



TECHNICAL DATA SHEET

| | |
|---------------|---------------|
| Document No | DD.8.2.6.2.02 |
| Validity | 01.06.2021 |
| Rev No / Date | - |
| Page No | 1 / 1 |

ITEM : 3 PARTS 5 ML SYRINGE with 22G x 1 1/2" NEEDLE

DESCRIPTION : Sterile hypodermic syringe for single use that is made of plastic material, pyrogen free, non-toxic, sterilized with ethylene oxide and used for aspiration of liquids or used for injection of liquid after filled

PROPERTIES

PHYSICAL PROPERTIES

| | STANDARD (TEST METHOD) | UNITE | RESULT |
|---|---------------------------------|--------------------|---|
| Material | TS EN ISO 7886-1 | - | Medical |
| Capacity | TS EN ISO 7886-1 | ml | 5 (± % 5) |
| Death Space | TS EN ISO 7886-1 | ml | Max.0,075 |
| Total graduated capacity | TS EN ISO 7886-1 | ml | 5 ml |
| Dimensions | TS EN ISO 7886-1 | mm | Ø inside = 12,40 |
| | | | Ø outside = 13,10 |
| | | | l barrel = 62,00 |
| | | | l plunger = 73,50 |
| | | | l plunger + gasket = 75,70 |
| Air Leakage during aspiration | TS EN ISO 7886-1 | kPa/sn | No leakage at 88 kPa vacuum at 60 second |
| Liquid leakage under compression | TS EN ISO 7886-1 | kPa/sn | No leakage at 300 kPa pressure at 30 second |
| Conic fittings (centric) | TS 3521-1 EN 20594-1 | % | 6% (Luer) |
| Needle size | TS 4002 EN ISO 7864 | mm | 0.70 x 40 |
| Needle penetration force | TS 4002 EN ISO 7864 | N | 0.48-0.53 |
| Bond between needle and tube | TS 4002 EN ISO 7864 | N | Does not broken by 40N |
| Cylinder-piston difference | TS EN ISO 7886-1 (Article 12) | mm | 15 mm |
| Scale length | TS EN ISO 7886-1 (Article 10.3) | mm | 5 ml : 41,4 mm |
| Scale interval | TS EN ISO 7886-1 (Article 10.2) | ml | 0,2 ml |
| Increment between graduation lines to be numbered | TS EN ISO 7886-1 (Article 10.2) | ml | 1 ml |
| Lubricant | TS EN ISO 7886-1 | gr/cm ² | 0,25 polydimethyl siloxane |
| Weight | AldarMed | gr | 4,50-4,65 |

CHEMICAL PROPERTIES

| | | | |
|------------------------|------------------|-------|------------------------|
| Neutrality | TS EN ISO 7886-1 | pH | Difference less than 1 |
| Pb, Zn, Sn, Fe | TS EN ISO 7886-1 | mg/lt | Totally less than 5 |
| Cd | TS EN ISO 7886-1 | mg/lt | Less than 0,1 |
| Ethylene oxide residue | TS 9897 | mg/lt | Less than 5 |

BIOLOGICAL PROPERTIES

| | | | |
|------------------|---|--|--|
| Cytotoxicity | EN ISO 10993 | | Not cytotoxic |
| Toxicity | EN ISO 10993 | | Does not cause acute systemic toxicity |
| Pyrogenity | EN ISO 10993-11. European Pharmacopoeia 7 th | | Apyrogen |
| Sterility | EN ISO 556, TS 10409/October 1992 | | Sterile |
| Hemolytic effect | EN ISO 10993-11, TS 6459/January | | Not hemolytical |
| Sensitization | EN ISO 10993-10/March 1998 | | No sensitivity |
| Irritation | EN ISO 10993-10/March 1998 | | No irritation effect |

PACKAGING PROPERTIES AND HANDLING

| | | | |
|---------------------------|------------------|---|---|
| Primary Packing | TS EN ISO 7886-1 | - | Transparent film + Blister Packing from medical grade paper and statements expressed in the standards |
| Secondary Packing | TS EN ISO 7886-1 | - | inner and out surface testliner, fluting wave, offset printed box and statements expressed in the standards |
| Transport-Storage-Packing | AldarMed | - | 6 inner boxes are put in outer boxes or wrapped container |
| Storage Condition | AldarMed | - | Kept out of direct sun light and stored in clean and dry storage areas at max. 45 °C |

| | | |
|---------------------------|-----------------------------|--------------------|
| | PREPARED BY | |
| NAME & SURNAME | Sümeyye Ersoy | APPROVED BY |
| DUTY | Quality Control Responsible | Sevda Nur Tay |

ALDARMED
 Sağlık Kurumları İşleri Genel Müdürlüğü
 Bakanlık Binası Kat: 15. Kat No: 15
 Milli Pazarlama Dairesi Başkanlığı
 Sağlık Bakanlığı
 T.C. Sağlık Bakanlığı
 Milli Pazarlama Dairesi Başkanlığı
 İletişim No: 0050094595500001