

<b>Art. Code</b>	<b>20010/20020</b>
Date	30-8-2019
Version Nr.	v3

## TECHNICAL DATA SHEET - CONFIDENTIAL

This information shall not be disclosed to any other other party



**Product** Surgical Face Masks, 3 ply

**Quality** Norm EN 14683, Type II

BFE % BFE ≥98%

Differential Pressure (Pa/cm<sup>2</sup>) ≤ 29,4

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 23 gsm printed tissue

2nd ply, 22 gsm melt blown filter

3rd ply, inside 24 gsm nonwoven

**Size & fixture** earloop: body 17,5 x 9 cm, ultrasonically welded latex free earloops at the outside of mask body

item REF	description	Case
<b>20010</b>	earloop mask, blue bear	case: 10x50 pcs
<b>20020</b>	earloop mask, red bear	case: 10x50 pcs



**Packaging**

primary 50 pcs per box with lot numer and color marked on the square on the box

secundary earloop case 10x50 pcs case white with full color label, size 51x19,8x21,7 cm

**Intended Use**

The intended use of a surgical / procedure mask is to help prevent large particles expelled by the wearer (e.g. spit, mucous) from reaching the patient or work environment. Some surgical masks also have fluid resistant properties to help reduce the risk of splashes or sprays of blood, body fluids, secretions and excretions from reaching the wearer's mouth and nose. 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**

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

**Fit**

Surgical 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**

three digits, to be traced back by the factory in case of recall or QA issues

**QA documents**

MDD 93/42/EEC Guideline, EN 14683

ISO 90001, risk analyses, CoA