

DATE	28.03.2025
DOC.NO	FRM-KLT-BYM-069
PAGE NO	1
REV.NO	
REV.DATE	

TECHNICAL DATA SHEET

PRODUCT: Sterile disposable surgical set for interventions

Description of Product:

Sterile disposable set for interventions		
1	1 pc. field with adhesive board - dimensions 175x175 cm (~5cm), 2 layers: absorbent layer of viscose minimum 20 g/m ² , waterproof layer of polyethylene minimum 40 µm thickness; absorbent rate minimum 0.75g/dm ² with integrated adhesive board (double-sided glue will not be accepted).	175x175 cm
2	1 pc. 2-layered field with adhesive board - dimensions 90x75 cm (~5cm), adhesive board - min 5cm; 2 layers: absorbent layer of viscose minimum 20 g/m ² , waterproof layer of polyethylene minimum 40 µm; absorbent rate minimum 0.75g/dm ² with integrated adhesive board (double-sided glue will not be accepted).	90x75 cm
3	1 pc. reinforced table field for instruments - 150x190 cm (~5cm), 2 layers: absorbent layer of polypropylene minimum 30 g/m ² , waterproof layer of polyethylene minimum 35 µm; absorbent degree minimum 2.0g/dm ² ; absorbent area over the entire surface.	150x190 cm
4	1 pc. Mayo field for operating table, reinforced, dimensions 80x145 cm (~5cm), absorbent area of viscose minimum 25 g/m ² with absorption area 65x85 cm (~5cm) (Mayo with hydrophobic area will be excluded). Pentagon for guidance.	80x145 cm
5	3 pcs. hand towels, cellulose, minimum 15x25cm.	15x25 cm min
6	1 pc. adhesive tape - 10x50 cm (~2cm), 2 layers: a) waterproof polyethylene minimum 25µm thick; b) polyester absorbent minimum 40g/dm ² for fixing tubes.	10x50 cm
7	200 pcs. Viscose polyester absorbent pad - dimensions 10x10 cm (~3cm), minimum 4 layers, liquid absorption capacity - minimum 100%.	10x10 cm
8	1 pc. Angiography field with dimensions 240x330 cm (~10cm), integral 100% waterproof on the entire surface: a) Critical area 90x110 cm (~10cm) - reinforced, triple layered, viscose minimum 50g/m ² , polyethylene minimum 50µm, polypropylene minimum 10g/m ² , with a high degree of absorption of not less than 3.5 g/dm ² , with 2 holes of 5x10 cm (~2cm), with an integrated adhesive border around the holes (double-sided glue will not be accepted); b) Absorbent semi-critical area, minimum 100x320cm; c) Transparent side edges, dm. 70x320cm. All areas of the field will ensure 100% tightness, will be heat sealed, will not peel off in dry and/or liquid environment.	240x330 cm
9	3 pcs. Surgical gown XL - a) Made of non-woven material, polypropylene fibers, minimum 3 types of fibers - SMS; b) Repliflex, SMS material thickness minimum 3.5 g/m ² ; c) Last seven sleeves to ensure impermeability to microbes and liquids, needle-seven sleeve will be excluded; d) Sleeve length 80cm (~5cm), gown length (from shoulders to hem) - 130cm (~5cm), gown width in the axillary area 75cm (~5cm).	kol: 60 cm uzunluk: 130 cm genislik: 75 cm
10	4 pairs. Sterile, powder-free gloves (size: N7.0 - 2 pairs; N8.0 - 2 pairs) - made of deproteinized rubber, with low allergenic potential (extractable proteins no more than 50mcg/g), resistant to surgical interventions with the use of metal guides; non-pyrogenic; tear strength - not less than 15N; thickness at the fingers - not less than 0.27mm; coated on the inside with biogel for double protection and tear resistance, AQL - not more than 0.65 (AQL - standard for the protection of medical personnel during long-term interventions (level of penetration of microorganisms) and liquids, chemicals - according to the EN 374-2:2014 standard).	N7.0 N8.0
11	1 pc. circular screen cover - 140cm made of polyethylene, transparent, with elastic.	140 cm
12	1 pc. surgical lamp handle cover.	ST
13	2 pcs. 500 ml bowl made of polypropylene, graduated, transparent.	500 mL
14	2 pcs. 250 ml bowl made of polypropylene, graduated, colored.	250 mL
15	1 pc. Bowl min. 120 ml made of polypropylene, graduated, transparent, with thread and lid, minimum height 7cm, unscribed with the label "biological risk".	120 mL
16	5 pcs. Applicator - length approx. 15cm.	15 cm
17	1 pc. Scalpel with blade protection No. 22.	no 22
18	1 pc. Forceps - approx. 12cm.	12 cm
19	4 pcs. Forceps - approx. 10cm.	10 cm
20	5 pairs. White non-woven booties.	ST
21	5 pcs. Surgical mask 3 layers, incl. antibacterial layer.	ST
22	5 pcs. Surgical cap for men.	ST
23	2 pcs. Surgical cap for women.	ST

Raw Materials: Triflex / SMS + Reinforcement / PE + NW / Biflex / PE / Cellulose

Product Colour: Medical Blue

Reference Code: SP-05004-68

Weight in Grams: 77 gsm (Triflex) / 35 gsm SMS + 110 gsm (Reinforcement) / 28 gsm(SS)+65 mic.(PE) / 56 gsm Biflex / 48 mic (PE) / 60 gsm (Cellulose) /

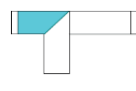
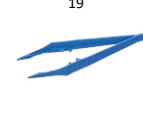
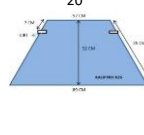
Package: Flat Pouch

Product: Medical Device Directive MDR 2017/745 ECC ANNEX XI A ALL VERSIONS. / Products and materials used do not contain metal.
Product Shelf Life - 5 Years

Product Materials

Unit / Size

PROPERTIES

Unit / Size	Properties
1 Biflex 175x175 cm	
1 Biflex 90x75 cm	
1 NW+PE 150x190 cm	
1 NW+PE 80x145 cm	
3 Cellulose 15x25 cm min	
1 *** 10x50 cm	
200 *** 10x10 cm	
1 Triflex 240x330 cm	
3 SMS + Reinforcement kol: 60 cm uzunluk: 130	
2 pair *** N7.0	
2 pair *** N8.0	
1 PE 140 cm	
1 PE ST	
2 *** 500 mL	
2 *** 250 mL	
1 *** 120 mL	
5 *** 15 cm	
1 *** no 22	
1 *** 12 cm	
*** 10 cm	
5 pair *** ST	
5 *** ST	
5 *** ST	
2 *** ST	

Tolerances: +/- 2% cm

Measurement: cm

Package Information

The products in the sterilization bag are double-packaged to reduce all risks during transportation. Double packaged products are put into Baymed's standard sized carton; dimensions are as follows:
Height = 44 cm; Length = 40 cm ve Width = 60 cm.

Preparation Date

QUALITY CONTROL APPROVAL