

See-through packaging made of DuPont™ Tyvek® and film VP code/quality: TYO-3/PE62-4



1. Product description

Sterile barrier system for medical disposables and reprocessed medical devices.

2. Sterilisation suitability

VH202 (plasma)-, EO-, Form- and IRRAD (radiation sterilization)

3. Normative requirements

- Tyvek® is FDA listed and complies with DIN EN 868 Part 9 Section 4.1, 4.2 and 4.3
- The film complies with DIN EN ISO 11607 Part 1 and DIN EN 868 Part 5 Section 4.2.2.1 to 4.2.2.5.
- The packaging material complies with DIN EN ISO 11607 Part 1 and Part 2.
- The biocompatibility and toxicological properties were tested and evaluated for cytotoxicity according to ISO 10993 Part 5.
- Microbial barrier for moisture and when dry according to DIN 58953 Part 6.
- The process indicators comply with DIN EN ISO 11140 Part 1.

Any standards is applicable in its current version.

4. Statutory requirements

Our see-through pouches and see-through reels are accessories to medical device and as such medical devices of class I “non-sterile”. This classification is according to annex VIII, rule 1 of the Medical Device Regulation (EU) 2017/745.

As an indication of compliance with the regulation the label of the shipping carton carries the CE marking.

In addition, our products comply with the following regulations and directives:

- Regulation (EU) No. 10/2011
 - Regulation (EC) 1935/2004
 - Regulation (EC) No. 1907/2006
 - Directive 2011/65/EU Art. 4 and Annex II
 - Directive 94/62/EC
- The sums of the concentrations of lead, cadmium, mercury and hexavalent chromium (Cr VI) are below 100 ppm.

5. Substances

Our products do not contain natural latex, PVC, Bisphenol A, Colophony, TSE/BSE risk materials, SVHC/CP65-Substances and Phthalates as part of the formulations.

6. Product properties

Tyvek® 1073B

Tyvek® is physiological harmless and free of foreign substances.

Inspection characteristic	Typical value	Unit	Standards
Grammage	75	g/m ²	ASTM D3776
Tensile strength MD	205	N	DIN EN ISO 1924-2
Tensile strength CD	219	N	DIN EN ISO 1924-2
Tear strength MD	3,2	N	ASTM D1424
Tear strength CD	4,0	N	ASTM D1424
Air porosity Bendtsen	540	ml/min.	ISO 5636-3

Film

The PET-O/PE 12/50 film is transparent, physiological harmless and heat-sealable against Tyvek®.

Inspection characteristic	Typical value	Unit	Standards
Configuration	12/50 PET-O/PE		
Thickness	64	µm	DIN 53370
Tear strength MD	>35	N/15mm	ASTM D882
Tear strength CD	>40	N/15mm	ASTM D882
Elongation at breakage MD	>80	%	ASTM D882
Elongation at breakage CD	>80	%	ASTM D882

7. Seal seam design

The seal seam allows the sterile barrier system to be easily opened. The seal seam consists of three parallel seal lines (grooved seal seam).

The minimum width of the seal(s) is 6 mm. In grooved seals the sum of the rib width of ribs is minimum 6 mm.

The minimum value of the seal strength in the sterilisation process is >1,2 N je 15 mm.

8. Peel direction



The correct peel direction is printed on the see-through pouch or see-through reel to ensure its safe, fibre-free opening.

9. Identification

See-through pouch

Carton label

steriCLIN®		REF	
UDI		Beschreibung: Description: Description: Description:	
Box No.		Production	
Production		Expiry date	
Expiry date		LOT-No.	

Control document for pouches without secondary packaging.

Kontrollzettel Quality control Fiche de Contrôle
Auftrags-Nr. Order No. No. de Commande
Liefern-Nr. Carton No. No. de Carton
Datum Date 08.05.2015
Kontroll-Nr. Controlled by No. de Contrôle

Printed on the secondary packaging

REF 220106	15x5x28 cm	LOT 3018217	2015-03	2020-03	100 St./pcs	995	000705
LOT-No.	Production	Expiry date	Package No.	Personnel No.			

Control document for see-through reels

Kontrollzettel Quality control Fiche de Contrôle	
Auftrags-Nr. Order No.	
Rollen-Nr. Reel No. No. de Carton	Herstellung
	Halbzeit
Kontroll-Nr. Controlled by No. de Contrôle	

10. Disposal

The sterile barrier systems are composites or mixed packaging (waste codes 15 01 05 and 15 01 06) and must be disposed of in the non-recyclable waste.

11. Assortment

See-through pouches Tyvek®/film

<https://www.stericlin.de>

See-through reels Tyvek®/film – length: 100 m

<https://www.stericlin.de>

12. Field of application

This Technical Data Sheet refers to the above-mentioned product group/quality and applies until the next revised edition. Other product-related documents are available on request if required.

13. Additional information

The information contained in this Technical Data Sheet (TDS) is based on our current knowledge and experience.

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