



Doc No. 68
Doc Rev No: 03
Spec Rev No: 00
DCR No: 23-0049

Product Specifications

Specification No: 260811

Cartons of 100 Wipes

Customer: Qualicare

Product: Qualicare Sterile Saline Wipes

Customer Product Code: QW0351

Expiry: 5 years

Brief Description: Sterile Saline Spun Lace Wipe (0.9% w/v)

Weight per 10 Sachets: 25g (+/-2) g

Product Class: Class IIa Medical Device

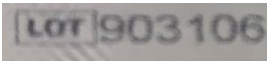

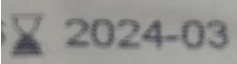

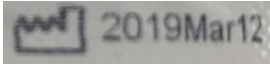
Sterilization Method: Gamma Irradiation

Validation Reference: Synergy Westport: I-GSP-079
Synergy Daventry: 5633






Formulation Details


% Conc.	Formulation Component	Fill Volume per sachets	Formulation Testing	Release Specification of finished blend
0.9% w/v	Sodium Chloride (EP Grade) (ref: P226)	2ml of solution per sachet	Salinity is tested using an in-house salinity meter.	8-10 ppt
Up to 100 w/v	Purified Water (>5MΩ/>15MΩ) UV Treated		N/A	N/A

Lot Number format	Expiry Date	Date of manufacturing	UDI codes
<p>The Lot number is assigned from Naturelle’s Lot Number Log. It is printed on the reverse of the sachet.</p> <p>e.g. LOT 903106</p> 	<p>The Expiry Date is 5 years and is printed on the reverse of the sachet.</p> <p>e.g.  2024-03</p> 	<p>The Date of Manufacture and the time is printed on the reverse of the sachet. The date of manufacture refers to the date and month of production:</p> <p>e.g.  2019Mar12</p> 	<p>The UDI code is created as follows: (01) 14-digit GTIN code which will be 15017599002010 (17) expiry date YYMMDD (10) Batch/Lot number</p>

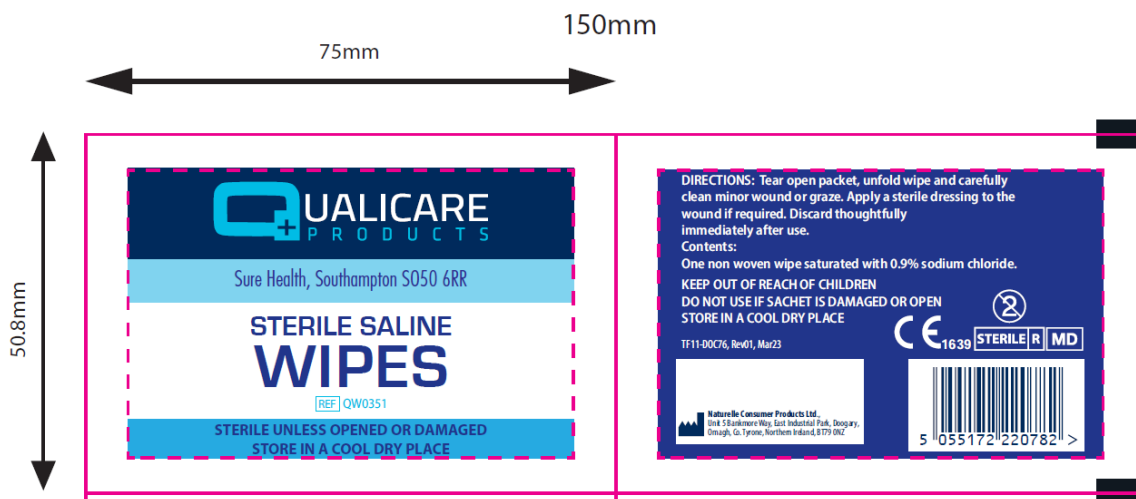
--	--	--	--

<p>Printed Foil Ref Code:</p> <p>QW0351</p>	<ul style="list-style-type: none"> • Single sachets • 75mm x 50.8mm • CCP50/PE12/AL6,35/ION2 3 • The text on the foil should be legible. • The lot number, expiry date, and date of manufacture will be clearly printed on the sachet. • All four seals must be intact. 	
<p>Towelette Ref Code:</p> <p>20.040.019.0080.01.0 4</p>	<ul style="list-style-type: none"> • 100 mm x 105 mm • 40g Spunlace (50% viscose, 50% PET) • 4-fold 	

<p>Inner Carton Ref. Code:</p>	<ul style="list-style-type: none"> • 100 single sachets per plain inner carton. • The lot number and expiry date will be printed onto an inner label with is applied to each inner carton. 	
<p>Shipper Carton Ref. Code:</p> <p>N101-56</p>	<ul style="list-style-type: none"> • For bulk packed wipes each outer carton is poly lined • 20 inners or 2000 bulk packed sachets per shipper carton. • The shipper cartons are completely sealed with clear adhesive tape. • A Gammatex™ sticker will be fixed to the top corner of the shipper carton. The sticker is a visual indicator which changes from yellow to red upon exposure to Gamma irradiation. Sterility and dose levels are only confirmed by the Certificate of Irradiation, issued to Naturelle by the sterilization supplier. • The approved shipper carton label will be affixed to each shipper carton. 	

