# TECHNICAL DATA SHEET

## STERILIZATION FLAT/GUSSET REEL, 60gsm

**PRODUCT CODE** : **4AFR (Flat Reel) - 4AGR (Gusset Reel)**

**RELATED STANDARDS** : 4A Medical flat and gusset reels are in compliance with the provisions of the Medical Device Regulation 2017/745 for medical devices. It is compatible with ISO 11607.

**INTENDED USE** : 4A Medical reels are designed to provide excellent barrier for sterile medical device packaging purposes. One side is 40micron CPP + 12 micron PET film material and other side is 60 gsm bacterial filter paper. Edges are sealed as trible welding.   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 6 month after the sterilization in a clean room conditions. Sealing temparature is 170-200C. 4A Medical reels can be used between 120 to 140 degress for sterilization.

**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 demage 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. Process indicators are on printed on edge of pouches. All related informations are printed on edge of pouches such us Standard, dimension, Lot no and so on.

**SPECIFICATIONS** :

| | PROPERTIES | UNITS | STANDARD | TYPICAL VALUE |
|---|---|---|---|---|
| **MEDICAL PAPER** | SUBSTANCE | g/m² | 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/m² | ISO 535 | 15,0 |
| | WATER REPELLENCY | s | EN 868-2 (app.E) | 30,0 |
| | FLOUORESCENCE | pts/dm² | EN 868-2 (app.B) | 0,0 |
| | FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS | | | |

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

**PRODUCT SPECIFICATION**  :

| | PROPERTIES | UNIT | TYPICAL VALUE |
|---|---|---|---|
| **POUCH** | 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 |

| | STERILIZATION METHOD | BEFORE STERILIZATION | AFTER STERILIZATION |
|---|---|---|---|
| **INDICATOR** | **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 |
| 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 |
| 450mm X 200m / 450mm X 100m | 2 |
| 500mm X 200m /500mm X 100m | 2 |

**MANUFACTURER**  :  **DORT-A TIP MALZEMELERI SAN. ITH. IHR. TIC. LTD. STI.**
Balıkhisar Mahallesi, Köyiçi Serpmeleri, No:795 Akyurt, Ankara, Turkey
Tel: +90 312 363 50 52 / 53  Fax: +90 312 363 52 10
Web: http://www.4amedical.com    E-mail: export@4amedical.com