Technical Data Sheet

See-through packaging made of non-woven and film
VP code/quality: MM60-11/PP50-1



1. Product description

Sterile barrier system for medical disposables and reprocessed medical devices.

2. Sterilisation suitability

Steam, ethylene oxide and formaldehyde sterilisation

- Indicator change

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

3. Normative requirements

- The non woven complies with DIN EN ISO 11607 Part 1.
- 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 applicate 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

Non woven

The blue non woven is physiological harmless, free of foreign substances, and referred to as **elemental chlorine-free (ECF)**.

Inspection characteristic	Typical value	Unit	Standards
Grammage	**56**	g/m²	DIN EN ISO 536
Tensile strength MD dry	**55**	N/15 mm	DIN EN ISO 1924-2
Tensile strength CD dry	**35**	N/15 mm	DIN EN ISO 1924-2
Tensile strength MD wet	**25**	N/15 mm	DIN ISO 3781
Tensile strength CD wet	**15**	N/15 mm	DIN ISO 3781
Burst strength dry	**200**	kPa	DIN EN ISO 2758
Burst strength wet	**100**	kPa	DIN ISO 3689
Tear strength MD	**800**	mN	DIN EN 1974
Tear strength CD	**900**	mN	DIN EN 1974
Air porosity Bendtsen	**1600**	ml/min.	ISO 5636-3
Water resistance	**26**	sec.	DIN EN 868-3
pH value	**6,5**		ISO 6588-2
Chloride content	**< 0,05**	%	ISO 9197
Sulphate content	**< 0,25**	%	ISO 9198
Pore size	**12**	µm	DIN EN 868-3

Film

The 12/40 PET/PP film is blue, physiological harmless and heat-sealable against non woven.

Inspection characteristic	Typical value	Unit	Standards
Configuration	**12/40 PET/PP**		
Thickness	**54**	µm	DIN 53370
Grammage	**54**	g/m²	Internal
Tear strength CD	**> 35**	N/15mm	ASTM-D 882
Taer strength MD	**> 30**	N/15mm	ASTM-D 882
Elongation at breakage CD	**> 70**	%	ASTM-D 882
Elongation at breakage MD	**> 80**	%	ASTM-D 882

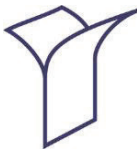
7. Seal seam design

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 of ribs is minimum 6 mm.

The minimum value of the seal strength in the sterilisation process with STEAM is 1.5 N per 15 mm, and with other sterilisation processes used in healthcare 1.2 N per 15 mm.

8. Peel direction

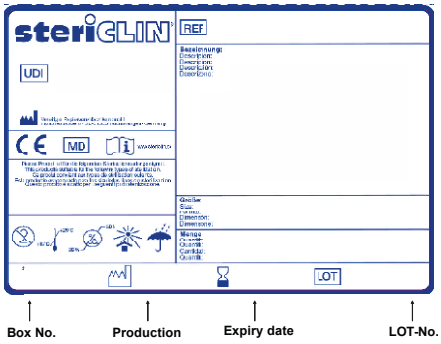


The correct peel direction is printed on the see-through pouch or see-through reel to ensure its safe, fibre-free opening.

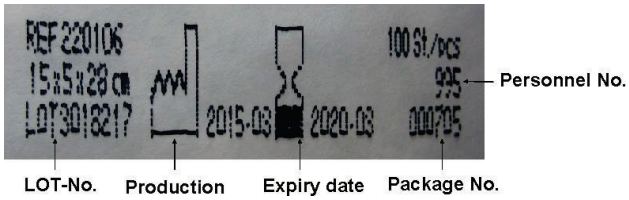
9. Identification

See-through pouch

Carton label



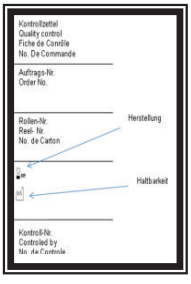
Printed on the secondary packaging



Control document for pouches without secondary packaging.



Control document for see-through reels



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 packaging made of non-woven and film (pouches/reels)

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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