



PAUL HARTMANN AG
89522 Heidenheim
Germany

Visit our Website:
www.hartmann.info



Safety is our strength
Single-use surgical products according to
European Standard EN 13795

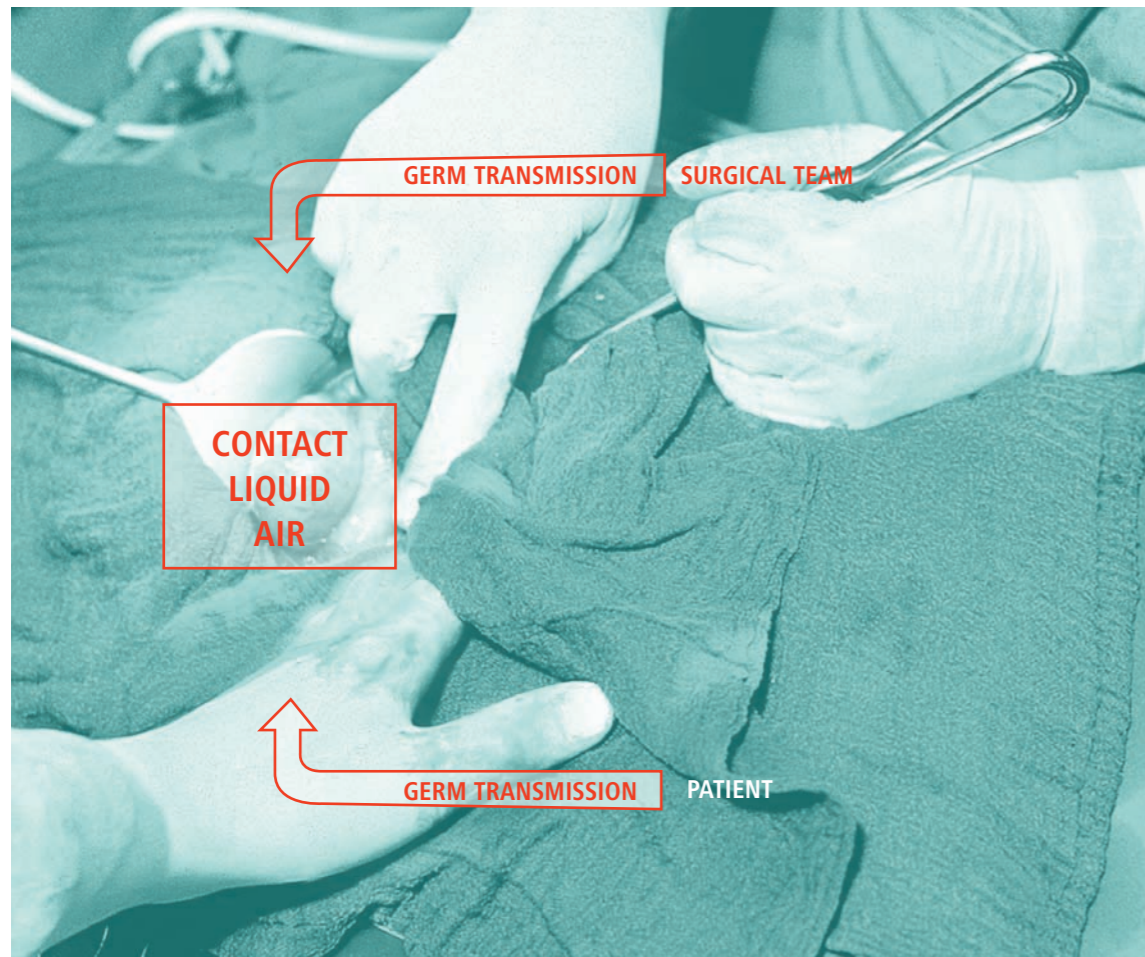


P 284 (05/06) 086 467/3

Risks arising during a surgical procedure

The natural germ barrier of our skin is damaged by surgical, invasive procedures. As a result, infections may occur.

