Sterilization Pouches and Reels made of DuPont™ Tyvek®

SATISFY YOUR STERILE PACKAGING NEEDS
FROM THE TIME OF ASSEMBLY, UNTIL ASEPTIC PRESENTATION AT THE POINT OF USE

STERIS is a global leader in infection prevention, decontamination, endoscope reprocessing, surgical equipment and service. STERIS is present in over 100 countries with production & manufacturing facilities in 17 countries and 12,000 employees worldwide. Inspired by our Customers' efforts to create a healthier and safer world, and guided by our legacy of leadership and innovation, we strive to be a Great Company. Holding one of the broadest portfolios of products in the industry, we pride ourselves on excellence, and our sterile barrier systems are no exception.

Sterilization Tyvek® Pouches & Reels

Description

Tyvek® is a unique material used in sterile barrier systems. Tyvek® is known for its outstanding strength, durability, and tear resistance. As well as industrial use for EO and Gamma Sterilization, Tyvek® is also used for VHP™ (Vaporised Hydrogen Peroxide) Sterilization
Systems such as V-PRO™ Low Temperature Sterilizers and STERRAD Sterilization Systems.
o CE marked
o Conform to EN ISO 11607-1 and 2, and EN ISO 868-5
o Manufactured EN ISO 13485 Quality Systems in a Class 9 Cleanroom.

Order Code Description Size Qty

Sterilization Pouches made of DuPontTM Tyvek®
NWTP07520 Sterilization Tyvek Pouch 7.5 cm x 20 cm 1000/Pack.
NWTP1028 Sterilization Tyvek Pouch 10 cm x 28 cm 1000/Pack.
NWTP1530 Sterilization Tyvek Pouch 15 cm x 30 cm 1000/Pack.
NWTP2040 Sterilization Tyvek Pouch 20 cm x 40 cm 1000/Pack.
NWTP2545 Sterilization Tyvek Pouch 25 cm x 45 cm 750/Pack.
NWTP3060 Sterilization Tyvek Pouch 30 cm x 60 cm 750/Pack.

Sterilization Reels made of DuPontTM Tyvek®
NWTY0570 Sterilization Tyvek Reel (Flat) 5 cm x 70 cm 1 Reel.
NWTY7570 Sterilization Tyvek Reel (Flat) 7.5 cm x 70 cm 1 Reel
NWTY1070 Sterilization Tyvek Reel (Flat) 10 cm x 70 m 1 Reel
NWTY1570 Sterilization Tyvek Reel (Flat) 15 cm x 70 m 1 Reel
NWTY2070 Sterilization Tyvek Reel (Flat) 20 cm x 70 m 1 Reel
NWTY2570 Sterilization Tyvek Reel (Flat) 25 cm x 70 m 1 Reel
NWTY3070 Sterilization Tyvek Reel (Flat) 30 cm x 70 m 1 Reel
NWTY3570 Sterilization Tyvek Reel (Flat) 35 cm x 70 m 1 Reel
NWTY4070 Sterilization Tyvek Reel (Flat) 40 cm x 70 m 1 Reel
NWTY4570 Sterilization Tyvek Reel (Flat) 45 cm x 70 m 1 Reel

NWTY5070 Sterilization Tyvek Reel (Flat) 50 cm x 70 m 1 Reel

Manufacturing Process

STERIS Sterilization Tyvek® Pouches & Reels are manufactured in an ISO 9001 and ISO 13485 certified plant. As a requirement for certification, the plant has an established Quality System Manual.

This plant strictly complies with the environmental, health and safety regulations in force and conforms with Clean Room HVAC System Performance Qualifications according to ISO14644-1. All regulations and standards are followed during every step, from the purchase of raw materials to the delivery of the finished product.

As a requirement of ISO 11607-2 all equipment, machines and processes used for the manufacturing of STERIS Sterilization Tyvek® Pouches & Reels are validated. Standard Operation Procedure (SOP), general validation plan and IQ, OQ and PPQ plans and reports for manufacturing equipment are frequently updated and revised by the Quality Assurance Department.

In-House Laboratory

The product facilities benefit from and in-house laboratory providing state-of-the-art product quality control. Trained and specialized personnel are on hand to conduct the various sterilization packaging tests required by relevant product standards and can test chemical indicator performance according to ISO 11140-1.

