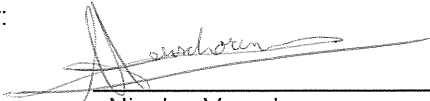


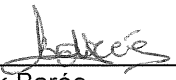
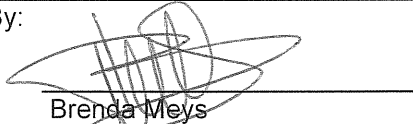
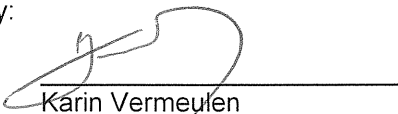
 ATMI	SPECIFICATION	
	Ultraclean bags, TY8	Code: VERSP TY8E16
		Revision: 05
		Date: 11 Oct 2011

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1. Product Description

1.1. General

This specification document applies to ultraclean Tyvek/HDPE (TY8) bags with a transparent seal.

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

The product can be subjected to steam sterilization. Steam sterilization processing temperatures for HDPE film should not exceed 124 °C.

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 Tyvek	185 µm	-96 µm, +97 µm
Thickness HDPE	80 µm	± 10 µm

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2. Compliances

HDPE:

- The film complies with the requirements of the US Pharmacopoeia USP <87>, <88> (USP Class VI test) and <661>
- 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)
 - EU Commission Directive 2002/72/EC
- The material is considered safe to use in respect with BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) transmissions (EMA 410/01 rev.3 July 2011)

Tyvek:

- The film complies with the requirements of US Pharmacopoeia USP <87>, <88> (USP Class VI test)
- 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)
 - EU Commission Directive 2002/72/EC
- The material is Animal Derived Component Free (ADCF)

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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). Extrusion of the HDPE film is done in an ISO Class 8 environment (ISO 14644-1).

3.2. Process Steps

- Step 1:** Blow extrusion of HDPE film
- Step 2:** Winding of the HDPE film
- Step 3:** Unwinding of HDPE and Tyvek, followed by automatic cutting and sealing of the bags
- Step 4:** Packaging of bags
- Step 5:** Labeling of 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, 1/3500, end

Tests	Method	Frequency (order ≤ 12000 pcs.)	Frequency (order > 12000 pcs.)
Cleanliness	ATMI	Begin, middle, end	Begin, 1/4000, end

Visual control

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

Seal strength:


- Seal strength: ≥ 20N/15 mm

Seal integrity

- No leaks detected with seal pinhole test

Cleanliness:

- Cleanliness level 200 according to IEST-STD-CC1246D

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4. Packaging & Labeling

Finished 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
- 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.