SURGICAL

Gowns - Sterile

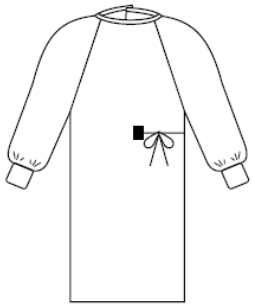
TECHNICAL DATA SHEET

CE

Description:

90002: Surgical Gown, S
90012: Surgical Gown, L
90042: Surgical Gown, XL
90013: Surgical Gown, L ,X-Long
90043: Surgical Gown, XL, X-Long

SMS Fabric, Raglan sleeves, Adjustable Neckline – Hook and Loop, Yellow Binding, Drop fold. With 1 Hand Towel.



Dimensions:

	90002	***90012***	***90042***	***90013***	***90043***
Length *(front, neck to bottom)*	105 cm	113 cm	117 cm	134 cm	142 cm
Length *(back, neck to bottom)*	114 cm	123 cm	127 cm	145 cm	150 cm
Sleeve length *(underarm to cuff)*	53 cm	57 cm	63 cm	54 cm	62 cm
Neck length *(overall)*	55 cm	57 cm	63 cm	71 cm	69 cm
Body width *(overall)*	142 cm	156 cm	174 cm	154 cm	174 cm

Properties:
Basis weight of base material: 44 g/m^2
Standard Performance Gown as defined by EN 13795.
Test results as per EN 13795 available upon request.

Indication:

To prevent the transfer of infective agents between the operating room personnel and the patient.
Single use product.

Counter indication:

None in particular.

Main materials:

Base material: SMS Fabric (polypropylene), topically treated for alcohol repellency and static dissipation.
Cuffs and Threads: Polyester
Hook and Loop Fastener: Nylon, Polyethylene
Does not contain Natural rubber latex.
Does not contain DEHP.

Sterilization:

Products are sterilized by ethylene oxide (ETO).

Packaging:

90002: Shipping case of 36 units.
90012: Shipping case of 36 units.
90042: Shipping case of 34 units.
90013: Shipping case of 34 units.
90043: Shipping case of 34 units.

All units are placed within 1 polyethylene bag.
Unit packaging: CSR Wrap, FFS (Form/Fill/Seal) peal-bag,
1 traceability sticker. Bar coding: GS1-128 symbology, linear, on shipping case and unit packaging.

Manufacturing:

Products are manufactured in China or Honduras.
The quality system of the manufacturing sites is ISO 13485 compliant.

Regulatory information:

Products CE marked as per 93/42/EEC Directive on Medical Devices.
Class of the device: I, sterile.
These products are EN 13795 compliant.

Storage:

Store in a dry and cool place, away from intense sources of heat.
Keep as much as practicably possible in its shipper box.

Shelf life:

5 years, from date of manufacture.

**Registered trademark or trademark of Halyard Health Inc.*
©2014 Halyard Belgium BV/BA. All rights reserved.
Created 09-dec-2014, version 0

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.