



In House Specifications

Specification No: 130811B

Customer: St Johns Ambulance Supplies

Customer Product Code: F11508 (Singles) 4000 wipes per outer carton
: F11509 (Pack of 10) 400 x 10 per outer carton
: F11510 (Pack of 100) 20 x 100 per outer carton

Brief Description: Sterile Saline Crepe Paper Wipe (0.9% w/v)

Weight per 10 Sachets: 25 g

Expiry Date: 2 years

Product Class: IIa Medical Device

Product Code: STRSAL01

Sterilization Method: Gamma Irradiation

Min Dose: 25 kGy

Solution Composition
(Per 1000L Mixing Tank Solution)

% Conc.	Component
0.9% w/v (±5%)	Sodium Chloride BP Grade
99.1% w/v	Purified Water (>5MΩ/>15MΩ) UV Treated

Sachet and Material Composition

Solution Amount	Tissue Type	Foil Type
2ml solution per sachet (±10%)	40g crepe paper	CCP50/PE12/AL16.35/ION23
	100mm x 105mm	75mm x 50.8mm

Art Work for Printed Foil



In House Specifications

Packing Instructions:

1. Each carton is poly-lined
2. Carton must be completely sealed with clear adhesive tape

Labeling Details:

1. The Product Code, Lot No., Quantity and Expiry Date will be printed on to a template sticker.
2. The A5 sized preprinted sticker is intended for the out side of the cardboard box
(see attached sticker)

Outer Label:

1. The machine operator will check that the information on the outer sticker agrees with the batch to be packed.
2. The sticker is then placed on the end of the box.

Palletisation:

1. Each pallet must have a cardboard lining on the base.
2. Each pallet must contain 50 outer cartons
3. All four corners must be protected with pallet corners

4. Each pallet must be completely shrink wrapped to avoid damage in transit and sealed with security tape.

Documentation:

1. Each delivery will have a packing slip detailing how many sachets per batch
2. Certificate of Conformity
3. Certificate of Irradiation/Irradiation Number

Foil size:

The foil sachet should measure 75mm x 50.8mm.

Foil Appearance:

1. Single sachet.
2. The text on the foil should be clear and free from smudges.
3. The batch no. and Exp. Date should be clearly embossed in the area indicated by the Lot symbol and Exp Date symbol
4. There should be no stains on the foil.
5. All four seals should be intact, without leaks or bubbles.




Lot No. and Expiry Date:

1. The Lot. No. is generated from the week and year of manufacture e.g. week 8 in 2011 is lot no. 0811
2. The expiry date is 2 years and is in the format YYYY-WW e.g. week 8 in 2011 exp date 2013-08

Approved Inner/Outer Box Art Work (if any):

No inner or outer box art work. Product is packed in clear grip lock bags

Approved Labeling: (See printed label attached)

Managing Director:		Authorized By:		Date:	<u>03/02/12</u>
Operations Director:				Date:	<u>03/02/12</u>
Customer:				Date:	<u>03/02/12</u>