

Foliodrape® Protect single drapes

General Product Description/Intended Purpose

Foliodrape® Protect surgical drapes and covers consist of a variety of products and materials: different layers of nonwoven material laminated with Polyethylene-film (PE) that are available in different designs, sizes and for different applications. They are single-use sterile patient drapes and covers for short-term use for prevention of infection on humans in clinical environment.

Foliodrape® patient drapes and covers are intended to be used as sterile draping of the patient and dedicated inventory in operating theatres and all other surgical environments (e.g. day surgery, ambulance, doctor's surgery). The main task of drapes consists of the prevention of pathogen entry into the surgical wound. Consequently, the risks of infections and blood-borne diseases are reduced.

Foliodrape® self-adhesive 75 x 75 cm drape can be used as additional reinforcement for the front of a gown, which is added after putting on the gown.

The Foliodrape® products are placed on the market sterile and are in Medical Device Class I

Application/Indication

Draping is the perioperative process of covering a patient and surrounding areas in the operating theater with sterile drapes and covers to create and maintain a barrier, which protects the wound from the entry of microorganisms. The microorganisms can originate from the patient's skin, the OR, or the healthcare personnel. The aim of draping is to prevent the passage of pathogens between non-sterile and sterile areas. The different layers of hydrophilic nonwoven material laminated with Polyethylene-film act together as a fluid and bacteria barrier and minimize the transmission of micro-organisms. Depending on the procedure for which they are used, the Foliodrape® products usage time will vary from few minutes to several hours of continuous usage.

* Definitions according to Reg. (EU) 2017/745 (MDR)

Reference Numbers

Name of product	REF number	size	Attributes
Foliodrape® Protect Arthroscopy drape	938 820/2	245 x 320 cm	With fenestration, hook and loop fastener, pouch, and elastic cuff; wrapped in crepe paper
Foliodrape® Protect Back table cover	936 151/1	100 x 150 cm	-
	250 224/5	150 x 200 cm	-
	936 354/1	245 x 295 cm	Wrapped in crepe paper
Foliodrape® Protect Epidural drape, adhesive	936 276/1	75 x 60 cm	Self-adhesive, with fenestration
	938 809/2	90 x 60 cm	Self-adhesive, with fenestration
Foliodrape® Protect Fenestrated drape	277 549/2	50 x 60 cm	With fenestration
	277 503/2	45 x 75 cm	With fenestration
	277 511/2	75 x 90 cm	With fenestration
	936 200/1	150 x 100 cm	With fenestration
Foliodrape® Protect Fenestrated drape, adhesive	277 537/2	50 x 60 cm	Self-adhesive, with fenestration
	936 184/0	50 x 60 cm	Self-adhesive, with fenestration
	936 180/0	90 x 75 cm	Self-adhesive, with fenestration
	277 517/2	90 x 75 cm	Self-adhesive, with fenestration
	277 555/2	90 x 75 cm	Self-adhesive, with fenestration
	936 177/0	100 x 150 cm	Self-adhesive, with fenestration
	936 186/0	150 x 120 cm	Self-adhesive, with fenestration
	936 176/1	150 x 170 cm	Self-adhesive, with fenestration

