

TECHNICAL DATA SHEET - CONFIDENTIAL



This information shall not be disclosed to any other party

Product Medical Face Masks, 3 ply

Quality Norm EN 14683, Type II
BFE % ≥ 98
Differential Pressure (Pa/cm²) ≤ 40
Splash Resistance Pressure (mm Hg) not required
CfU/g < 30



Lab test lab test must be provided, showing that the lot meets the EN 14683 Type II requirements

Material Latex free, 3 ply mask:
1st ply, outside 28 gsm non-woven
2nd ply, 25 gsm melt blown filter
3rd ply, inside 25 gsm nonwoven

Size & fixture earloop: body 17,5 x 9.5 cm, ultrasonically welded latex free earloops at the outside of mask body

Packaging

primary 50 pcs per box with lot number and color marked on the square on the box
secondary earloop case 40x50 pcs case white with full color label, size 52x38x30 cm

Intended Use The intended use of a medical face mask is to help prevent large particles expelled by the wearer (e.g. spit, mucous) from reaching the patient or work environment. Fluids contacting the outer surface of the surgical mask will not immediately soak through to the interior of the surgical mask and contact the wearer's lips or skin.

Wear Medical face masks are typically donned for a specific procedure. For infection control purposes masks are typically disposed of after each procedure/patient activity.

Fit Medical face masks are not designed to pass a fit test. Flat surgical masks fit loosely over the face leaving large gaps between the mask and the wearer. It is unlikely that most of the air will pass through the mask material. The air (and any airborne particles) will go through the gaps

Shelf life 5 years after production date

Lot to be traced back by the factory in case of recall or QA issues

QA documents MDD 93/42/EEC Guideline, EN 14683

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