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TECHNICAL DATA SHEET

PRODUCT: **Sterile disposable surgical set for angiography**

Description of Product:

75	Sterile disposable surgical set for angiography		
1	1. 1 pc.: Angiography field - 240x330cm (+/-3cm), integral, 100% waterproof on the entire surface. a) Critical area - triple-layered reinforced, with a high degree of absorption, minimum dimensions: 240x80cm, with 4 holes: 2 holes of 8x10cm (+/-3cm) and 2 holes of 5x7cm (+/-3cm), with an impregnated adhesive border around the holes (double-sided glue will not be accepted); b) Absorbent semi-critical area, minimum 100x220cm. c) Transparent side edges, dim. 70x220cm. All areas of the field will ensure 100% tightness, will be heat-sealed, will not peel off in a dry and/or liquid environment.	240x330 cm	1
2	2. 1 pc.: super absorbent field - 35x45cm (+/-3cm), extra-absorbent, multilayered, minimum 6 layers, with adhesive tape, absorption capacity - minimum 500ml liquids.	35x45 cm	1
3	3. 1 pc.: field with adhesive board - 50x50cm (+/-3cm). Triple layered on the entire surface: cellulose comfort layer for the patient, waterproof layer, absorbent layer, with impregnated adhesive board (double-sided glue will not be accepted), the adhesive board applied directly to the edge of the field to avoid the accumulation of liquids.	50x50 cm	1
4	4. 1 pc.: instrument table field - 150x190cm (+/-5cm), absorbent area - minimum 190x75cm, 2 layers, waterproof.	150x190 cm	1
5	5. 4 pcs.: hand towels, made of cellulose, minimum 30x40cm.	30x40 cm	4
6	6. 2 pcs.: Surgical gown XL - a) Made of non-woven material, polypropylene fibers, minimum 3 types of fibers - SMS; b) Repellent, SMS material thickness minimum 35 g/m²; c) Laser-sewn sleeve to ensure impermeability to microbes and liquids, needle-sewn sleeve will be excluded; d) Sleeve length 60cm (±3cm), gown length (from shoulders to hem) - 130cm (+/-5cm), gown width in the axillary area 75cm (±3cm).	Kol: 60 cm uzunluk: 130 cm genişlik: 75 cm	2
7	7. 3 pairs: Sterile, powder-free gloves (sizes: N7.5 - 2 pairs; N8.0 - 1 pair) - made of deproteinized rubber, hypo-allergenic/with low potential to cause allergies, resistant to surgical interventions with the use of metal guides; non-pyrogenic, breaking strength – not less than 18N, thickness at the fingers – not less than 0.27mm; coated on the inside with biogel for double protection and breaking strength, AQL – not more than 0.65 (AQL – standard for the protection of medical personnel during long-term interventions (penetration level for microorganisms and liquids, chemicals – according to the EN 374-2:2014 standard)).	N7.5 N8.0	2 pair 1 pair
8	8. 2 pcs.: circular screen cover - 140cm made of polyethylene, transparent, with elastic.	140 cm	2
9	9. 1 pc.: C-arm radiological tube cover, circular, 75cm made of polyethylene, transparent, with elastic.	75 cm	1
10	10. 1 pc.: 120 ml polypropylene bowl, graduated, transparent, with thread and lid, minimum height 7cm, Inscribed with the label "biological risk".	7 cm	1
11	11. 1 pc.: Bowl minimum 100 ml made of polypropylene, transparent.	100 mL	1
12	12. 1 pc.: Bowl minimum 250 ml made of polypropylene, colored.	250 mL	1
13	13. 1 pc.: Kidney bowl minimum 800 ml.	800 mL	1
14	14. 1 pc.: Forceps for field fixation – 15cm (+/-3cm).	15 cm	1
15	15. 1 pc.: Clamp – 10cm (+/-3cm).	10 cm	1
16	16. 1 pc.: Tray 2500 ml, round, made of polypropylene, colored,with "wings", minimum height 9cm (+/-1cm) – to ensure the firm position of the metal guide and prevent its slipping.	2500 mL	1
17	17. 1 pc.: Angio syringe 12 ml with rotator.	12 mL	1
18	18. 1 pc.: 3-way OFF ramp, "wing" valves, resistant to 35 bar integrated with: a) polyurethane contrast system minimum 1800mm; b) polyurethane infusion system minimum 1900mm; c) polyurethane tube, minimum 1500mm.	STD	1
19	19. 1 pc.: E11 scalpel.	E11	1
20	20. 1 pc.: Angiographic guide – minimum length 175cm, J3, 0.034-0.036".	175 cm	1
21	21. 30 pcs.: Gauze pad, absorbent 10x10cm, minimum 8 layers.	10x10 cm	30
22	22. 1 pc.: Syringe needle 18G.	18G	1
23	23. 2 pcs.: Syringe needle 21G.	21 G	2
24	24. 1 pc.: Syringe needle 22G	22G	1
25	25. 1 pc.: Luer Lock syringe 20 ml.	20 mL	1
26	26. 1 pc.: Luer Lock syringe 10 ml.	10 mL	1
27	27. 1 pc.: Luer Lock syringe 5 ml.	5 mL	1
28	28. 1 pc.: Luer Lock syringe 2 ml.	2 mL	1
29	29. 1 pc.: Tubing bowl – 30x30cm (+/-3cm).	30x30 cm	1
30	30. 1 pc.: Sterile field for tubing - 100 x 150cm (+/-3cm).	100x150 cm	1

Raw Materials:	Triflex / SMS + Reinforcement / PE + NW / Biflex / SMS / Cellulose / PE
Product Colour:	Medical Blue
Reference Code:	SP-05004-56
Weight in Grams:	77 gsm (Triflex) / 35 gsm SMS + 110 gsm (Reinforcement) / 28 gsm(SS)+65 mic.(PE) / 56 gsm Biflex / 48 mic (PE) / 40 gsm (SMS) / 60 gsm (Cellulose) / 60 mic (PE)
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		
1	:Triflex	240x330 cm
1	Reinforcement	35x45 cm
1	Triflex	50x50 cm
1	NW+PE	150x190 cm
4	Cellulose	30x40 cm
2	SMS	Kol: 60 cm uzunluk: 130
2 pair 1 pair	***	N7.5 N8.0
2	PE	140 cm
1	***	75 cm
1	***	7 cm
1	***	100 mL
1	***	250 mL
1	***	800 mL
1	***	15 cm
1	***	10 cm
1	***	2500 mL
1	***	12 mL
1	***	STD
1	***	E11
1	***	175 cm
30	***	10x10 cm
1	***	18G
2	***	21 G
1	***	22G
1	***	20 mL
1	***	10 mL
1	***	5 mL
1	***	2 mL
1	***	30x30 cm
1	Biflex	100x150 cm

PROPERTIES

Digitally signed by Granaci Boris
Date: 2025.06.25 11:15:46 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

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