

# Product Data Sheet

Drapes and sets



## Ref. 1225-02 Vertical drape set, small

Page 1 (2)

Version: 19.02.2013, rev 1.

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<p>CE0434 The product complies with legal requirements for medical devices EO sterilized according to valid version of ISO 11135 standard <b>[ NATURAL LATEX FREE ]</b></p>	
<p><b>Components</b></p>	<p><b>Raw material</b></p>
<p>4 hand towels</p>	<p>Pulp, natural white, thread reinforced</p>
<p>1 mayo stand cover 78 x 145 cm, reinforced</p>	<p>Laminate: blue PP nonwoven/blue-white PE film/blue PE film</p>
<p>1 vertical drape 240 x 330 cm, with integrated incision film 40 x 30 cm and fluid collection pouch with sieve and bottom outlet, 2 tube holders and 2 x two-compartment suction/diathermy pouches 24 x 24 cm</p>	<p>vertical drape transparent polyethylene film, incision film adhesive coated polyurethane, fluid collection and suction/diathermy pouches transparent polyethylene, fluid collection pouch wire metal with blue polyethylene coating, valve white polyethylene, tube holders blue polyethylene film</p>
<p>1 instrument table cover 150 x 190 cm</p>	<p>Laminate: PP nonwoven/PE film laminate, blue</p>
<p><b>REACH regulations:</b></p>	<p>The product covered by this data sheet specification does not contain carcinogenic, mutagenic or toxic substances, including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).</p>
<p><b>Features:</b></p>	<p>Surgical draping set that provides a vertical barrier to keep the C-arm isolated from the sterile surgical field during hip/femur fracture or trauma procedures</p>
<p><b>Shelf life:</b></p>	<p>5 years</p>
<p><b>Pack count, carton measurements</b></p>	<p>1 pc/unit pack, 7 pcs/dispenser, 14 pcs/ctn</p>
<p><b>Sales unit:</b></p>	<p>Transport carton (14 pcs)</p>
<p><b>Unit pack:</b></p>	<p>White tyvek/polyethylene/polyester film pouch 420 x 603 mm</p>
<p><b>Dispenser box</b></p>	<p>Cardboard, totally chlorine free, 285 x 287 x 485 mm</p>
<p><b>Transport carton:</b></p>	<p>Cardboard, totally chlorine free, 300 x 590 x 500 mm</p>
<p><b>Packing tape:</b></p>	<p>Transparent, PVC-free</p>
<p><b>Compliance with legal requirements:</b></p>	<p>Medical Devices Directive 93/42/EEC, Class Is</p>
<p><b>Compliance with product standards:</b></p>	<p>EN13795</p>
<p><b>Quality standards:</b></p>	<p>The product is manufactured in compliance with ISO13485</p>
<p><b>Label information:</b></p>	<p>in accordance with EN ISO 15223-1 and EN1041</p>
<p><b>Storage recommendation:</b></p>	<p>Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone</p>
<p><b>Disposal recommendation</b></p>	<p>Follow local instructions</p>
<p><b>Risk if reused:</b></p>	<p>The product is single use. If reused performance of product may deteriorate, cross contamination may occur</p>

<p><b>Barcodes:</b> Unit pack</p>	<p>Dispenser</p>	<p>Transport carton</p>
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# Product Data Sheet

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Page 2 (2)

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<p>6438129116748 1225-02 single</p>  <p>6 438129 116748</p>	<p>6438129316742 1225-02 dispenser</p>  <p>6 438129 316742</p>	<p>6438129516746 1225-02 carton</p>  <p>6 438129 516746</p>
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