Foliodrape® Protect single drapes

Name of product	REF number	size	Attributes
Foliodrape® Protect Fenestrated drape, adhesive	936 183/0	150 x 180 cm	Self-adhesive, with fenestration, wrapped in crepe paper
	936 154/0	170 x 250 cm	Self-adhesive, with fenestration, wrapped in crepe paper
	936 185/0	200 x 280 cm	Self-adhesive, with fenestration, wrapped in crepe paper
Foliodrape® Protect Instrument collection drape	936 335/0	100 x 150 cm	Self-adhesive
Foliodrape® Protect Patient underlay	936 250/0	100 x 120 cm	-
	936 652/0	100 x 120 cm	With Bag
	936 252/0	100 x 120 cm	With 2 Bags
Foliodrape® Protect Split sheet, adhesive	936 225/1	110 x 75 cm	Self-adhesive
	938 815/3	200 x 150 cm	Self-adhesive, wrapped in crepe paper
	938 817/2	225 x 280 cm	Self-adhesive, wrapped in crepe paper
Foliodrape® Protect Surgical drape	277 516/3	45 x 37,5 cm	-
	277 500/3	45 x 75 cm	-
	277 547/4	50 x 50 cm	-
	277 501/3	75 x 75 cm	-
	277 502/3	75 x 90 cm	-
	277 504/3	90 x 100 cm	-
	277 506/3	90 x 150 cm	-
	277 505/4	95 x 120 cm	-
	936 152/1	150 x 120 cm	-
	277 548/5	150 x 175 cm	-
	938 810/2	150 x 240 cm	-
Foliodrape® Protect Surgical drape, adhesive	277 507/3	45 x 75 cm	Self-adhesive
	277 546/4	50 x 50 cm	Self-adhesive
	936 277/1	75 x 75 cm	Self-adhesive
	277 508/3	75 x 90 cm	Self-adhesive
	936 275/1	75 x 90 cm	Self-adhesive
	277 542/4	90 x 100 cm	Self-adhesive
	277 551/3	240 x 150 cm	Self-adhesive
	277 543/5	150 x 175 cm	Self-adhesive, wrapped in crepe paper
	277 544/6	170 x 175 cm	Self-adhesive, wrapped in crepe paper
	938 812/2	175 x 200 cm	Self-adhesive, wrapped in crepe paper

Foliodrape® Protect single drapes

Name of product	REF number	size	Attributes
Foliodrape® Protect Surgical drape, adhesive	936 280/0	240 x 200 cm	Self-adhesive, wrapped in crepe paper
	277 538/5	300 x 170 cm	Self-adhesive, wrapped in crepe paper
Foliodrape® Protect Turban drape	938 828/2	100 x 65 cm & 90 x 75 cm	Self-adhesive
	936 331/0	175 x 150 cm & 100 x 110 cm	With Slit
Foliodrape® Protect 2 parts variable fenestrated drape, adhesive	277 509/2	45 x 75 cm	Self-adhesive, 2 pieces variable
	277 510/2	75 x 90 cm	Self-adhesive, 2 pieces variable

Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

No contraindications known.

Preparatory Treatment

Sterile surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings.

Skin and mucosis disinfection prior drape application: Prepare the surface with antiseptic solution, the solution should remain in contact with the skin as per the instruction on the disinfectant label. Do not make contact with any other area of the patient. Lay the drapes on the patient as per their intended purpose recommended by the product name. Leave uncovered only the operative field and those areas necessary for the maintenance of anesthesia.

Sterile Device

Do not use when sterile packaging or the product are damaged or were unintentionally opened before use.

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Foliodrape® products should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards. All infected waste is recommended to be disposed of by incineration.

Non-contaminated material such as waste paper, packaging and non-sterile but not biologically contaminated materials can be disposed separately. Separate disposal containers should be available where waste is created, so that staff can sort the waste as it is being discarded.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

Foliodrape® PROTECT offers pleasant usage, as the products are made of skin tolerable, soft material. The products are odor-neutral, and do not make any distracting noises while being handled. Drape design and easy-to-handle folding are developed in cooperation with operating theater staff and surgeons. They offer hygienic and efficient draping that can, in many cases, be done by a single person.

The Foliodrape® range is developed under high-quality standards to ensure safety and infection prevention.


Foliodrape® Protect single drapes

All products are free of CMR/PBT/vPvB substances (substances which are carcinogenic, mutagenic and toxic to reproduction, etc.). There are no added flame-retardants (like polybrominated bi-phenyls, etc.).

Because of the hydrophilic nature of the non-woven, the Foliodrape® material itself has antistatic properties, a special antistatic treatment is not necessary. Most Foliodrape® patient drapes and covers meet the highest demand level of EN 13795-1:2019. They fully support patient and OR environment safety.

Material Characteristics

Composition	Details
Nonwoven Material:	Hydrophilic PP-spunbond, 30 g/m ² , color: aqua
Film:	Pore-free polyethylene-film, 25 g/m ² , color: aqua
Total Laminate:	Thermobonded, 55 g/m ² , latex-free
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-1

- 
1. Hydrophilic PP spunbond
 2. PE-Film (impermeable for moisture and bacteria)

Foliodrape® PROTECT drapes correspond to all requirements of European standard EN 13795-1:2019 for the highest performance level "High performance, critical area". For more detailed information, please visit page 11.