In accordance with ISO 11140-1 all chemical indicator performance tests are conducted in a resistometer which conforms to ISO 18472. These highly accurate, computerized test autoclaves with adjustable sterilization parameters are specially designed for biological and chemical indicator testing.

Product Description

STERIS Sterilization Tyvek® Pouches & Reels are registered under Class 1 as accessories in compliance with the European Medical Device Directive 93/42/EEC with the amendment of 2007/47/EC. The CE mark is printed on the shipping carton labels to demonstrate their compliance with directive.

STERIS Sterilization Tyvek® Pouches & Reels are constructed of transparent multilayer PET/PE copolymer film web and Tyvek web in compliance with EN 868-9. Chemical process indicator for H2O2 plasma sterilization is applied on the Tyvek surface for intended sterilization methods.

STERIS Sterilization Tyvek® Pouches & Reels are constructed of Tyvek 2FS 1073B with H2O2

plasma chemical process indicator and PET/PE film web.

STERIS Sterilization Tyvek® Pouches & Reels is 1073B grade and is available with an imprinted chemical process indicator for hydrogen peroxide.

Intended Use

STERIS Sterilization Tyvek® Pouches & Reels are intended for use as packaging of medical devices to be sterilized in low temperature hydrogen peroxide sterilizers with and without plasma stages. Sterilization packaging will maintain its sterility until the point of use.

Sterilization Method

STERIS Sterilization Tyvek® Pouches & Reels are designed to be used in low temperature hydrogen peroxide sterilizers. The sterilization packaging provides a protection of the medical device from contamination of bacteria through its high and proven microbial barrier properties and will keep its sterility after successful sterilization until use of the sterilized medical device.

STERIS Sterilization Tyvek® Pouches & Reels is also suitable for ethylene oxide, formaldehyde and gamma sterilization methods. To ensure optimum sterility conditions, instructions for use, handling and storage condition recommendations should be taken in consideration and followed.

Characteristics of the Packaging

STERIS Sterilization Tyvek® Pouches & Reels are designed, produces and distributed to provide highest quality standards.

The main characteristics of the packaging:

- 3 independent seal lines
- Tear free 5 layers PET/PE film web
- Clean peel for aseptic presentation
- Proven microbial barrier properties
- Lead free water based chemical indicator
- Clear and accurate indicator color change
- Wide sealing temperature window (100°C - 120°C)
- Compatible with all Low Temperature Hydrogen Peroxide Sterilization Systems
- Wide range of product sizes and types

Instructions for Use

STERIS Sterilization Tyvek® Pouches are ready for use, the Tyvek sterilization reels need to be cut to required length and sealed at one end to form a ready to fill pouch.

1. Sharp ends of instruments must be covered with an instrument protector to prevent puncturing or cutting.
2. The medical device to be sterilized must be placed in the pouch and it should not be filled more than 75% of its capacity.
3. A gap of minimum 1.5cm between the material and each seal edge of the pouch must be left for a smooth airflow.
4. Before sealing, as much air as possible must be removed from the pouch.
5. The filled pouch must be sealed with a calibrated and validated heat sealer according to the manufacturer's recommendation.
6. STERIS Sterilization Tyvek® Pouches & Reels are suitable for sealing between 100°C - 120°C. Strength of the seal must assure a clean peel.
7. During the handling seal stress must be avoided by filling the pouch horizontally or by working on a flat surface.
8. When loading into the sterilizer the pouches must be placed into the basket in a way that film faces film and paper side faces paper side.
9. Sterilization pouches should be put upright in the basket or container and not too tight together so such that a hand can slide in between them.
10. Process the load according to established internal procedures.
11. Handle pouches with care when removing from the sterilizer to prevent puncturing or tearing. Store pouches in an area protected from sunlight, water and other liquids.
12. Do not use wet pouches. In case of wet pouches, change the packaging and repeat the sterilization process.
13. To open the pouch, use thumb and index finger to hold plastic side of the pouch and thumb and index finger to pull back the paper side of the pouch. Always open the pouch towards the opening direction. Open the pouch slowly for a clean and aseptic presentation.

