

TECHNICAL SHEET DMTD FR AND FP REV 02 FOR FLAT REELS AND FLAT POUCHES FOR HYDROGENE PEROXIDE PLASMA STERILIZATION

Flat reels and flat pouches "SQS Quality System Sogeva" are made by TYVEK1073B and FILM PET12PE50peelit and they are especially suitable for hydrogen peroxide plasma sterilization. They are made by a plastic medical use material called laminated transparent film which comes from a special film of polyester (PET) and polypropylene (CPP) and by a special material TYVEK certificated with registered mark in sole agency by DuPont, with certificated ink indicator for flexographic printing.

These reels and pouches produced by SOGEVA SRL in TYVEK 1073B DUPONT TRADE MARK offer an excellent resistance to bacterial attacks, better strengthness to lacerations and perforations and a better strengthness when closed. TYVEK is a packaging material very strong and flexible which doesn't break and doesn't tear with the same facility of the medical paper; TYVEK the special flexibility and bacterial resistance guarantee a good protection for medical devices packed to be sterilized. TYVEK is very resistance to water and other liquids penetration.

These products can be sterilized only once because they are DISPOSABLE medical devices CE Class I (with Ministry Certification with Technical File 01-I-CE BRS dated 14.07.2004 DIR 93/42/CEE), **disposable** so once they have been used, reels and pouches must be thrown away because they can not be used for a second cycle of sterilization.

It is forbidden using the reel or the pouch if they are damaged.

Besides, we inform the end-user that reels and pouches have to avoid the direct sunlight and it has to be stored in a dry place; our products have to be used only after having checked that no dust is on the packaging and if they are partially used, they must be hermetically closed.

Lot number, made by 2 letters and 6 numbers, has to be read as specified here as follows:

- first two letters identify the lot of the film used;
- third number identifies the operator which works on the production machine at that moment
- last numbers identify the date: first two numbers are the day, further two numbers are the month and the latest one is the year of production.

Our items, not sterilized yet, can be used for 5 years from production date, respecting indicated norms considering that the packaging, if opened, has to be suitably closed and stored far from light, heat, humidity and cold.

Our delivery method is based on FIFO (first in - first out); this means that the material is delivered in order of production' date (the items get out of warehouse in chronological order) and we recommend users to do the same in order to have in stock only the latest lots.

Technically, the hot sealings are “Multiline” and made by bars with regular width (with minimum 10 mm and maximum 12 mm) and distance in order to assure higher resistance to pressure rises and to burst; they also grant the needed peelability.

Flat reel and flat pouch assure a packaging with a high technological quality content in order to satisfy the different needs of packaging in hospital, dental and industrial fields.

Flat reels and flat pouches are packed in a transparent plastic material and put into a carton in order to protect them from dust and humidity.

Cautions:

- 1) before sterilization process, please, check that reel and pouch are filled for maximum $\frac{3}{4}$ of their volume so that sealings are not obstructed at the edges
- 2) cover the end and the cutting surfaces of instruments with appropriate protection
- 3) put the instruments with the handle at the opening of the reel or the pouch
- 4) do not use solvent substances on the printing
- 5) possible words have to be written on a label and stucked on paper or film side; please do not write directly on flat reel and on flat pouch and, anyway, use the maximum care to avoid contamination problem during using.
- 6) Please carefully check the weight of the instruments to be sterilized in order to avoid risks of breaking.

TECHNICAL DETAILS

indicator colour : from light blue to pink

We would like to point out that the ink used for steam indicator is not a graphic printing ink. It is a chemical process ink. The sterilization process causes a chemical reaction which causes a color change. The reaction is based on many variables and the user can expect a final colour that changes from the light brown to medium brown as per certification of ink's producer.

FLAT REELS 70 MT. LENGTH

CODE	SIZE	PACKING	
R1P.7 50X70	mm 50x70mtl	8 reels/carton	
R1P.7 75x70	mm 75x70mtl	5 reels/carton	
R1P.7 100x70	mm100x70mtl	4 reels/carton	
R1P.7 150x70	mm150x70mtl	2 reels/carton	*
R1P.7 200x70	mm200x70mtl	2 reels/carton	
R1P.7 250x70	mm250x70mtl	1 reels/carton	
R1P.7 300x70	mm300x70mtl	1 reels/carton	
R1P.7 350x70	mm350x70mtl	1 reels/carton	
R1P.7 400x70	mm400x70mtl	1 reels/carton	

FLAT REELS 100 MT. LENGTH

CODE	SIZE	PACKING
R1P.1 50X100	mm 50x100mtl	8 reels/carton
R1P.1 75x100	mm 75x100mtl	5 reels/carton
R1P.1 100x100	mm100x100mtl	4 reels/carton
R1P.1 150x100	mm150x100mtl	2 reels/carton *
R1P.1 200x100	mm200x100mtl	2 reels/carton
R1P.1 250x100	mm250x100mtl	1 reels/carton
R1P.1 300x100	mm300x100mtl	1 reels/carton
R1P.1 350x100	mm350x100mtl	1 reels/carton
R1P.1 400x100	mm400x100mtl	1 reels/carton

FLAT REELS 200 MT. LENGTH

CODE	SIZE	PACKING
RP 50X200	mm 50x200mtl	8 reels/carton
RP 75x200	mm 75x200mtl	5 reels/carton
RP 100x200	mm100x200mtl	4 reels/carton
RP 150x200	mm150x200mtl	2 reels/carton *
RP 200x200	mm200x200mtl	2 reels/carton
RP 250x200	mm250x200mtl	1 reels/carton
RP 300x200	mm300x200mtl	1 reels/carton
RP 350x200	mm350x200mtl	1 reels/carton
RP 400x200	mm400x200mtl	1 reels/carton

FLAT POUCHES

CODE	SIZE	PACKING
BP 100X250	mm100x250	1.000 pcs/carton
BP 150x300	mm150x300	1.000 pcs/carton
BP 200x400	mm200x400	1.000 pcs/carton
BP 250x450	mm250x450	500 pcs/carton
BP 300x550	mm300x550	500 pcs/carton

Rete/Dominio/NtServer/Dsogeva/Ministero della Sanità Sogeva 2006/dmtd-tecFR FP tyvek 85 REV 02

Amministratore Delegato Enrico Sala	Data 02.11.2006
Responsabile Assicurazione Qualità Dr. Gianluca Minutola	REV 02 dated 02.11.2006
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