Routes of germ transmission



Hazards caused by germ transmission

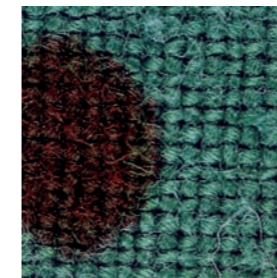
(according to the Robert Koch Institute)

- A post-operative wound infection leads to a prolongation of hospitalisation by six days on average.¹
- The mortality rate of patients having undergone surgery doubles, if a hospital infection develops.

¹ Geffers C et al.: Gesundheitsberichterstattung des Bundes: Nosokomiale Infektionen Robert- Koch-Institut, Heft 8, Berlin 2002.

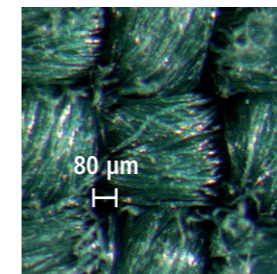
Risks caused by reusable materials made of cotton

Only effective barrier materials impermeable to liquids contribute significantly to a reduction of post-operative wound infections. Scientific studies have shown that reusable materials of cotton or mixtures of cotton and polyester without any specific equipment do not constitute a safe germ barrier.¹



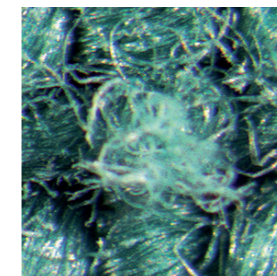
Wick effect

- Cotton fibres absorb liquids.
- Several layers on top of each other may even intensify the capillary effect.



Large pore size

- The pore size of cotton fabric amounts to at least 80 micrometers.
- The size of bacteria, however, is about 1 micrometer.
- Even multi-layer draping do not offer a safe resistance to microbial penetration, in particular in wet conditions.



Fiber ruptures

- Multiple reprocessing may lead to fiber rupture.
- They increase particle release.

Not visible, but obvious

Results of a study carried out in England, Wales and France.²

- More than fifty percent of the products reprocessed failed during the visual inspection at the light table as holes in the barrier material were found.
- In the critical area, most of the reprocessed materials were permeable to liquids already when subjected to a short-time wetting or the pressure values were below a water column of 50 cm.
- More than seventy percent of the surgical drapes reprocessed did not pass the microbial penetration test "wet" in the critical area.

¹ Moylan JA, Fitzpatrick KT, Davenport KE. Reducing wound infections. Improved gown and drape barrier performance. Arch Surg. 1987 Feb; 122 (2): 152-7.

² Werner HP et al.: Quality of Surgical Drapes and Gowns. HygMed. 2001; 26 (3): 62-75.

