



# Product datasheet

## Abena face mask with ear loops, Type IIR, art. no. 1000010123



### Description:

Face mask with soft and strong elastic ear loops and nose clip to ensure proper fit. The mask has a low respiratory resistance and a high bacterial filtration efficiency.

Material: PP, Spandex, Aluminium

Produced for Abena A/S, DK under ISO 13485:2016

### Application:

It is intended for use by health care professionals in operation rooms or other medical settings with similar hygiene requirements in order to minimize cross contamination. The working environment is protected against transmission and the wearer against spray or splashes at a pressure of 120 mmHg.

Fit the nose piece and position mask on face, making sure to cover nose and mouth. Place the ear loops around the ears. The mask is put on with the colored layer facing out and should always be completely unfolded.

Suited for long term use; though, if the mask is contaminated/impure it should be changed. Furthermore, national health care guidelines should be followed.

### CE

CE labelled according to EU Regulatory for medical devices (MDR) 2017/745 Annex VIII, Class 1

Type IIR approved according to EN 14683:2019.

### Test and requirements according to medical face masks

EN 14683:2019			
Test	Type 1 <sup>a</sup>	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm <sup>2</sup> )	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (CFU/g)	≤ 30	≤ 30	≤ 30
a. Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by health care professionals in an operating room or in other medical settings with similar requirements.			



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## Packaging:

Inner packaging: Dispenser box Transport carton: Carton

## Storage, durability and waste management:

Storage: store dry and keep away from direct sunlight

Durability unopened: 3 years

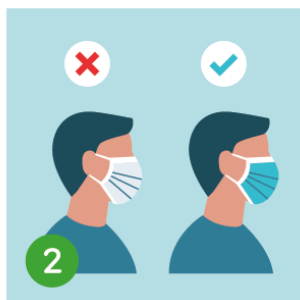
Waste management: Carton is combusted or recycled

Art. no.	Product	Size	Quality	Units per pack/cil
1000010123	Face mask with ear loops, Type IIR	17x18 cm	3-layer	50/1000

## User Manual:



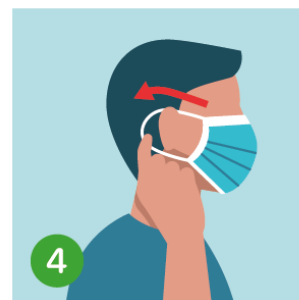
1  
Wash hands before touching the facemask



2  
Make sure that the facemask's colored side is facing outwards



3  
Find the metal strip and place it on the nose



4  
Attach the elastic bands behind both ears



5  
Cover nose and mouth. There must not be spaces on the side



6  
Press the metal strip down, so it sticks to the nose



7  
Do not touch the facemask during use. Wash hands if you do



8  
Replace the facemask if it gets damp. Do not reuse



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## Alternative

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*For protection of the user against splashes we recommend a Type IIR face mask.  
Please see below alternatives:*

Art.no	Product
1999902596	Face mask with ear loops, Type IIR

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