Restrictions in Use

STERIS Sterilization Tyvek® Pouches & Reels are not designed to be used in dry heat and high temperature steam sterilization due to product's technical specifications. Packaging alternatives suitable for mentioned sterilization methods should be selected and used to provide optimum sterilization efficiency.

Product Size List

STERIS Sterilization Tyvek® Pouches & Reels is available in different types and dimensions to meet requirements of various medical devices to be packed and sterilized further.

Order Code Description Size Qty

NWTP07520 Sterilization Tyvek Pouch 7.5 cm x 20 cm 1000/Pack
NWTP1028 Sterilization Tyvek Pouch 10 cm x 28 cm 1000/Pack
NWTP1530 Sterilization Tyvek Pouch 15 cm x 30 cm 1000/Pack
NWTP2040 Sterilization Tyvek Pouch 20 cm x 40 cm 1000/Pack
NWTP2545 Sterilization Tyvek Pouch 25 cm x 45 cm 750/Pack
NWTP3060 Sterilization Tyvek Pouch 30 cm x 60 cm 750/Pack
NWTY0570 Sterilization Tyvek Reel (Flat) 5 cm x 70 cm 1 Reel
NWTY7570 Sterilization Tyvek Reel (Flat) 7.5 cm x 70 cm 1 Reel
NWTY1070 Sterilization Tyvek Reel (Flat) 10 cm x 70 m 1 Reel
NWTY1570 Sterilization Tyvek Reel (Flat) 15 cm x 70 m 1 Reel
NWTY2070 Sterilization Tyvek Reel (Flat) 20 cm x 70 m 1 Reel
NWTY2570 Sterilization Tyvek Reel (Flat) 25 cm x 70 m 1 Reel
NWTY3070 Sterilization Tyvek Reel (Flat) 30 cm x 70 m 1 Reel
NWTY3570 Sterilization Tyvek Reel (Flat) 35 cm x 70 m 1 Reel
NWTY4070 Sterilization Tyvek Reel (Flat) 40 cm x 70 m 1 Reel
NWTY4570 Sterilization Tyvek Reel (Flat) 45 cm x 70 m 1 Reel
NWTY5070 Sterilization Tyvek Reel (Flat) 50 cm x 70 m 1 Reel

Tyvek Web

Tyvek is a rather unique material in the stable packaging materials classification. It is known for its outstanding strength, durability and tear resistance. Tyvek is used for low temperature hydrogen peroxide gas plasma sterilization methods and has also industrial use for ethylene oxide, formaldehyde and gamma sterilization.

Tyvek is made of 100% High Density Polyethylene (HPDE) filaments, flashspun and bonded using heat and pressure. The unique multiple layer structure with high porosity enables the penetration of sterilization gases into the package while preventing the ingress of microorganisms.

STERIS Sterilization Tyvek® Pouches & Reels Tyvek webs are available in Tyvek 1073B grade is suitable for hydrogen peroxide gas plasma, ethylene oxide, formaldehyde and gamma sterilization methods.

Chemical Indicator

STERIS Sterilization Tyvek® Pouches & Reels are imprinted with a water based and non-toxic Type 1 chemical process indicator especially designed for hydrogen peroxide plasma sterilization. The indicator complies with ISO 11140-1 and fulfils the requirements of related standards.

The new H2O2 chemical process indicator offers a more stable and more accurate verification of successfully completed sterilization cycles.

Colour Change of Chemical Indicators

STERIS Sterilization Tyvek® Pouches & Reels use an environmentally friendly, water based, non-toxic indicator. The indicator is tested under different printing conditions and accelerated aging studies are applied to the indicator printed on Tyvek web.

	PRE Sterilization	POST Sterilisation
Colour change	Yellow	Blue

Indicator Performance Testing

Chemical process indicators are defined by the international standard ISO 11140-1 and must fulfil the requirements at all time. STERIS Sterilization Tyvek® Pouches & Reels H2O2 chemical process indicators have been tested by an independent and accredited laboratory for performance requirements according ISO 11401-1.

H2O2 Indicator Performance Testing

The provided test samples with new H2O2 chemical process indicator have been processed in ISO compliant and calibrated low temperature hydrogen peroxide resistometer for pass and fail cycles per Table 6 of ISO 11140-1.

The results of the performance testing verify that the new H2O2 indicator used for STERIS Sterilization Tyvek® Pouches & Reels performed as specified and met the requirements for a Type 1 hydrogen peroxide process indicator according ISO 11140-1.

