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REV.DATE	

TECHNICAL DATA SHEET

PRODUCT: Maxillofacial osteosynthesis set

Description of Product:

Maxillofacial osteosynthesis set			
1	1 pc.: Mayo drape for operating table, dimensions 80 x 145cm (± 5cm); 2 layers in the absorbent area 65 x 85cm (± 5cm), of viscose minimum 25g/m ² and polyethylene minimum 60 mcm. Absorption capacity in the critical area minimum 2 g/dm ² (Mayo with hydrophobic area will be excluded). Pictogram for guidance.	80x145 cm	1
2	2) 1 pc.: Craniotomy drape 230 x 300cm (± 10cm), transparent incision area 30 x 20cm (± 2cm), with liquid collection bag, with tap, super absorbent area in the working area. Poly layered, minimum 3 layers over the entire surface, reinforced in the critical area: a) comfort layer for the patient made of polypropylene; b) waterproof layer of polyethylene at least 40 mcm thick; c) absorbent layer of viscose at least 20g/m ² . Pictograms for guidance.	230x300 cm	1
3	3) 2 pcs.: Standard surgical gown, size XL, made of SMS non-woven material at least 40g/m ² , with polyester cuffs; length from shoulder to hem 145cm (± 10cm); thoracic region at least 60cm; laser-sewn sleeve.	length: 145 cm / thoracic area: 60 cm	2
4	4) 1 pc.: Reinforced table field 150 x 190cm (± 10cm), absorbent area 150 x 190cm (± 10cm) over the entire surface. Composed of at least 2 layers: a) waterproof layer, reinforced, made of polyethylene at least 55 mcm thick; b) absorbent layer of polypropylene at least 30g/m ² .	150x190 cm	1
5	5) 1 pc.: Standard surgical gown, size L, made of SMS non-woven material, min. 40g/m ² , with polyester cuffs; length from shoulder to hem 135cm (± 5cm); chest area min. 55cm; laser-sewn sleeve.	length: 135 cm / thoracic area: 55 cm	1
6	6) 2 pcs.: Bowl 120 ml, transparent	120 ml	2
7	7) 1 pc.: Graduated bowl 250 ml, blue	250 ml	1
8	8) 3 pcs.: Adhesive strips for fine wounds 12 x 100mm (± 5mm)	12 x 100mm (± 5mm)	3
9	9) 1 pc.: Skin marker, standard.	ST	1
10	10) 1 pc.: Container with lid, 120 ml, transparent.	120 ml	1
11	11) 1 pc.: Suction cannula type Yankauer 12 CH	12 CH	1
12	12) 2 pcs.: Surgical tapes with adhesive layer on the entire surface, dimensions 10x50cm (± 5cm); of 2 layers: a) polyethylene waterproof minimum 25mcm thick; b) polyester absorbent minimum 40g/m ² .	10x50 cm	2
13	13) 1 pc.: Vicryl Plus 4-0 equivalent suture, length 45cm.	45 cm	1
14	14) 1 pc.: N15 scalpel	size 15	1
15	15) 1 pc.: 800 ml renal bowl	800 ml	1
16	16) 1 pc.: 10 ml Luer lock syringe	10 ml	1
17	17) 2 pcs.: 20 ml Luer lock syringe	20 ml	2
18	18) 1 pc.: Cable holder, velcro type with glue minimum 2 x 30cm.	2x30 cm	1
19	19) 1 pc.: Patient field, absorbent, dimensions 175 x 175cm (± 2cm), with adhesive border on one edge; absorbent area on the entire surface, composed of at least 3 layers: a) patient comfort layer, polypropylene minimum 10g/m ² ; b) polyethylene layer of minimum 40 mcm thickness; c) absorbent layer of viscose, minimum 20 g/m ² . Absorption capacity - minimum 1 g/dm ² .	175x175 cm	1

Raw Materials: Triflex / PE + NW / SMS

Product Colour: Medical Blue

Reference Code: SP-01005-35

Weight in Grams: 77 gsm (Triflex) / 28 gsm(SS)+65 mic.(PE) / 40 gsm (SMS)

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

1	2	3	4
1	NW+PE	80x145 cm	
1	Triflex	230x300 cm	
2	SMS	length: 145 cm / thoracic area: 60 cm	
1	NW+PE	150x190 cm	
1	SMS	length: 135 cm / thoracic area: 55 cm	
2	***	120 ml	
1	***	250 ml	
3	***	12 x 100mm	
1	***	ST	
1	***	120 ml	
1	***	12 CH	
2	***	10x50 cm	
1	***	45 cm	
1	***	size 15	
1	***	800 ml	
1	***	10 ml	
2	***	20 ml	
1	***	2x30 cm	
1	Triflex	175x175 cm	

Tolerances: +/- 2% cm	Package Information
Measurement: cm	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