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-07-06 Irradiation Work Order No. 3995387
(yyyy-mm-dd)

Minimum Dose Result (kGy) 24.4 kGy Maximum Dose Result (kGy) 32.2 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.

Chao
Quality Assurance

07-15-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 64215

Lot # 64215-E1316

Product Description McKesson 1000 mL Empty EVA Container with Female Screw Connector

Date of Manufacture 2026-05-25
(yyyy-mm-dd)

Use by Date 2029-05-25
(yyyy-mm-dd)

Irradiation Date 2026-07-06
(yyyy-mm-dd)

Irradiation Work Order No. 3995387

Minimum Dose Result (kGy) 24.4 kGy

Maximum Dose Result (kGy) 32.2 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

07-15-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 66040 Lot # 66040-E1317

Product Description Secure 100 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-06-01 Use by Date 2029-06-01
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-07-06 Irradiation Work Order No. 3995387
(yyyy-mm-dd)

Minimum Dose Result (kGy) 24.4 kGy Maximum Dose Result (kGy) 32.2 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)



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CERTIFICATE OF COMPLIANCE

Part # 66043 Lot # 66043-E1318

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

Date of Manufacture 2026-06-02 Use by Date 2029-06-02
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-07-06 Irradiation Work Order No. 3995387
(yyyy-mm-dd)

Minimum Dose Result (kGy) 24.4 kGy Maximum Dose Result (kGy) 32.2 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. Hoag

Date (mm-dd-yyyy)

07-15-26

CERTIFICATE OF COMPLIANCE

Part # 66045 Lot # 66045-E1319

Product Description Secure 250 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-06-02 Use by Date 2029-06-02
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-07-06 Irradiation Work Order No. 3995387
(yyyy-mm-dd)

Minimum Dose Result (kGy) 24.4 kGy Maximum Dose Result (kGy) 32.2 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.

Q Hoag
Quality Assurance

07-15-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 66050 Lot # 66050-E1320

Product Description Secure 500 mL Empty EVA Container with 2 Ports

Date of Manufacture 2026-06-08 Use by Date 2029-06-08
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-07-06 Irradiation Work Order No. 3995387
(yyyy-mm-dd)

Minimum Dose Result (kGy) 24.4 kGy Maximum Dose Result (kGy) 32.2 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

07-15-2026
Date (mm-dd-yyyy)

CERTIFICATE OF COMPLIANCE

Part # 66225 Lot # 66225-E1321

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

Date of Manufacture 2026-05-29 Use by Date 2029-05-29
(yyyy-mm-dd) (yyyy-mm-dd)

Irradiation Date 2026-07-06 Irradiation Work Order No. 3995387
(yyyy-mm-dd)

Minimum Dose Result (kGy) 24.4 kGy Maximum Dose Result (kGy) 32.2 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)