

ISOL/8[®]

SPECIFICATION SHEET

*Designed by Healthcare Professionals,
For Healthcare Professionals*



FLUIDSAFE Surgical Mask

File no.: SPEC-IS8RM01S
Version-005

ISOL8 HEALTHCARE LTD

Unit 4 Joyce House,
Barrack Square, Ballincollig,
Co Cork, P31 HW35
Ireland

CONTACT

info@isol8health.com
IE: +353 (0) 66 71 21659
GB: +44 (0) 191 816 1966
www.isol8health.com

Fluid resistant and extra soft

Our **FLUIDSAFE** standard surgical mask is manufactured from high quality fabric with an extra 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 surgical masks are most suited for use in the operating theatre and adjustable head ties provide a comfortable fit for extended use.



FLUIDSAFE™

Packaging Information

Product packaging (inner pack)	50 masks per dispenser box Dispenser box: 190x102x85 mm
Product packaging (outer carton)	40 inner boxes per carton (2000 masks), Outer carton: 440x400x530 mm, Gross weight: 13Kg
Recycling Information	Inner box and outer carton are 100% recyclable (cardboard), Mask is non-recyclable

Product Specification

Product Name	FLUIDSAFE Surgical Mask
Manufacturer Product Codes (MPN)	IS8RM01S
Manufacturer	ISOL8 Healthcare Ltd.
Mask type	Fluid resistant standard surgical mask
Compliance with standard	EN14683:2019 Type IIR
Mask size (Length x Width)	175x95 mm
Mask fit	Ties
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
Ties	Spunbond Polypropylene 400±15mm x 10mm
Nose bar material	Full length aluminium nose piece
Latex status	Not made with natural rubber latex
Metal status	Nickel and cadmium free
CE certification	MDR 2017/745 – Class I medical device
Manufacturer QMS	ISO 13485
GTIN code inner box	05391541270034
GTIN code outer carton	05391541270805



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.

© 2023 ISOL8 HEALTHCARE LTD
Unit 4 Joyce House, Barrack Square, Ballincollig,
Co Cork, P31 HW35. Company No. 687076

info@isol8health.com
IE: +353 (0) 66 71 21659
GB: +44 (0) 191 816 1966
www.isol8health.com

ISOL/8[®]

**Designed by Healthcare Professionals,
For Healthcare Professionals**