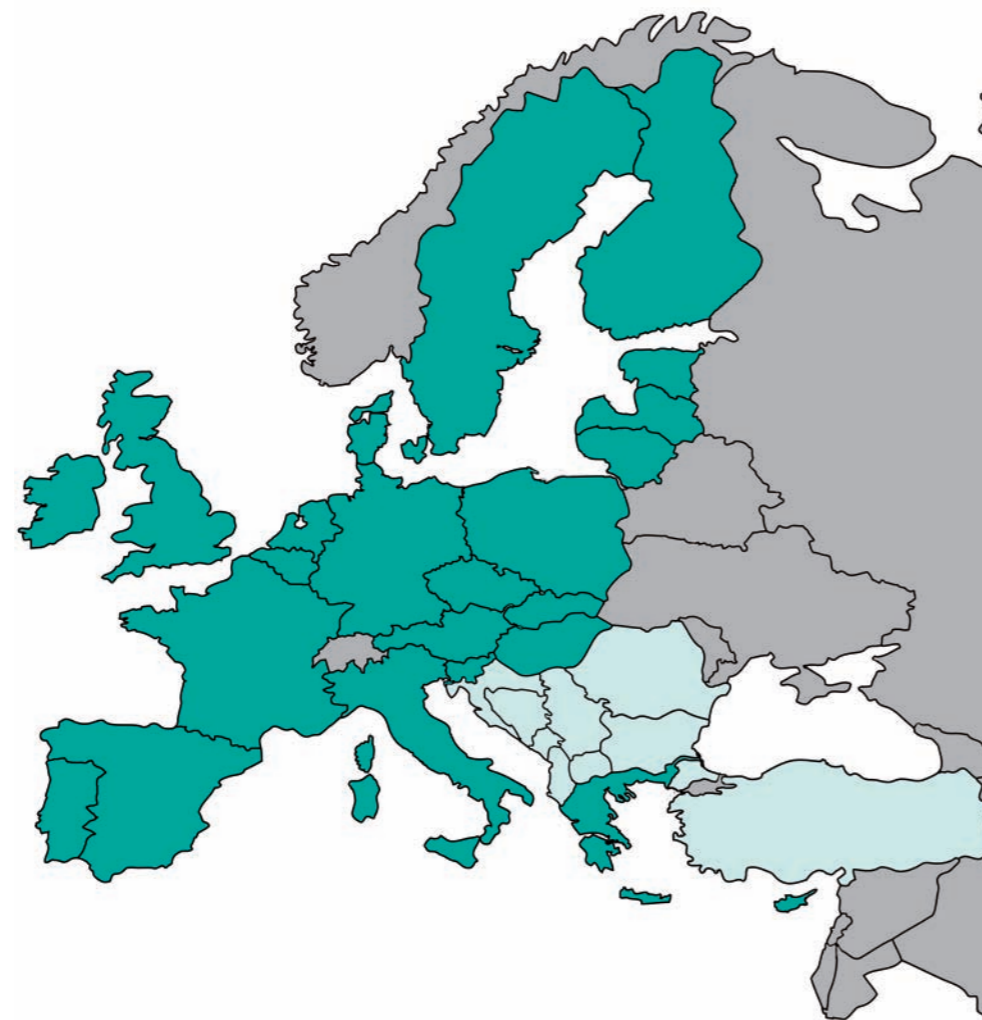
EN defines safety requirements within the European Union

The EN has defined fundamental requirements for the production and reprocessing of surgical barrier materials as well as test methods and performance requirements.

Surgical barrier materials ...

... are the most important measures for protection against infection

... have to provide a safe germ barrier when dry as well as when wet



- European Union
- Candidates for accession

- The European Standard sets up standards applicable for the whole of Europe, which improve the safety of patients.
- For hospitals and surgical staff, it offers easy orientation for the selection of barrier materials.
- The European Standard is applicable for reusable as well as for single-use products.
- In case of reusable products, high requirements are set for the reprocessing (standardisation, validation).

European Standard EN 13795 for the protection of patients and users

Characteristics to be evaluated

- Resistance to microbial penetration – wet
- Resistance to microbial penetration – dry
- Resistance to liquid penetration
- Cleanliness – particulate matter
- Particle release (linting)
- Cleanliness – microbial
- Tensile strength – wet
- Tensile strength – dry
- Bursting strength – wet
- Bursting strength –dry

For surgical drapes



For surgical gowns

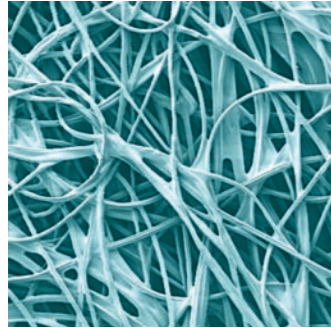


Clean air suits



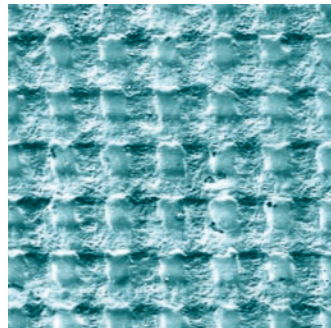
The main objective of this standard is to prevent the transmission of infections between patients and hospital staff which may take place during surgical and other operative procedures. If a product meets the requirements of European Standard EN 13795, it meets all significant legal requirements in safety during the application of the product as well as in **CE** marking at the same time

Foliodrape® Innovative materials



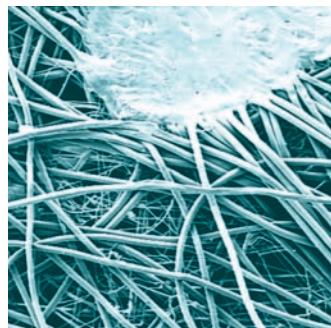
Absorbent viscose non-woven

Binder-bonded viscose non-woven. Viscose is a textile fibre on cellulose basis. The individual fibres are bonded to each other by means of a binding agent, which gives the non-woven the required stability and especially good abrasion strength. As the viscose fibres originate in cellulose, they are absorbent by nature. Thus, the viscose non-woven is able to absorb and distribute liquid by means of intra and inter-capillary spaces. For this reason, the non-woven is able to absorb and store seven to eight times of its own weight in liquid.



