

ISOL/8[®]

SPECIFICATION SHEET

*Designed by Healthcare Professionals,
For Healthcare Professionals*



FLUIDSAFE Procedure Mask

File no.: SPEC-IS8RM01P
Version-006

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

Product packaging (inner pack)	50 masks per dispenser box Dispenser box: 190x102x89 mm
Product packaging (outer carton)	40 inner boxes per carton (2000 masks), Outer carton: 465x400x420 mm, Gross weight: 13Kg
Recycling Information	Inner box and outer carton are 100% recyclable (cardboard), Mask is non-recyclable

Product Specification

Product Name	FLUIDSAFE Procedure Mask
Manufacturer Product Codes (MPN)	IS8RM01P
NPC	BWM85106
Manufacturer	ISOL8 Healthcare Ltd.
Mask type	Fluid resistant standard procedure mask
Compliance with standard	EN14683:2019 Type IIR
Mask size (Length x Width)	175x95 mm
Mask fit	Earloops
Colour	Light blue (Other colours available on request)
Sterility	Non-sterile
Mask fabric (3-layers)	Outer: 35gsm Spunbond Polypropylene, Middle: 30gsm Melt-blown Polypropylene, Inner: 20gsm Extra-soft Spunbond
Earloops	Spandex polyurethane coated with nylon thread 160±5mm x 3mm
Nose bar material	Full length aluminium nose piece
Latex status	Not made with natural rubber latex
Metal status	Nickel and cadmium free
Shelf-life	5 years
CE certification	MDR 2017/745 – Class I medical device
Manufacturer QMS	ISO 13485
GTIN code inner box	05391541270287
GTIN code outer carton	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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