Foliodrape® PROTECT drapes were tested according to STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES (16 CFR 1610) and belong to class 1.

Product Characteristics

Name of Product	REF number	size of drape	size of self-adhesive area	size of fenestration or split
Foliodrape® Protect Arthroscopy drape	938 820/2	245 x 320 cm	---	Ø 5 cm (round) 5 x 7 cm (oval)
Foliodrape® Protect Back table cover	936 151/1	100 x 150 cm	---	---
	250 224/5	150 x 200 cm	---	---
	936 354/1	245 x 295 cm	---	---
Foliodrape® Protect Epidural drape, adhesive	936 276/1	75 x 60 cm	60 x 4,5 cm & 16 x 18 cm	10 x 10 cm (rhomboid)
	938 809/2	90 x 60 cm	60 x 4,5 cm	10 x 12 cm (rhomboid)
Foliodrape® Protect Fenestrated drape	277 549/2	50 x 60 cm	---	Ø 5 cm
	277 503/2	45 x 75 cm	---	Ø 7 cm
	277 511/2	75 x 90 cm	---	Ø 10 cm
	936 200/1	150 x 100 cm	---	7 x 10 cm (oval)

Foliodrape® Protect single drapes

Name of Product	REF number	size of drape	size of self-adhesive area	size of fenestration or split
Foliodrape® Protect Fenestrated drape, adhesive	277 537/2	60 x 50 cm	17 x 18 cm	Ø 7 cm (round)
	936 184/0	50 x 60 cm	2,5 cm wide around fenestration	Ø 7 cm (round)
	936 180/0	90 x 75 cm	1 cm wide around fenestration	8 x 6 cm (oval)
	277 517/2	90 x 75 cm	18 x 17 cm	Ø 7 cm (round)
	277 555/2	90 x 75 cm	2,5 cm wide around fenestration	Ø 10 cm (round)
	936 177/0	100 x 150 cm	14 x 14 cm	Ø 10 cm (round)
	936 186/0	150 x 120 cm	18 x 17 cm	Ø 7 cm (round)
	936 176/1	150 x 170 cm	18 x 18 cm	Ø 12 cm (round)
	936 183/0	150 x 180 cm	20,5 x 25 cm	5 x 15 cm (oval)
	936 154/0	170 x 250 cm	20,5 x 17 cm	Ø 10 cm (round)
	936 185/0	200 x 280 cm	22 x 25 cm	Ø 15 cm (round)
Foliodrape® Protect Instrument collection drape	936 335/0	100 x 150 cm	96 x 6 cm	---
Foliodrape® Protect Patient underlay	936 250/0	100 x 120 cm	---	---
	936 252/0	100 x 120 cm	---	---
	936 652/0	100 x 120 cm	---	---
Foliodrape® Protect Split sheet, adhesive	936 225/1	110 x 75 cm	3 cm around split	10 x 12 cm
	938 815/3	200 x 150 cm	5 cm around split	10 x 60 cm
	938 817/2	225 x 280 cm	5 cm around split	10 x 95 cm
Foliodrape® Protect Surgical drape	277 516/3	45 x 37,5 cm	---	---
	277 500/3	45 x 75 cm	---	---
	277 547/4	50 x 50 cm	---	---
	277 501/3	75 x 75 cm	---	---
	277 502/3	75 x 90 cm	---	---
	277 504/3	90 x 100 cm	---	---
	277 506/3	90 x 150 cm	---	---
	277 505/4	95 x 120 cm	---	---
	936 152/1	150 x 120 cm	---	---
	277 548/5	150 x 175 cm	---	---
	938 810/2	150 x 240 cm	---	---
Foliodrape® Protect Surgical drape, adhesive	277 507/3	45 x 75 cm	71 x 4,5 cm	---
	277 546/4	50 x 50 cm	48 x 4,5 cm	---
	936 277/1	75 x 75 cm	71 x 4,5 cm	---
	277 508/3	75 x 90 cm	86 x 4,5 cm	---
	936 275/1	75 x 90 cm	86 x 2,5 cm	---