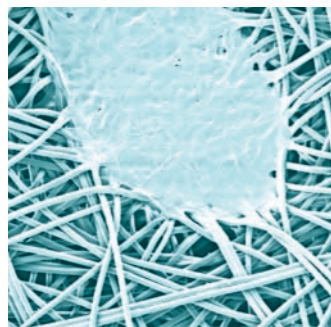
Polyethylene film impermeable to liquids and germs

PE film with micro-embossment. The embossment produces a matting effect. Thus, the film is less reflecting and obtains a softer touch. The film is absolutely impervious to liquids and is an impermeable barrier for germs.



Skin-friendly SMS nonwoven

SMS nonwoven made of polypropylene fibres. The nonwoven is used for comfort and stability. The individual fibres are bonded to each other by means of thermo-embossment, which gives the nonwoven the necessary stability



Hydrophilic spunlaid nonwoven

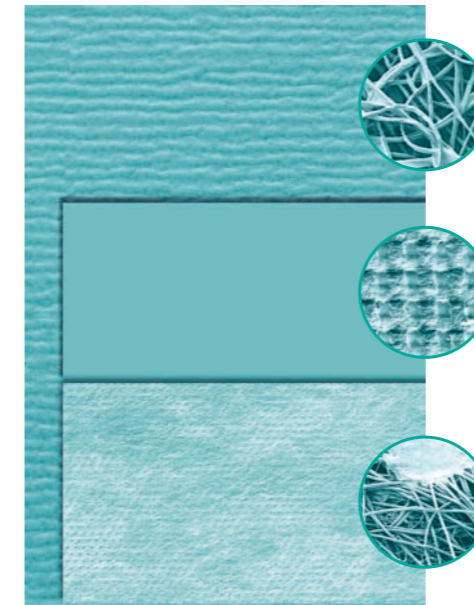
Spunlaid nonwoven of polypropylene filaments. The fibres have a diameter of about 20 µm (cf. human hair about 40 to 100 µm) and are bonded to each other by means of thermo-embossment (to be recognised by the embossed dots), which gives the nonwoven the necessary mechanical strength.

By nature, polypropylene fibres are hydrophobic (water-repellent). On account of a special surface treatment, the fibre is hydrophilised (which means it becomes absorbent), so that liquid is distributed and can be absorbed into the hollow spaces between the fibres (inter-capillary liquid intake). Thus, the non-woven can take up four to five times of its own weight.

Foliodrape® Advanced material compound

Foliodrape Comfort

Three-layer laminated. On account of a special embossment process, a surface is produced with a regular "orange skin structure", thus additionally creating a hollow-space storage medium which further improves the capacity to intake liquids.



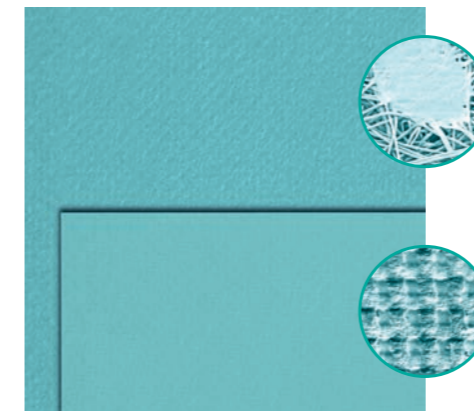
Upper layer:
absorbent

Medium layer:
liquid and
germproof

Lower layer:
stability and
comfort

Foliodrape Protect

Two-layer laminated. The thermally bonded polypropylene spunlaid nonwoven retains its complete mechanical strength even in wet condition and thus ensures that Foliodrape Protect loses nothing of its mechanical strength, even during procedures involving a lot of liquid.

