

SPECIFICATION SHEET

Designed by Healthcare Professionals, For Healthcare Professionals



File no.: SPEC-IS8ES

ISOL8 HEALTHCARE LTD

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

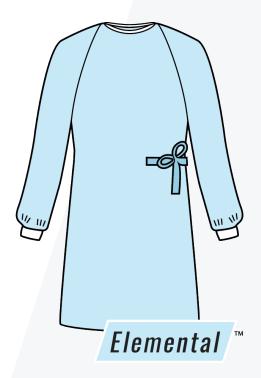
CONTACT

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High level of performance without compromising your comfort

Our *Elemental* gown provides an affordable solution for procedures where low to moderate levels of fluid are expected. Constructed from 48gsm SMMS fabric, it provides high level barrier properties while also offering a high level of breathability to ensure optimal comfort for the wearer.

The ergonomic fit with raglan sleeves provides the wearer with added comfort, a greater range of movement and allows for easier donning.







Product Specification

| Product Name | Elemental Standard Surgical Gown | | |
|--|---|--|--|
| Manufacturer Product Codes (MPN) | IS8E01 (M), IS8E02 (L), IS8E03 (XL), IS8E04 (XL-Long), IS8E05 (2XL), IS8E06 (2XL-Long), IS8E07 (3XL) | | |
| Manufacturer | ISOL8 Healthcare Ltd. | | |
| Gown type | Standard sterile surgical gown – Single use only | | |
| Compliance with standard | EN13795 - Standard Performance | | |
| Sizes (see size chart below for dimensions) | M, L, XL, XL-Long, 2XL, 2XL-Long, 3XL | | |
| Fabric | SMMS 48gsm (100% polypropylene) | | |
| Gown cut | Raglan sleeves for better unrestricted movement and easier donning | | |
| Sleeve Seam | Ultrasonic welded | | |
| Neck closure | Hook and loop | | |
| Cuffs | Soft knitted cuffs | | |
| Anti-static | Yes | | |
| Colour | Blue | | |
| Sterility | Sterile | | |
| Pack contents | 2 x sterile scrim towels – 50x40 cm 1 x SMS sterile wrap – 60x60 cm | | |
| Ties | Double bonded ultrasonic welded SMS ties, Inner ties: 40±2 cm (both), Outer ties: 75±5 cm and 40±5 cm | | |
| Latex status | Not made with natural rubber latex | | |
| Metal status | Nickel and cadmium free | | |
| Shelf-life | 5 years | | |
| CE certification | MDD 93/42/EEC – Class Is medical device Notified body ICIM (CE 0425) | | |
| Manufacturer QMS | ISO 13485 | | |

Packaging Information

| Product packaging (inner pack) | Gown pack (sterile pouch) 340x230x50±20 mm | | |
|----------------------------------|--|--|--|
| Product packaging (outer carton) | a) 40 gown packs per carton 600x390x350 mm | | |
| Recycling Information | Outer carton is 100% recyclable (cardboard) Inner pack and product are non-recyclable | | |

Size Guide

| Size | Length (cm) | Hem circumference (cm) |
|----------|-------------|------------------------|
| Μ | 115 | 145 |
| L | 127 | 150 |
| XL | 135 | 155 |
| XL-Long | 150 | 155 |
| 2XL | 145 | 160 |
| 2XL-Long | 160 | 160 |
| 3XL | 150 | 165 |



| MPN | NPC | Elemental gown type | Qty/ carton | GTIN (gown) | GTIN (carton) |
|--------|----------|---------------------|----------------|----------------|----------------|
| IS8E01 | BWK85323 | Standard M | 40 | 05391541270003 | 05391541270539 |
| IS8E02 | BWK85332 | Standard L | 40 | 05391541270010 | 05391541270546 |
| IS8E03 | BWK85327 | Standard XL | 40 | 05391541270027 | 05391541270553 |
| IS8E04 | BWK85321 | Standard XL-Long | 40 | 05391541270041 | 05391541270560 |
| IS8E05 | BWK85318 | Standard 2XL | 40 | 05391541270058 | 05391541270577 |
| IS8E06 | BWK85325 | Standard 2XL-Long | 40 | 05391541270065 | 05391541270584 |
| IS8E07 | BWK85314 | Standard 3XL | 40 | 05391541270072 | 05391541270591 |



ISOL8 gowns are CE certified class I sterile 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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