Foliodrape® Protect single drapes


Name of Product	REF number	size of drape	size of self-adhesive area	size of fenestration or split
Foliodrape® Protect Surgical drape, adhesive	277 542/4	90 x 100 cm	96 x 4,5 cm	---
	277 551/3	240 x 150 cm	90 x 5 cm	---
	277 543/5	150 x 175 cm	90 x 5 cm	---
	277 544/6	170 x 175 cm	90 x 5 cm	---
	938 812/2	175 x 200 cm	90 x 5 cm	---
	936 280/0	240 x 200 cm	240 x 6,25 cm	---
	277 538/5	300 x 170 cm	102 x 6,5 cm	---
Foliodrape® Protect Turban drape	938 828/2	100 x 65 cm & 90 x 75 cm	6 x 76 cm 6 x 15 cm x 2	---
	936 331/0	175 x 150 cm & 100 x 110 cm	---	75 cm slit
Foliodrape® Protect 2 parts variable fenestrated drape, adhesive	277 509/2	45 x 75 cm	18 x 33 cm	16,5 x 22 cm
	277 510/2	75 x 90 cm	28 x 34 cm	21,5 x 25 cm

Labelling

The Foliodrape® labeling describes the intended purpose of the device as supported by clinical evaluation. Safety information supplied by the legal manufacturer on the labeling are based on the risk management documentation and elaborately present all warnings and precautions according the new requirements of the standards concerning the product.

Lot-No. with 8-Digit Code

e.g.:

 0	12	XXXXX
year	Week of production	for internal purposes only

Manufacturing Date

e.g.:	 2020	04	07
	year	month	day

Use-by-Date

e.g.:	 2025	04	07
	year	month	day

Shelf Life: 5 years

Medical Device 

Unique Device Identification (UDI)





Single Sterile Barrier System  Single sterile barrier system


Do not use if the product sterile barrier system or its packaging is compromised



Foliodrape® Protect single drapes


Single use device 


Keep dry 


Sterilized using ethylene oxide 


Legal manufacturer  **PAUL HARTMANN AG**
Paul-Hartmann-Straße 12
89522 HEIDENHEIM, GERMANY


European Conformity 

Dispose of your waste in an appropriate manner 


Recycling symbols – Corrugated cardboard / Polyethylene Low-Density 

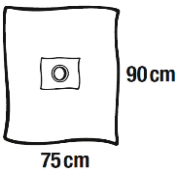
Producer contributes to recycling of packaging 

Global trade identification number  **GTIN**

Indication arrow where to open the packaging 

Name and intended purpose of the product **Lochtuch, selbstklebend**
Fenestrated drape, adhesive

Reference / catalogue number 

Pictogram with product look and dimensions 

Storage and transport conditions

Transport and store in conditions for climatic regions I-IVa according to WHO Technical Report 953, 2009.

Foliodrape® Protect single drapes

Logistic data

Name of Product	REF number	Peel Pouch size [mm]	Products per Peel Pouch	Peel Pouches per dispenser	Dispenser size	EAN of dispenser	Dispensers per carton
Foliodrape® Protect Arthroscopy drape	938 820/2	Size: XL 345 x 510	1	6	Size: XL 374 x 545 x 234	4052199212302	1
Foliodrape® Protect Back table cover	936 151/1	Size: M 266,5 x 360	1	35	Size: L 274 x 368 x 296	4052199501581	2
	250 224/5	Size: M 266,5 x 360	1	18	Size: L 274 x 368 x 296	4052199501994	2
	936 354/1	Size: M 266,5 x 360	1	7	Size: L 274 x 368 x 296	4052199574660	2
Foliodrape® Protect Epidural drape, adhesive	936 276/1	Size: S 133,5 x 290	1	36	Size: M 140 x 300 x 370	4052199501758	4
	938 809/2	Size: S 133,5 x 290	1	50	Size: M 140 x 300 x 370	4049500113151	4
Foliodrape® Protect Fenestrated drape	277 549/2	Size: S 133,5 x 290	1	70	Size: M 140 x 300 x 370	4049500639224	4
	277 503/2	Size: S 133,5 x 290	1	65	Size: M 140 x 300 x 370	4049500497831	4
	277 511/2	Size: S 133,5 x 290	1	40	Size: M 140 x 300 x 370	4049500562324	4
	936 200/1	Size: M 266,5 x 360	1	40	Size: L 274 x 368 x 296	4052199501918	2
Foliodrape® Protect Fenestrated drape, adhesive	277 537/2	Size: S 133,5 x 290	1	70	Size: M 140 x 300 x 370	4049500627276	4
	936 184/0	Size: M 266,5 x 360	1	80	Size: L 274 x 368 x 296	4052199577463	2
	936 180/0	Size: L 265 x 365	1	40	Size: L 275 x 374 x 234	4052199521619	2
	277 517/2	Size: S 133,5 x 290	1	40	Size: M 140 x 300 x 370	4052199501383	4
	277 555/2	Size: S 133,5 x 290	1	35	Size: M 140 x 300 x 370	4049500647472	4
	936 177/0	Size: M 266,5 x 360	1	26	Size: L 274 x 368 x 296	4052199509587	2
	936 186/0	Size: M 266,5 x 360	1	25	Size: L 274 x 368 x 296	4052199577616	2
	936 176/1	Size: M 266,5 x 360	1	22	Size: L 274 x 368 x 296	4052199501543	2
	936 183/0	Size: M 266,5 x 360	1	17	Size: L 274 x 368 x 296	4052199570587	2
	936 154/0	Size: M 266,5 x 360	1	11	Size: L 274 x 368 x 296	4052199530413	2
936 185/0	Size: L 360 x 580	1	15	Size: XL 368 x 568 x 300	4052199577425	1	

