



Released

**Specification TY8E16P - Newform
Cleansteam Bag (Printed)**

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1. Product Description

1.1. General

This specification document applies to Newform™ Cleansteam™ bags with a printed steam indicator.

1.2. Shelf life

The shelf life of the product is limited to 1 year after manufacturing date. Unused bags should be stored in the closed package as received from Pall Life Sciences at 10-40°C, RH < 70%.

1.3. Sterility

Cleansteam™ bags can be subjected to steam sterilization. Steam sterilization processing temperatures should not exceed 124°C. A steam indicator is printed on the bag.

1.4. Dimensions

Description	Value
Inner width of the bag	xxx ± 10 mm
Inner length of the bag	xxx ± 10 mm
Thickness Tyvek film ¹	185 µm
Thickness HDPE film	80 ± 10 µm

2. Production process

2.1. General

Manufacturing and assembly of Cleansteam™ bags is performed under ISO Class 5 at rest cleanroom conditions (ISO 14644-1). The extrusion of the HDPE film is done in an ISO Class 8 environment (ISO 14644-1).

2.2. Process Steps

Step 1: Blow extrusion of HDPE film

Step 2: Winding of HDPE film


Step 3: Printing of Tyvek

Step 4: Unwinding of HDPE and Tyvek, followed by automatic cutting and sealing of the bags

Step 5: Packaging of finished bags

Step 6: Labelling of packaged bags

¹ Typical value

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2.3. In Process Controls

Test	Method	Frequency
Dimensions	Internal	Per batch
Visual control	Internal	100%
Sealing strength	ASTM-F88	Per batch
Seal integrity test	Internal	Per batch
Cleanliness	IEST-STD-CC1246D	Per batch

Visual control

No disconformities which affect the functionality or quality of the bag.

Seal strength

The seal strength of the film/film weld is tested according to ASTM-F88.

Seal strength film/film: ≥ 20 N/15mm

Seal integrity test

No leaks detected with seal pinhole test.

Cleanliness

Cleanliness level 200 according to IEST-STD-CC1246D


3. Compliances

HDPE layer

- The film complies with the requirements of the US Pharmacopoeia USP <87>, USP <88> (Class VI) and USP <661>.
- The film complies with the requirements of the European Pharmacopoeia 3.1.5 section "tests"
- The resin complies with the requirements for use in contact with food of FDA regulation 21 CFR 177.1520 (c) 3.2 a
- The resin complies with the compositional requirements for use in contact with food of Commission Regulation (EU) No 10/2011.
- The material is considered safe to use in respect with BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) transmissions (EMEA 410/01 rev. 3 July 2011).

Tyvek layer

- The film complies with the requirements of US Pharmacopoeia USP <87> and USP <88> (USP Class VI).
- The film complies with the requirements of the European Pharmacopoeia 3.1.5.
- The resin complies with the requirements for use in contact with food of FDA regulation 21 CFR 177.1520.
- The resin complies with the compositional requirements for use in contact with food of Commission Regulation (EU) No 10/2011.
- The material is Animal Derived Component Free (ADCF).

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4. Packaging & Labeling

Finished Cleansteam™ bags are double packed into sealed bags under cleanroom conditions. Each pack is labelled as follows:

- Customer name
- Product type(=item number)
- Product reference (= customer item number) (If applicable)
- Description
- Quantity
- Batch number
- Package number
- Manufacturing date
- Expiry date
- Warning statements

Packs are packed into cardboard boxes. Each box is labelled as follows:

- Customer name
- Order number
- Product type(=item number)
- Product reference (= customer item number) (If applicable)
- Description
- Quantity
- Batch number
- Package number
- Manufacturing date
- Expiry date

5. Traceability

There is traceability of raw materials for each lot. There is traceability of the product through Pall Life Sciences processes.

6. Certificates

A certificate of conformity (COC) is supplied with each shipment stating that the requirements of this specification have been met.