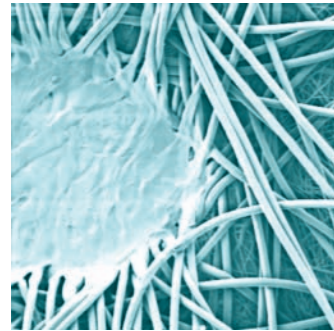


Upper layer:
absorbent

Lower layer
liquid and
germproof

Foliodress® Innovative materials

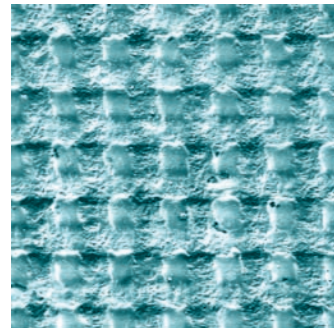
Base material



Skin-friendly SMMS nonwoven

The skin-friendly high-tech nonwoven fabric consists of 100 % pure polypropylene in a four-ply sandwich construction. The two outer layers consist of strong spunbond filaments which give the material its strength. The diameter of the spunbonded fibres is 20 µm. The two middle meltblown layers give the material its outstanding barrier properties to liquids and germs. The diameter of the meltblown fibres interlaced by air-flow is 2 µm. The four layers are thermally bonded to each other by embossed dots. On account of the innovative material mix, SMMS has better barrier properties than conventional spunlaced materials on polyester-cellulose basis. SMMS is used as a base material for Foliodress Comfort, Foliodress Protect and Foliodress Suit.

Reinforcing materials



Embossed polyethylene film and polypropylene nonwoven

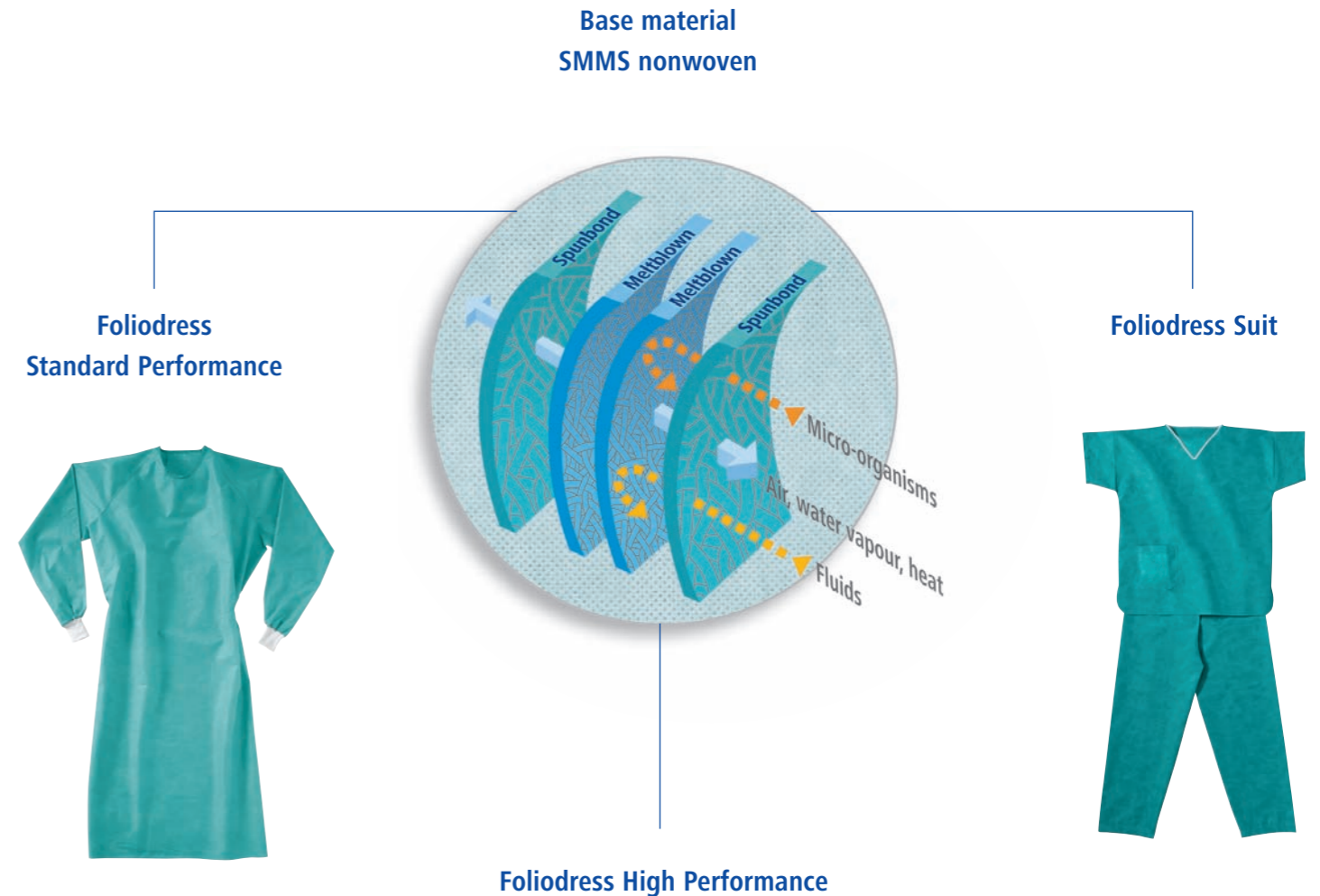
PE film with micro-embossment. The film is absolutely liquidproof and is an impermeable barrier for germs. The nonwoven provides added wear comfort.