Foliodrape® Protect single drapes

Foliodrape® Protect Instrument collection drape	936 335/0	Size: M 266,5 x 360	1	30	Size: L 274 x 368 x 296	4052199521916	2
Foliodrape® Protect Patient underlay	936 250/0	Size: M 266,5 x 360	1	21	Size: L 274 x 368 x 296	4052199522180	2
	936 652/0	Size: M 266,5 x 360	1	25	Size: L 274 x 368 x 296	4052199577579	2
	936 252/0	Size: M 266,5 x 360	1	15	Size: L 274 x 368 x 296	4052199532493	2
Foliodrape® Protect Split sheet, adhesive	936 225/1	Size: S 133,5 x 290	2	15	Size: M 140 x 300 x 370	4052199570488	4
	938 815/3	Size: M 266,5 x 360	1	14	Size: L 274 x 368 x 296	4052199509747	2
	938 817/2	Size: L 360 x 580	1	13	Size: XL 368 x 568 x 300	4052199509266	1
Foliodrape® Protect Surgical drape	277 516/3	Size: S 133,5 x 290	1	125	Size: M 140 x 300 x 370	4049500570015	4
	277 500/3	Size: S 133,5 x 290	1	65	Size: M 140 x 300 x 370	4049500497558	4
	277 547/4	Size: S 133,5 x 290	1	100	Size: M 140 x 300 x 370	4052199028972	4
	277 501/3	Size: S 133,5 x 290	1	55	Size: M 140 x 300 x 370	4049500497756	4
	277 502/3	Size: S 133,5 x 290	1	35	Size: M 140 x 300 x 370	4049500497794	4
	277 504/3	Size: S 133,5 x 290	1	25	Size: M 140 x 300 x 370	4049500497879	4
	277 506/3	Size: S 133,5 x 290	1	20	Size: M 140 x 300 x 370	4049500562126	4
	277 505/4	Size: S 133,5 x 290	1	25	Size: M 140 x 300 x 370	4049500564953	4
	936 152/1	Size: M 266,5 x 360	1	30	Size: L 274 x 368 x 296	4052199501345	2
	277 548/5	Size: M 266,5 x 360	1	25	Size: L 274 x 368 x 296	4052199502199	2
	938 810/2	Size: M 266,5 x 360	1	16	Size: L 274 x 368 x 296	4052199500836	2
Foliodrape® Protect Surgical drape, adhesive	277 507/3	Size: S 133,5 x 290	1	60	Size: M 140 x 300 x 370	4049500562164	4
	277 546/4	Size: S 133,5 x 290	1	90	Size: M 140 x 300 x 370	4052199029016	4
	936 277/1	Size: S 133,5 x 290	1	45	Size: M 140 x 300 x 370	4052199501284	4
	277 508/3	Size: S 133,5 x 290	1	40	Size: M 140 x 300 x 370	4049500562201	4

