

Product Data Sheet



Cover Headphones 100p

Ref.:	Product name:	Dimensions:	Weight:	Packaging dimensions:
1106-A	Cover Headphones 100p	Diameter: 200mm	140 g	260 x 260 x 40 mm

Intended use	Sanitary Cover to use with short-term patient positioning and stabilization device during invasive and non-invasive procedures to be used on intact patient's skin. Non-Sterile and not to be used in the sterile field.	
Directives & classification	CE according to MDD – Directive 93/42/ECC and MDR – Regulation 2017/745 Class 1 product	
Applied quality assurance	SN EN ISO 13485:2016	
Instructions for use	Enclosed to the product	
Restrictions of use	Do not use the product with children below the age of 3. Do not use the product for purposes other than those described.	
General safety notes	Single use. Non-sterile. Using the cover is NOT a substitute for disinfecting the positioning aids. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare professional (Rx only).	
MR safety note	MR Safe	
Materials	Material Polypropylene Cotton Polyester (latex-free)	Component fabric yarn elastic
Marking	CE, single-use	
Pieces	Bag contains 100 pcs.	
Storage	Store in dry place / room temperature	

Figures are subject to usual tolerances. All information to the best of our current knowledge. They do not guarantee a warranted quality and are no foundation for a contractual relationship. Errors excepted.