

Technical Data Sheet



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Date: May 03, 2018

Version: A/5

Supplier: Kingstar Medical (Xianning) Co., Ltd.

Art.No.:	11117		
Description:	Face mask with ear loop, Baehr, non-sterile		
Material:	-First/outer layer (liquid barrier): Polypropylene Spunbond Nonwoven, white, 20g/m2±10%, soft unfolded size:180x210mm(±5mm) -Second/middle layer (bacteria filter): Meltblown Nonwoven, white, 20g/m2±10%, soft unfolded size:180x220mm(±5mm) -Third/inner layer (face contact): ES non-woven, white, 18g/m2±10%, unfolded size: 180x230mm(±5mm) -Ear loop: 75D, high elasticity,18.5cm±1.5cm -Nose wire: PP-coated aluminium wire, length>135mm, width: 2.5mm±0.5mm Above materials are free of Nickel, PVC, glass fibers, latex		
Folded size of face masks:	180x90mm (±5mm)		
Unfolded size of face masks:	180x190mm (±5mm)		
Welding	Ultrasonic		
Sterilization	Suitable for EO sterilization		
Shelf life	5 years		
Bioburden	≤100 CFU/g		
Product picture:	 BAEHR size: 2.1x0.5cm(±0.1cm) BAEHR LOGO printed on the right upper side		
Quality requirement:	-BFE: >99 %, particle Size: 3.0 μm, tested by TSI8130. -Differential pressure: <40 ΔP (Pa/cm²), tested by TSI8130. -Appearance: no foreign material, dirt, broken, additional material processed ≤3mm. -Tensile strength of ear loop fixed to the mask: >20N.		
AQL of defects:	Defects	AQL	Permitted defective rate
	BFE		according to the test result tested by TSI8130.
	Differential pressure		according to the test result tested by TSI8130.
	Defective appearance	1.5	The defective rate is calculated according to AQL which is decided by sample size, the rate will be different if the sample size is different. For example if the sample size taken is 200pcs, then the permitted defective rate should be 7/200=3.5%.
	Ear loop missing or loose	1.5	
Primary packing:	Folding box		
Dimension:	19x10x10cm (LxWxH)		
Material:	Paperboard, 350g/m2(±50g/m2), inner side in grey, outer side in white and additional coated, stuck together by glue, not by staple, .		

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Art.No.:	11117
Description:	Face mask with ear loop, Baehr, non-sterile
Printing:	According to the layouts confirmed by Meditrade.
Content/box:	50 pcs/box
Packing way into the box	50pcs of face masks are in the same direaction and the first layer of face masks face to the cover of box. 
Secondary packing:	Brown carton
Dimension:	40x32x32cm (LxWxH)
Material:	Cardboard, brown, thickness 5mm, stuck together by glue, not by staple.
Printing:	According to the layouts confirmed by Meditrade.
Content/carton:	18 boxes/carton

Date	Version	Revision history	Prepared by
Dec. 27, 2017	A/0	New version	Anna
Jan. 22, 2018	A/1	Revise below information according to original samples received in Jan., 2018: 1) Revise the materias' information 2) Revise folded size and unfolded size of face mask 3) Revise packing way in the box according to 680006.	Anna
Mar. 19, 2018	A/2	1) Add logo information according to latest requirement. 2) Revise box size and carton size. 3) Revise the differential pressure value to the level the supplier could reach at the moment. After it's settled, we will revise again.	Anna
Mar. 21, 2018	A/3	We notice there is a mistake about face masks size and correct face masks' size	Anna
Apr. 12, 2018	A/4	Revise the folded size and unfolded sizes of face masks	Anna
May 03, 2018	A/5	1)Add the picture of face masks in the TDs 2)Add coating requirements for boxes	Anna