Foliodrape® Protect single drapes

	936 275/1	Size: S 133,5 x 290	1	40	Size: M 140 x 300 x 370	4052199501505	4
	277 542/4	Size: S 133,5 x 290	1	25	Size: M 140 x 300 x 370	4052199502038	4
	277 551/3	Size: M 266,5 x 360	1	15	Size: L 274 x 368 x 296	4052199502076	2
	277 543/5	Size: M 266,5 x 360	1	19	Size: L 274 x 368 x 296	4052199502151	2
	277 544/6	Size: M 266,5 x 360	1	15	Size: L 274 x 368 x 296	4052199502854	2
	938 812/2	Size: M 266,5 x 360	1	17	Size: L 274 x 368 x 296	4052199500546	2
	936 280/0	Size: M 266,5 x 360	1	11	Size: L 274 x 368 x 296	4052199522968	2
	277 538/5	Size: M 266,5 x 360	1	11	Size: L 274 x 368 x 296	4052199509761	2
Foliodrape® Protect Turban drape	938 828/2	Size: L 265 x 365	1	22	Size: L 275 x 374 x 234	4052199211718	2
	936 331/0	Size: M 266,5 x 360	1	13	Size: L 274 x 368 x 296	4052199523163	2
Foliodrape® Protect 2 parts variable fenestrated drape, adhesive	277 509/2	Size: S 133,5 x 290	2	65	Size: M 140 x 300 x 370	4052199533377	4
	277 510/2	Size: S 133,5 x 290	2	40	Size: M 140 x 300 x 370	4052199533339	4

Latest Date of Revision: 2020-12-15

Foliodrape® Protect single drapes

Foliodrape® Protect, base material, testing results according EN 13795-1:2019

Property	Test method	Unit	Product requirement (PR) according EN 13795 -1:2019 for level "High Performance"	Test results ¹
Resistance to microbial penetration - Wet	EN ISO 22610	I _B	Less critical product area: Not required Critical product area: 6.0	6.0 (no penetration)
Cleanliness – microbial	EN ISO 11737-1	CFU/ 100 cm ²	Less critical product area: ≤ 300 Critical product area: ≤ 300	Not required ³
Particle release	EN ISO 9073-10	log ₁₀ (lint count)	Less critical product area: ≤ 4,0 Critical product area: ≤ 4,0	M _d = 2.2 U _q = 2.3
Resistance to liquid penetration⁴	EN 20811	cm (H ₂ O)	Less critical product area: ≥ 10 Critical product area: ≥ 100	M _d = 155 L _q = 150
Bursting strength - Dry⁵	EN ISO 13938-1	kPa	Less critical product area: ≥ 40 Critical product area: ≥ 40	M _d = 134 L _q = 125
Bursting strength - Wet⁵	EN ISO 13938-1	kPa	Less critical product area: Not required Critical product area: ≥ 40	M _d = 132 L _q = 129
Tensile strength – Dry	EN 29073-3	N/50mm	Less critical product area: ≥ 20 Critical product area: ≥ 20	Longitudinal direction: M _d = 78,5 L _q = 75,1 Lateral direction : M _d = 46,3 L _q = 45,6
Tensile strength – Wet	EN 29073-3	N/50mm	Less critical product area: Not required Critical product area: ≥ 20	Longitudinal direction: M _d = 82,2 L _q = 81,5 Lateral direction: M _d = 46,8 L _q = 46,2
Absorbency (laminate)	EN ISO 9073-6	%	No normative requirement	285 (± approx. 156 ml/m ²)

¹ Example REF 938 707 – Lot 400114277, unreinforced part, Test report from independent Testing-Institute is available on request. Abbreviations: L_q = lower quartile value, U_q = upper quartile value and M_d = median value. Product conforms when: L_q ≥ PR_{min} resp. U_q ≤ PR_{max}.

² Not required when the product fulfill the criteria for high performance in critical product area for resistance to microbial penetration wet (see Annex B7 in EN 13795:2019)

³ see clause A1.2 in EN 13795-1:2019, Foliodrape® articles are sterile according to EN 556

⁴ measured without use of supporting tissue (according to EN 20811),

⁵ values after membrane correction (according to EN ISO 13938-1)