Microporous film and polypropylene nonwoven

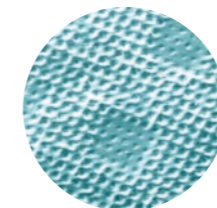
By adding calcium carbonate, micropores are produced in the film which are able to pass the water vapour of the carrier to the outside, thus optimising the wearing comfort. The protection properties are not affected. The microporous film is enclosed by an SMMS nonwoven fabric on both sides.

Foliodress® Advanced material compound



In order to meet the High Performance requirements during procedures involving a lot of liquid, the critical gown areas in the sleeve and breast are reinforced by an additional film impermeable to germs and liquids.

Foliodress Protect-Reinforcement



PE film impermeable to germs and liquids as well as polypropylene nonwoven fabric in the sleeve and breast area



Foliodress Comfort-Reinforcement



Microporous film permeable to water vapour but impermeable to germs and liquids in the sleeve and breast area

The current test results of Foliodrape®

Performance data of Foliodrape Comfort/three-layer:
Performance data of Foliodrape Protect/two-layer:



Characteristic	Unit	Performance data	
		Comfort	Protect
		Critical product areas	Critical product areas
Resistance to microbial penetration – dry	log ₁₀ (CFU)	not required	not required
Resistance to microbial penetration – wet	I _B	6.0	6.0
Cleanliness – microbial	log ₁₀ (CFU/dm ²)	sterile!	sterile!
Cleanliness – particulate matter	IPM	< 2	< 2.5
Linting	log ₁₀ (particle count)	< 2	< 2.5
Resistance to liquid penetration	cm H ₂ O	> 200	> 200
Bursting strength – dry	kPa	> 100	> 100
Bursting strength – wet	kPa	> 100	> 100
Tensile strength – dry	N	> 30	> 30
Tensile strength – wet	N	> 30	> 30
Absorption (non-woven) according to ISO 9073-6	%	700	500

In case of Foliodrape, no differentiation is made between critical and less critical areas.
The products fulfil the high-performance requirements for critical areas over the whole surface.

The current test results of Foliodress®

Performance data applying to the Standard Performance level



Characteristic	Unit	Performance data	
		Comfort	Protect
		Critical product areas	Critical product areas
Resistance to microbial penetration – dry	log ₁₀ (CFU)	not required	not required
Resistance to microbial penetration – wet	I _B	> 3	> 3
Cleanliness – microbial	log ₁₀ (CFU/dm ²)	sterile!	sterile!
Cleanliness – particulate matter	IPM	< 2.5	< 3.0
Linting	log ₁₀ (particle count)	< 2.5	< 3.0
Resistance to liquid penetration	cm H ₂ O	> 30	> 25
Bursting strength – dry	kPa	> 100	> 200
Bursting strength – wet	kPa	> 80	> 200
Tensile strength – dry	N	> 30	> 30
Tensile strength – wet	N	> 30	> 30

