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|  |                     | 1                  | TECHNICAL DATA SHEET   |             |   |  |  |
|--|---------------------|--------------------|--|-------------|---|--|--|
|  | PRODUCT:            | Sterile disposabl  | e set for diagnostic angiographic interventions  |             |   |  |  |
|  |                     |                    |  |             |   |  |  |
|  |                     |                    | 88 Sterile disposable set for diagnostic angiographic interventions  |             |   |  |  |
| Description of Product:  |                     |                    | Angiography field - 240x370cm (+/-5cm), integral, 100% waterproof on the entire surface. a) Critical area - triple-layered reinforced, with a high degree of absorption, made of viscose and polyester minimum 50g/m2, with an absorption capacity of not less than 4g/dm2, minimum dimensions: 70x70cm, with 2 holes of 7x10cm (+/-3cm), with an impregnated adhesive border around the holes (double-sided glue will not be accepted). b) Absorbent semi-critical area, made of viscose minimum 25g/m2, minimum dimensions 100x370cm. c) Transparent side edges, made of polyethylene minimum 40g/m2, minimum dimensions 70x370cm. All areas of the field will ensure 100% tightness, will be heat sealed, will not come off in dry and/or liquid environment. | 240x370 cm  | 1 |  |  |
|  |                     | uct:               | Field with adhesive board - 50x50cm (+/-5cm). Triple layered on the entire surface: a) comfort layer for the patient made of polypropylene, b) waterproof layer of polyethylene minimum 40 mcm thick, c) absorbent layer of viscose minimum 20g/m2; 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 |  |  |
|  |                     |                    | 3 C-arm radiological tube cover, circular, 140 cm made of polyethylene, transparent, with elastic.   | 140 cm      | 1 |  |  |
|  |                     |                    | Superabsorbent pad - 35x50cm (+/-5cm), extra-absorbent, multi-layered, minimum 6 absorbent layers of viscose and polyester minimum 50g/m2, with adhesive tape, absorption capacity - minimum 500ml liquids.  |             | 1 |  |  |
|  |                     |                    | 5 Table pad - 150x190cm (+/-5cm), 2 layers: a) absorbent area - minimum 75x190cm, of viscose minimum 20g/m2; b) waterproof layer of polyethylene minimum 55 mcm thick.   |             | 1 |  |  |
|  | Raw Materials       | ·                  | Differ / SMC + Deinfercement / DE + NIM / Differ / SMC / Collules / DE   |             |   |  |  |
|  | Product Colour      |                    | Biflex / SMS + Reinforcement / PE + NW / Biflex / SMS / Cellulose / PE  Medical Blue   |             |   |  |  |
|  | Reference Code      |                    | \$P.05004-89   |             |   |  |  |
| Weight in Grams: 5   |                     | is:                | 56 gsm Biflex / 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  |                     |                    |  |             |   |  |  |
|  |                     | Pro                | duct: 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 Mate        | rials              | PROPERTIES   |             |   |  |  |
|  | Unit / Size         |                    |  |             |   |  |  |
| 1  | Biflex              | 240x370 cm         | 2 3 4  |             |   |  |  |
| 1  | Triflex             | 50x50 cm           |  |             |   |  |  |
| 1  | PE<br>Reinforcement | 140 cm<br>35x50 cm |  |             |   |  |  |
| 1  | PE + NW             | 150x190 cm         |  |             |   |  |  |
|  |                     |                    |  |             |   |  |  |
|  |                     |                    | 5  |             |   |  |  |
|  |                     |                    |  |             |   |  |  |
|  | Televane            | . / 29/ 222        | Designer information   |             |   |  |  |
|  |                     | +/- 2% cm<br>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 of dimensions are as follows:  Height = 44 cm; Length = 40 cm ve Width = 60 cm. |                     |                    |  | carton;     |   |  |  |
|  | Preparation Da      | te                 | QUALITY CONTROL APPROVAL   |             |   |  |  |
|  |                     |                    |  |             |   |  |  |