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Medical Grade Polyethylene (PE)



Description

Any step of the manufacturing process can introduce contamination, which can affect the purity of the product. The Newform Medical Grade Bag provides an ultraclean way to package medical devices, pharmaceutical ingredients and other devices for sterilization. These bags are composed of a pure, pinhole-free, medical grade polyethylene film produced by ATMI LifeScience.

Product Design

- Standard thickness : 100 µm
- Other thicknesses available upon request
- Available in various shapes: tubing, centerfold, sheets, bags and other specialties upon request
- Standard cleanliness level 50

Applications

- Intravenous solutions
- Filters
- Active pharmaceutical ingredients
- Sensitive medical devices
- Medical components

Wir verweisen auf die technischen Datenblätter des Herstellers
Erstelldatum 11/03

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Specifications

- Cleanliness levels available from level 50 to visible clean (according to IEST-STD-CC1246D) for bag interiors and exteriors
- Sterilizable by gamma irradiation (25 kGray).
- Pinhole-free medical grade PE film extruded in a controlled environment. Bag is produced in a Cleanroom ISO Class 5 environment
- Multi-layered, puncture resistant PE

Benefits

- DMF-file registered with FDA
- Conforms to European and U.S. Pharmacopoeia
- Free of ionic and organic contaminants
- PE film is free of black points and gel
- No outgassing
- Certificate of sterilization delivered with every shipment
- Higher performance over paper and nonclean Tyvek® which can lead to particle and molecular contamination
- Gamma sterilizable

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