

# ISOL/8<sup>®</sup>

## SPECIFICATION SHEET

*Designed by Healthcare Professionals,  
For Healthcare Professionals*



### **FLUIDSAFE Procedure Mask**

File no.: SPEC-IS8RM01P  
Version-003

#### **ISOL8 HEALTHCARE LTD**

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# Fluid resistant and extra soft

Our **FLUIDSAFE** standard procedure mask is manufactured from high quality fabric with a super soft silk-like inner material providing excellent comfort to the wearer. Our type IIR masks provide the highest barrier performance and their fluid resistant properties offer protection against splashing during procedures.

Our procedure masks are most suited for use in clinical environments for patient encounters, examinations and minor procedures. Elastic earloops are easy to apply and provide a comfortable fit.



## Packaging Information

<b>Product packaging (inner pack)</b>	50 masks per dispenser box Dispenser box: 190x102x85 mm
<b>Product packaging (outer carton)</b>	40 inner boxes per carton (2000 masks), Outer carton: 430x400x440 mm, Gross weight: 13Kg
<b>Recycling Information</b>	Inner box and outer carton are 100% recyclable (cardboard), Mask is non-recyclable

# Product Specification

<b>Product Name</b>	FLUIDSAFE Procedure Mask
<b>Manufacturer Product Codes (MPN)</b>	IS8RM01P
<b>Manufacturer</b>	ISOL8 Healthcare Ltd.
<b>Mask type</b>	Fluid resistant standard procedure mask
<b>Compliance with standard</b>	EN14683:2019 Type IIR
<b>Mask size (Length x Width)</b>	175x95 mm
<b>Mask fit</b>	Earloops
<b>Colour</b>	Light blue (Other colours available on request)
<b>Sterility</b>	Non-sterile
<b>Mask fabric (3-layers)</b>	Outer: 35gsm Spunbond Polypropylene, Middle: 30gsm Melt-blown Polypropylene, Inner: 20gsm Extra-soft Spunbond
<b>Earloops</b>	Spandex polyurethane coated with nylon thread 160±5mm x 3mm
<b>Nose bar material</b>	Full length aluminium nose piece
<b>Latex status</b>	Not made with natural rubber latex
<b>Metal status</b>	Nickel and cadmium free
<b>CE certification</b>	MDR 2017/745 – Class I medical device
<b>Manufacturer QMS</b>	ISO 13485
<b>GTIN code inner box</b>	05391541270287
<b>GTIN code outer carton</b>	05391541270812



ISOL8 masks are CE class I medical devices intended for use by medical professionals. Before use, please consult the product labels and instructions.

For more information or any enquiries regarding our products, please contact your account manager at ISOL8 Healthcare.

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