30-5510 DEROYAL- ISOLATION BAG
PRODUCT LABELING STATES NON-STERILE, MAY CAUSE CONCERN, RISK NONE, PRODUCT WAS STERILIZED BY ETHYLENE OXIDE

July 12, 2016

GMDN Terms- Global Medical Device Nomenclature

Descriptor- Intraoperative Procedure Bag, GMDN: 33522

Product Identifier: DeRoyal Isolation Bag

Geographic Regions: Saudi Arabia

Manufacturer(s): DeRoyal, 200 DeBusk Lane, Powell, Tennessee, 37849, United States

Suggested Distribution: OR/Surgery, Materials Management

Problem:

The issue reported and confirmed is that the product labeling for this lot states the product lot is STERILE, however there is also a statement on the product labeling which states "Non-sterile". This lot affected was manufactured on production work order 14097259. The product is mislabeled, the error is that the product labeling states "Non-sterile". Upon investigation of this report, we have confirmed that this product, Isolation Bag 30-5510, is required to be sterilized with ethylene oxide gas during the operational processes at DeRoyal prior to release. The Isolation Bag product lot 14097259 was sterilized on a validated sterilization cycle. The sterile batch was reviewed and found to be processed within chamber validation parameters for the ethylene oxide cycle. This product lot is STERILE, there is no risk to the patient.

Action Needed

(1) Use DeRoyal product in accordance with recommended healthcare protocol
(2) In cause of visible damage to pouch or package, do not use. If product pouch packaging has no opening or tear, the product is sterile.
(3) The labeling statement "Non-sterile" could cause concern to the end user, however the product was sterilized and is guaranteed sterile unless open or damaged.
(4) Product labeling is incorrect and misleading, however product lot is sterile.

For Further Information: DeRoyal, 200 DeBusk Lane, Powell, Tennessee, 37849, United States

Comments

The labeling statement "Non-sterile" could cause concern to end user even though product lot also states STERILE. Product labeling is incorrect and misleading to the end user. The incorrect label may cause user to discard product and not use due to statement that product is non-sterile. There is no risk to patient, as product lot was sterilized and remains sterile as long as package is not damaged. Our Regulatory personnel have been in contact with the United States Food and Drug Administration, (FDA). Based on communication received, the product in commercial distribution does not pose a risk to patient health or potential for injury. The product lot does not pose risk, product lot relative to this report was confirmed to be STERILE. The Isolation Bag product lot 14097259 was sterilized on a validated sterilization cycle. The sterile batch was reviewed and found to be processed within chamber validation parameters for the ethylene oxide cycle. This product lot is STERILE, there is no risk to the patient.

30-5510 DEROYAL- ISOLATION BAG
PRODUCT LABELING STATES NON-STERILE, MAY CAUSE CONCERN, RISK NONE, PRODUCT WAS STERILIZED BY ETHYLENE OXIDE

July 12, 2016

GMDN Terms- Global Medical Device Nomenclature

Descriptor- Intraoperative Procedure Bag, GMDN: 33522

Product Identifier: DeRoyal Isolation Bag

Geographic Regions: Saudi Arabia

Manufacturer(s): DeRoyal, 200 DeBusk Lane, Powell, Tennessee, 37849, United States

Suggested Distribution: OR/Surgery, Materials Management

Problem:

The issue reported and confirmed is that the product labeling for this lot states the product lot is STERILE, however there is also a statement on the product labeling which states "Non-sterile". This lot affected was manufactured on production work order 14097259. The product is mislabeled, the error is that the product labeling states "Non-sterile". Upon investigation of this report, we have confirmed that this product, Isolation Bag 30-5510, is required to be sterilized with ethylene oxide gas during the operational processes at DeRoyal prior to release. The Isolation Bag product lot 14097259 was sterilized on a validated sterilization cycle. The sterile batch was reviewed and found to be processed within chamber validation parameters for the ethylene oxide cycle. This product lot is STERILE, there is no risk to the patient.

Action Needed

(1) Use DeRoyal product in accordance with recommended healthcare protocol
(2) In cause of visible damage to pouch or package, do not use. If product pouch packaging has no opening or tear, the product is sterile.
(3) The labeling statement "Non-sterile" could cause concern to the end user, however the product was sterilized and is guaranteed sterile unless open or damaged.
(4) Product labeling is incorrect and misleading, however product lot is sterile.

For Further Information: DeRoyal, 200 DeBusk Lane, Powell, Tennessee, 37849, United States

Comments

The labeling statement "Non-sterile" could cause concern to end user even though product lot also states STERILE. Product labeling is incorrect and misleading to the end user. The incorrect label may cause user to discard product and not use due to statement that product is non-sterile. There is no risk to patient, as product lot was sterilized and remains sterile as long as package is not damaged. Our Regulatory personnel have been in contact with the United States Food and Drug Administration, (FDA). Based on communication received, the product in commercial distribution does not pose a risk to patient health or potential for injury. The product lot does not pose risk, product lot relative to this report was confirmed to be STERILE. The Isolation Bag product lot 14097259 was sterilized on a validated sterilization cycle. The sterile batch was reviewed and found to be processed within chamber validation parameters for the ethylene oxide cycle. This product lot is STERILE, there is no risk to the patient.

7/12/2016