<p>Pallet:</p> <p>Standard</p>	<ul style="list-style-type: none"> • Each pallet must have a cardboard lining on the base. • Shipper cartons are placed so that labels are visible. • The completed pallets will contain 50 outer cartons built with 10 boxes per layer and 5 layers high. • All four corners must be protected with pallet corners. • Each pallet must be completely shrink wrapped to avoid damage in transit and sealed with security tape. • The packing slip generated for the product will be affixed to the pallet. 	
---------------------------------------	--	--

Artwork for Printed Foil- Approved by P. Vanstone (05Apr2023)



Art work for inner carton-



A WORLD OF PROTECTION

> INDUSTRIAL > CONSUMER > MEDICAL



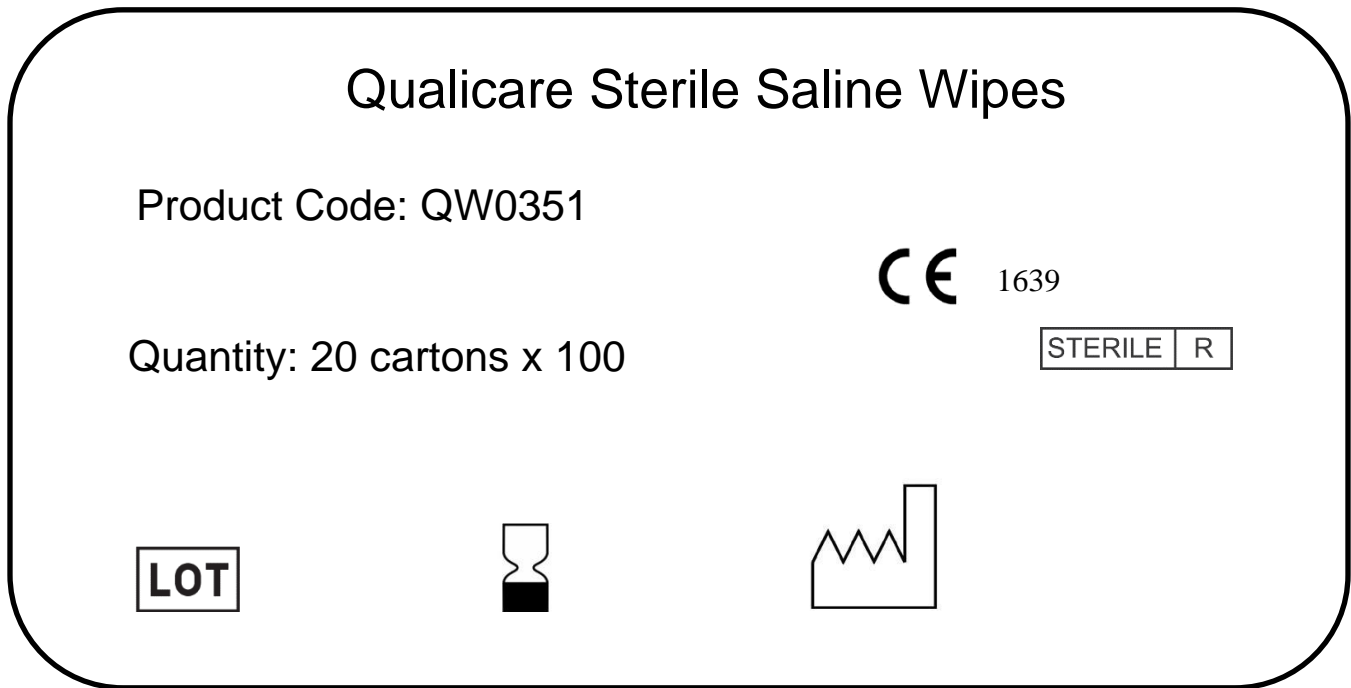


Logistical Details:

Shipper Carton Label:

- The customer name, product description, carton quantity, case weight, lot number, expiry, date of manufacture, etc will be printed onto the shipper carton label.
- The shipper carton label will be affixed to the side of the carton along with the Gammatex™ sticker.

Approved Shipper Carton Label:



Documentation:

- Each delivery to the customer will have a packing slip identifying the purchase order, the product, the quantity, lot number(s) and applicable product details.
- The customer will receive the Certificate of Irradiation for the delivery.
- The customer will receive the Certificate of Conformity for the delivery.



A WORLD OF PROTECTION

> INDUSTRIAL > CONSUMER > MEDICAL

Specification and Artwork Approval:

On Behalf of Qualicare: _____ **Date:** _____

On Behalf of Naturelle: _____ **Date:** _____