Technical Data Sheet

Wrapping material non-woven 59g
VP code/quality: 350_01
Colour: blue



1. Product description

Packaging material for medical products.

2. Sterilisation suitability

Steam, ethylene oxide, formaldehyde and gamma sterilisation

3. Normative requirements

- The packaging material complies with DIN EN ISO 11607 Part 1 and DIN EN 868 Part 2 Section 4.2.1 and 4.2.2.3.
- 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.

Any standards is applicate in its current version.

4. Statutory requirements

Our wrapping material 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 (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/CP65-Substances and Phthalates as part of the formulations.

6. Product properties

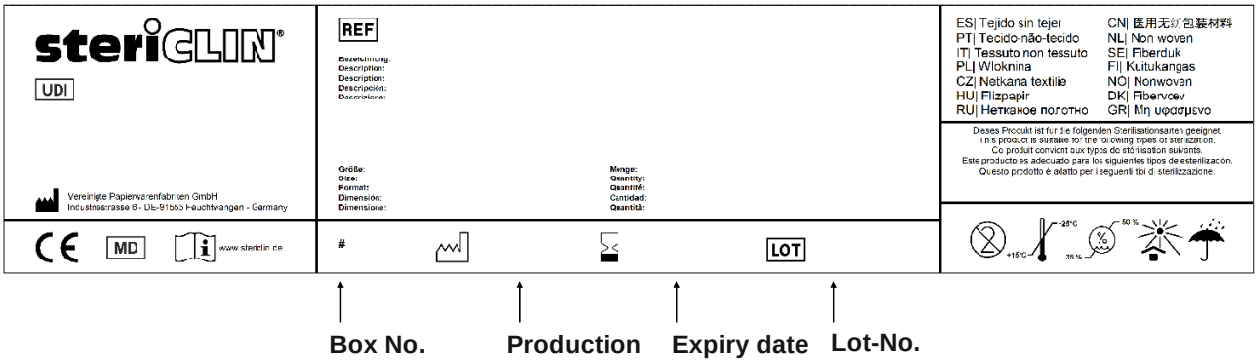
Wrapping material non-woven

The non-woven material is physiological harmless and free of foreign substances. The mass fraction of the non-woven material in chloride, expressed as sodium chloride is far below the required standard DIN EN 868 Part 2 Point 4.2.1.4.

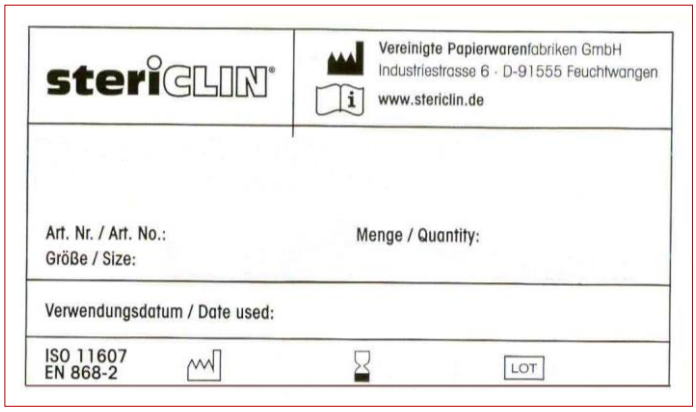
Inspection characteristic	Typical value	Unit	Standards
Grammage	**59**	g/m²	DIN EN ISO 536
Tensile strength MD dry	**1,67**	kN/m	DIN EN ISO 1924 T2
Tensile strength CD dry	**1,31**	kN/m	DIN EN ISO 1924 T2
Tensile strength MD wet	**1,15**	kN/m	DIN ISO 3781
Tensile strength CD wet	**0,93**	kN/m	DIN ISO 3781
Elongation at breakage MD	**11**	%	DIN EN ISO 1924 T2
Elongation at breakage CD	**10**	%	DIN EN ISO 1924 T2
Burst strength dry	**260**	kPa	DIN EN ISO 2758
Burst strength wet	**min. 90**	kPa	DIN EN ISO 3689

7. Identification

Carton label, outside



Carton label, inside



8. Disposal

The sterile barrier systems consist of cellulose and polyester fibres.
The sterile barrier systems have to be disposed of as non-recyclable waste (waste code 15 01 06).

9. Assortment

Wrapping material non-woven blue
https://www.stericlin.de

10. 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.

11. 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.