Performance data applying to the High Performance level



Characteristic	Unit	Performance data	
		Comfort	Protect Reinforced
		Critical product areas	Critical product areas
Resistance to microbial penetration – dry	log ₁₀ (CFU)	not required	not required
Resistance to microbial penetration – wet	I _B	6.0	6.0
Cleanliness – microbial	log ₁₀ (CFU/dm ²)	sterile!	sterile!
Cleanliness – particulate matter	IPM	< 3.0	< 3.0
Linting	log ₁₀ (particle count)	< 3.0	< 3.0
Resistance to liquid penetration	cm H ₂ O	> 150	> 150
Bursting strength – dry	kPa	> 200	> 200
Bursting strength – wet	kPa	> 200	> 200
Tensile strength – dry	N	> 30	> 30
Tensile strength – wet	N	> 30	> 30

The current test results of Foliadress®

Performance data of Foliadress Suit



Characteristic	Unit	Performance data
Resistance to microbial penetration – dry	log ₁₀ (CFU)	< 1.0
Cleanliness – microbial	log ₁₀ (CFU/dm ²)	< 2
Cleanliness – particulate matter	IPM	< 2.0
Linting	log ₁₀ (particle count)	< 2.5
Bursting strength – dry	kPa	> 100
Tensile strength – dry	N	> 30

The documents of the national implementation of Part 3 of this norm can be acquired at the respective national standards institutes. For Germany, the national standard DIN EN 13795-3 is expected to be published in German and English language versions in August 2006. For legal reasons it was not possible for us to publish the minimum performance requirements as stipulated in this standard.
 DIN Deutsches Institut für Normung e.V. (German Institute for Standardization). For applying DIN standards correctly you will need a copy of the latest issue of the standards available at Beuth Verlag GmbH, Burggrafenstraße 6, 10787 Berlin, www.beuth.de.

Foliadress® Products overview

Foliadress® Suit			
Code number	Product	Size	Units per case
992 515	Foliadress Suit green	S	50
992 517	Foliadress Suit green	M	50
992 519	Foliadress Suit green	L	50
992 521	Foliadress Suit green	XL	50
992 523	Foliadress Suit green	XXL	50
992 514	Foliadress Suit blue	S	50
992 516	Foliadress Suit blue	M	50
992 518	Foliadress Suit blue	L	50
992 520	Foliadress Suit blue	XL	50
992 522	Foliadress Suit blue	XXL	50

Foliadress® Comfort			
Code number	Product	Size	Units per case
992 172	Foliadress Comfort Basic peel & go	L	28
992 173	Foliadress Comfort Basic peel & go	XL	28
992 182	Foliadress Comfort Perfect with crepe and towels	L	28
992 183	Foliadress Comfort Perfect with crepe and towels	XL	28
992 184	Foliadress Comfort Perfect with crepe and towels	XXL	28
992 186	Foliadress Comfort Perfect peel & go	L	28
992 187	Foliadress Comfort Perfect peel & go	XL	28
992 192	Foliadress Comfort Special with crepe and towels	L	28
992 193	Foliadress Comfort Special with crepe and towels	XL	28
992 194	Foliadress Comfort Special with crepe and towels	XXL	28
992 196	Foliadress Comfort Special peel & go	L	28
992 197	FFoliadress Comfort Special peel & go	XL	28

Foliodress®

Products overview

Foliodress® Protect			
Code number	Product	Size	Units per case
992 178	Foliodress Protect Basic with crepe and towels	L	36
992 179	Foliodress Protect Basic with crepe and towels	XL	36
992 144	Foliodress Protect Standard with crepe and towels	M	36
992 145	Foliodress Protect Standard with crepe and towels	L	28
992 146	Foliodress Protect Standard with crepe and towels	XL	28
992 147	Foliodress Protect Standard with crepe and towels	XXL	28
992 154	Foliodress Protect reinforced with crepe and towels	M	36
992 155	Foliodress Protect reinforced with crepe and towels	L	28
992 156	Foliodress Protect reinforced with crepe and towels	XL	28
992 157	Foliodress Protect reinforced with crepe and towels	XXL	28