Technical Data Sheet

See-through pouches “White Line”
VP code/quality: WL90-1/PP50-3

1. Product description

See-through pouches “White Line” are made of a combination of transparent film laminate and porous polypropylene based material. They were specially designed for heavy and bulky medical devices that require special protection.

See-through pouches “White Line” provide excellent peeling properties and fibre free peelability. They have huge mechanical strengths, high air permeability and tremendous barrier performance.

Application

See-through pouches “White Line” are used flexibly for the packaging of single use and reusable medical devices, such asKits, trays, surgical packs, heavy and pulky devices.

2. Sterilisation suitability

Steam sterilization at 121°C and 134°C
Ethylene oxide, formaldehyde and low-temperature oxidative process sterilization.

Indicator change

STEAM:	pink to brown
EO:	light blue to yellow
FORM:	purple to green
VH²O²/Plasma	purple to pink

3. Normative requirements

- The polypropylene based material complies with DIN EN ISO 11607 - 1.
- The film complies with DIN EN ISO 11607 - 1 and DIN EN 868 – 5, Section 4.2.2.1 to 4.2.2.5.
- The packaging material complies with DIN EN ISO 11607 - 1.
- Microbial barrier for moisture and when dry according to DIN 58953 - 6.
- The process indicators comply with DIN EN ISO 11140 - 1.

4. Statutory requirements

Our see-through pouches are accessories to medical device and as such medical devices of class I “non-sterile”. This classification is according to annex IX, rule 1 of the directive 93/42/EEC “Medical Device Directive” and amendment 2007/47/EG.

As an indication of compliance with the directive 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 product does not contain natural latex, PVC, Bisphenol A, Colophony, TSE/BSE risk materials, SVHC Substances and Phthalates as part of the formulations.

6. Product properties

Polypropylen based material

The white polypropylene based material is physiological harmless and free of foreign substances.

The specially treated surface enables a firm seal against the film.

Inspection characteristic	Typical value	Unit	Standards
Grammage	**90**	g/m²	EN ISO 536
Tensile strength MD dry	**2.6**	kN/m	EN ISO 1924-2
Tensile strength CD dry	**2.3**	kN/m	EN ISO 1924-2
Burst strength dry	**650**	kPa	EN ISO 2758
Tear strength MD	**7600**	mN	EN ISO 1974
Tear strength CD	**7900**	mN	EN ISO 1974
Air porosity Bendtsen	**1000**	ml/min.	ISO 5636-3

Film

The 12/40 PET/PP peel film is transparent, physiological harmless and heat-sealable against polypropylene based material.

Inspection characteristic	Typical value	Unit	Standards
Configuration	**12/40 PET/PP peel**		
Thickness	**52**	µm	DIN 53370
Grammage	**52**	g/m²	Internal
Tear strength CD	**≥ 20**	N/15mm	ASTM-D 882
Taer strength MD	**≥ 20**	N/15mm	ASTM-D 882

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 is 6 mm minimum.

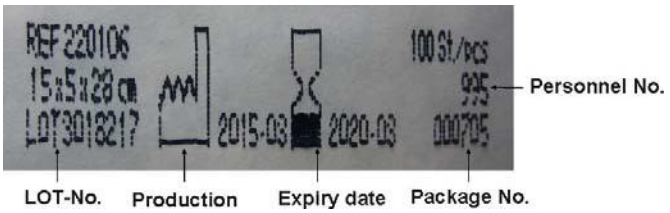
The minimum seal strength in a sterilisation process with STEAM is 1,5 N/15 mm and in other sterilisation processes used in healthcare 1,2 N/15 mm.

8. Identification

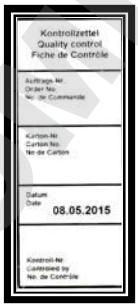
See-through pouches "White Line"

Carton label

Printed on the secondary packaging



Control document for pouches without secondary packaging



9. Disposal

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

10. Assortment

See-through pouches “White Line” are made exclusively in customer order.

11. 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.

12. Additional information

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

VP does not guarantee and makes no representation as to the accuracy or completeness of the information contained herein.

VP also assumes no responsibility regarding the consequences arising from the use of information or with regard to any misprints.

The user is responsible for thoroughly checking our products for their suitability for the specific application requirements of the user as well as to their suitability for the respective conditions to which the product is exposed.

The user also has the responsibility for the proper, safe and lawful use, processing and handling of our products, especially when recommendations for safe use and storage have been given. Under no circumstances shall the information contained herein be construed as representation, warranty or guarantee.