





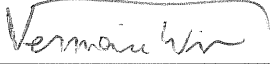
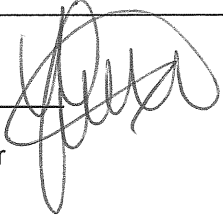


SPECIFICATION

Visible clean Low Density
Polyethylene Bags

Code: VERSP LD1B10

Revision:07

Date: 19 MAR 2012

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 ATMI <small>Advanced Technology Medical Inc.</small>	SPECIFICATION	
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1. Product Description

1.1. General

This specification document applies to Visible clean Low Density Polyethylene Bags.

1.2. Shelf life


The shelf life of the product is limited to 3 years after manufacturing date. Unused bags should be stored in the closed package as received from ATMI at 10-40°C, RH< 70%.

1.3. Sterility

NA


1.4. Dimensions

DESCRIPTION	DIMENSION	TOLERANCE
Inner width of the bag	xxx mm	± 10 mm
Inner length of the bag	xxx mm	± 10 mm
Thickness	xxx µm	If film ≥ 100 µm: ± 10 % If film < 100 µm: ± 10 µm

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2. Compliances

- The resin complies with the requirements for use in contact with food of:
 - FDA regulation 21 CFR 177.1520 (c) 2.1 and (c) 2.2
 - Commission Regulation No10/2011
- 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)

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3. Production process

3.1. General

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

3.2. Process Steps

Step 1: Blow extrusion of LDPE film

Step 2: Unwinding, followed by automatic cutting and sealing of the bags

Step 3: Packaging of Visible Clean Bags

Step 4: Labeling of packaged Visible Clean Bags

3.3. In Process Controls

Tests	Method	Frequency (order ≤ 6000 pcs.)	Frequency (order > 6000 pcs.)
Dimension	ATMI	Begin, middle, end	Begin, 1/1000, end
Visual control	ATMI	Begin, middle, end	Begin, 1/1000, end
Sealing strength	ASTM-F88	Begin, middle, end	Begin, 1/1000, end
Seal integrity	ATMI	Begin, middle, end	Begin, 1/1000, end

Visual control


- Visual inspection: no disconformities which affect the functionality or quality of the bag.

Seal strength:

- Seal strength: film/film: ≥ 10N/15 mm (for a 50 µm thick film)
film/film: ≥ 15N/15 mm (for a 60-125 µm thick film)
film/film: ≥ 20N/15 mm (for a 150-175 µm thick film)

Seal integrity:

- No leaks detected with seal pinhole test

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4. Packaging & Labeling

Finished Visible clean Low Density Polyethylene Bags are double packed into sealed bags under cleanroom conditions. Each pack is labelled as follows:

- Customer name
- Product type(=ATMI 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 cardboard box is labelled as follows:

- Customer name
- Order number
- Product type(=ATMI 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 ATMI processes.

6. Certificates

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