

Data Sheet Mistral-Air® Blankets Plus

Description	Mistral-Air® Blankets Plus										
Intended Use	<p>The Mistral-Air® Warming System is a forced air warming system and comprises of a warming unit and a variety of blankets. It is intended to raise and/or maintain patient temperature by means of surface warming.</p> <p>Intended patient population: adults and paediatric patients.</p> <p>Intended to be used only by trained clinicians in clinical areas during the entire perioperative pathway.</p>										
Use	<p>Single use</p> <p>Mistral-Air® Blankets should be used only with a Mistral-Air® Warming Unit (Commingling Use statement)</p>										
S1, S2, S3											
Composition	<ul style="list-style-type: none"> Blankets Plus: Non-woven materials Polypropylene and Polyethylene Adhesive tape: Pressure sensitive hot-melt on synthetic rubber base Face shield: Polyethylene Connector: Cardboard 										
Compliance	<p>16 CFR 1610 in relation to: Flammability of Clothing Textiles, Class 1.</p> <table> <tr> <td>EN 13795-1 in relation to:</td><td>ISO 10993 series in relation to:</td></tr> <tr> <td>Resistance to microbial penetration</td><td>Cytotoxicity</td></tr> <tr> <td>Cleanliness</td><td>Sensitization</td></tr> <tr> <td>Linting</td><td>Irritation</td></tr> <tr> <td>Bursting strength</td><td>Tensile strength</td></tr> </table>	EN 13795-1 in relation to:	ISO 10993 series in relation to:	Resistance to microbial penetration	Cytotoxicity	Cleanliness	Sensitization	Linting	Irritation	Bursting strength	Tensile strength
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Resistance to microbial penetration	Cytotoxicity										
Cleanliness	Sensitization										
Linting	Irritation										
Bursting strength	Tensile strength										
Regulatory	<p>Class I device and CE marked as per Regulation (EU) 2017/745 (EC Declaration of Conformity)</p> <p>Class Is device and CE marked as per Directive 93/42/EEC (CE certificate 2081762CE04)</p>										
Disposability	According to hospital protocol or local regulation (Disposal Statement)										
Packaging	<p>Details indicated in the Packaging overview below</p> <p>Double corrugated cardboard box</p> <p>Inner bags: Polyethylene</p> <p>Individual blanket bags*: Polyethylene or Tyvek pouches (in case of sterile blankets)</p> <p>One Instructions For Use (IFU) per box</p> <p>LOT number and REF number printed on single bag label and box label</p> <p>Time stamp printed on blanket and box label</p> <p>PVC free (PVC Free Statement); MA2286 has a PCV tube</p>										
Recommended storage conditions	Clean, dry, between + 16 °C and + 25 °C (preferably room temperature), keep away from sunlight										
Manufacturing	The Netherlands										
Note	Always consult the latest User and Technical Manual of the Mistral-Air Warming System										

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Specifications

	Description	Reference number	GTIN 14 Barcode (1 piece)	Blanket size (mm x mm)	Warming surface (mm x mm)	Weight (grams)
S1	Adult Plus	MA2220	18719867000540	2270 x 1330	1730 x 790	180
	Paediatric Plus	MA2230	18719867000588	1660 x 1330	790 x 1010	131
	Neonatal Plus	MA2240	18719867000625	1160 x 1330	1080 x 570	126
	Lower Body Plus	MA2250	18719867000663	1320 x 1330	945 x 790	115
	Upper Body Plus	MA2260	18719867000700	2010 x 760	1880 x 580	110
S2	Half Upper Body Plus	MA2265	18719867000748	1600 x 760	1375 x 580	98
	Torso Plus	MA2270	18719867000786	1240 x 760	900 x 530	78
S3	Full Underbody Plus	MA2400	18719867000984	2200 x 900	2160 x 840	184
	Half Underbody Plus	MA2450	18719867001028	1680 x 900	1020 x 840	141
	Paediatric Underbody Plus	MA2475	18719867001066	1680 x 900	1630 x 840	133
	Surgical Access Plus Sterile	MA2280	18719867000823	2200 x 1330	1297 x 840	203
	Surgical Access Plus	MA2290	18719867000946	2200 x 1330	1297 x 840	194
	Lower Surgical Access Plus Sterile	MA2285	18719867000861	1830 x 1330	890 x 840	174
	Cardiac Blanket Plus Sterile	MA2286	18719867000908	1700 x 1330	745 x 840	410
	Tube	MA0510	18719867000205	1750 x 150	170 x 150	65
	Lithotomy Plus	MA2455	18719867002639	1675 x 900	1200 x 840	129