

TECHNICAL DATA SHEET

STERILIZATION FLAT/GUSSET REEL, 60gsm

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|-----------------------------|---|---|
| PRODUCT CODE | : | 4AFR (Flat Reel) - 4AGR (Gusset Reel) |
| RELATED STANDARDS | : | 4A Medical flat and gusseted reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the reel production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. 4A Medical Reels meet the requirements of 93/42/EEC Medical Device Directive regulations |
| INTENDED USE | : | 4A Medical reels are designed to provide excellent barrier for sterile medical device packaging purposes. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. 4A Medical reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. 4A Medical reels are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices. Sterilized material in sterilization package is storable for up to 5 years after the sterilization in a clean room conditions. Sealing temperature is 180-200C. |
| FILLING VOLUME | : | According to DIN 58953-7 (German national standard): Seleable paper bags and seleable pouches and reals shall be filled up to 3/4 max of their volume. This limits avoids too high stress / burdon to the seals. Belowe the buttom seal there must be space of minimum 30 mm between load and sealing area. There is no known limit bu standarts for weight and it is based on experience. However, it is suggested to follow the 3/4 rule. In terms of solid, heavy load (metal instruments), it is the weight itself, in case of any sharp objects which could damage the material, and the volume of condensate (directly related to mass=weight) which is created during the steam sterilization. |
| OPERATION CONDITIONS | : | 4A Medical reels are used for steam, ethylene oxide, formaldehyde sterilization methods. The sterilization conditions should be determined by the end user regarding to material to be sterilized. |
| SPECIFICATIONS | : | |

| MEDICAL PAPER | PROPERTIES | UNITS | STANDARD | TYPICAL VALUE |
|---------------|---|---------------------|------------------|---------------|
| | SUBSTANCE | g/m ² | ISO 536 | 60,0 |
| | THICKNESS | µm | ISO 534 | 76 |
| | BENDTSEN POROSITY | ml/min | ISO 5636-3 | 650 |
| | AIR PERMEANCE | µm (Pa*s) | ISO 5636-3 | 7,4 |
| | BENDTSEN ROUGHNESS FS | ml/min | ISO 8791-2 | 250 |
| | BENDTSEN ROUGHNESS WS | ml/min | ISO 8791-2 | 250 |
| | PORE SIZE | µm | EN 868-2 (app.D) | 17 |
| | TENSILE STRENGTH, MD | kN/m | EN ISO 1924-2 | 5,9 |
| | TENSILE STRENGTH, CD | kN/m | EN ISO 1924-2 | 2,9 |
| | WET TENSILE STRENGTH, MD | kN/m | ISO 3781 | 1,6 |
| | WET TENSILE STRENGTH, CD | kN/m | ISO 3781 | 0,9 |
| | BURST STRENGHT | kPa | ISO 2758 | 300 |
| | WET BURST | kPa | ISO 3689 | 100 |
| | TEARING STRENGHT MD | mN | ISO 1974 | 600 |
| | TEARING STRENGHT CD | mN | ISO 1974 | 650 |
| | COBB TEST (60s) | g/m ² | ISO 535 | 15,0 |
| | WATER REPELLENCY | s | EN 868-2 (app.E) | 30,0 |
| | FLOUORESCENCE | pts/dm ² | EN 868-2 (app.B) | 0,0 |
| | FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS | | | |

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| LAMINATED FILM | PROPERTIES | UNIT | TYPICAL VALUE | |
|----------------|---|-------------|---------------|--------|
| | THICKNESS | Micron | LAM.FILM | 52 ± 5 |
| | | | PE | 40 ± 5 |
| | | | PET | 12 ± 2 |
| | BREAKING FACTOR | N/15mm | 35 | |
| | TEAR STRENGTH MD/CD | mN | 300 | |
| | BOND STRENGTH | N/m | 265 | |
| | ELONGATION | % | 70 | |
| | TEMPERATURE DURABILITY | min/degrees | 30 min/140C | |
| | FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS | | | |

PRODUCT SPECIFICATION :

| POUCH | PROPERTIES | UNIT | TYPICAL VALUE |
|-------|-----------------------|----------|-----------------------------|
| | SEAL STRENGTH | N/15mm | 2,5 |
| | BUBBLE TEST | | None |
| | PINHOLE DETERMINATION | | None |
| | DIMENSION CONTROL | cm or mm | Desired dimensions |
| | LEAKAGE TEST | | None |
| | PEEL DIRECTION | | None |
| | INDICATOR CONTROL | | Returns the specified color |

| INDICATOR | STERILIZATION METHOD | BEFORE STERILIZATION | AFTER STERILIZATION |
|-------------------|----------------------|---|---------------------|
| | STEAM | BLUE | GREEN |
| | EO | PINK | ORANGE |
| | FORMALDEHYDE | PURPLE | GREEN |
| PACKAGING: | | 4A Medical reels are packaged in carton boxes as below: Flat Reels are 200m long and Gusset Reels are 100m long. | |

| Product dimensions | Pieces in carton |
|-----------------------------|------------------|
| 50mm X 200m / 50mm X 100m | 10 |
| 75mm X 200m / 75mm X 100m | 8 |
| 100mm X 200m / 100mm X 100m | 8 |
| 120mm X 200m / 120mm X 100m | 4 |
| 150mm X 200m / 150mm X 100m | 4 |
| 200mm X 200m / 200mm X 100m | 4 |
| 250mm X 200m / 250mm X 100m | 2 |
| 300mm X 200m / 300mm X 100m | 2 |
| 350mm X 200m / 350mm X 100m | 2 |
| 400mm X 200m / 400mm X 100m | 2 |
| 420mm X 200m / 420mm X 100m | 2 |
| 450mm X 200m / 450mm X 100m | 2 |
| 500mm X 200m / 500mm X 100m | 2 |

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