Figure 1 | H2O2 Chemical Indicator Testing Report

TESTING RESULTS

Test Environment	Test Time	Test Temperature	Gas Concentration mg/L	Test Result
Absence of Hydrogen Peroxide	45 min ± 5 min	50°C ± 0.5°C	None	Acceptable
Hydrogen Peroxide Test At:	7 s ± 1 s		2.3mg/L ± 0.4mg/L	Acceptable
	6 min ± 1 s			Acceptable

TABLE 2

Indicator Accelerated Ageing Study

STERIS Sterilization Tyvek® Pouches & Reels samples printed with new H2O2 plasma indicator have been accelerated aged by effect of high temperature (58°C) and humidity (%70Rh). The accelerated ageing periods have been simulated for 6, 12, 24 and 36 months and further exposed to hydrogen peroxide plasma sterilization and the required color change controlled.

The new H2O2 plasma process indicator of accelerated aged STERIS Sterilization Tyvek® Pouches & Reels Tyvek sterilization packaging met the expected colour change performance after 6, 12, 24 and 36 months. All colour changes are in acceptable limits.

Laminated PET/PE Film Web

The film web used for STERIS Sterilization Tyvek® Pouches & Reels are constructed of transparent, reinforced multilayer (five) laminated PET/PE (Polyester/Polyethylene) film manufactured by specialists in PE film extrusion for hydrogen peroxide plasma sterilization. This special PE film for hydrogen peroxide plasma sterilization provide a very wide sealing temperature range and reliable seal to uncoated Tyvek web and ensures a fibre-free aseptic presentation every time. This PE film offers a clean and uniform peel, it can withstand sterilization procedures and its solvent-free production is more environmentally friendly.

Properties of PET/PE Film Web

STERIS Sterilization Tyvek® Pouches & Reels use specially developed laminated PET/PE film web for hydrogen peroxide plasma sterilization. The film web complies with requirements defined by the European Standard EN 868-5 and all properties listed in below table are fulfilled at any time.

Final Product Testing

STERIS is committed to meet customer expectations by highest quality and standard conforming products. Implemented and applied quality control stages and in-house and/or external laboratory tests help us to ensure high product quality and sustainable production outcome. All final product of STERIS Sterilization Tyvek® Pouches & Reels are tested in compliance to ISO 11607-1, ISO 11140-1 and EN 868-5.

Final Product Specifications

Quality control testing is applied during various manufacturing stages and to the final product in determined frequencies. STERIS Sterilization Tyvek® Pouches & Reels specific properties listed in below table are fulfilled at any time.

Properties	Unit	Value	Method	Frequency
Seal Width	mm	10±2 mm	EN 868-5 Annex D	For film and paper changes & every 2 hour.
Bubble Test	pcs	No leakage acc. Standard	ASTM F2096-04	Film and paper changed
Pinhole Determination	pcs	No pinhole acc. Standard	EN 868-5 Annex C	Each film roll

Dimension Control	cm	Refer to internal documentation	ASTM F2203-02 (13)	Film and paper changed
Leakage Test	pcs	No seal leaks acc. Standard	ASTM F 1929-98 (15)	Film and paper changed
Peel Direction	pcs	No fibers on the testing tape	EN 868-5 Annex E	Each printed roll
H2O2 Indicator Control	pcs	Color change from yellow to blue	Visual	Each printed roll
PET/PE film Bond Strength	N/15mm	>2,7 n/15 mm	ASTM F88	Each film roll
PET/PE film Delaminating	pcs	None Allowed	H2O2 Plasma Sterilization	Each film roll
Aseptic Presentation	pcs	No film or paper tear	Peel off / open slow	Each 2 hour of production
Bioburden Testing	pcs	Run and record	ISO 11737-1	At least every 3 month
Particles/Cleanliness	pcs	None Allowed	Visual	Each 2 hour of production
Microbial Barrier	pcs	Fulfill requirements of ASTM F1608	ASTM F 1608	Internal determined period
Wrinkles in Films or Seals	pcs	None Allowed	Visual	Each 2 hour of production
Jagged Edges	pcs	None Allowed	Visual	Each 2 hour of production
Stewed Printing	pcs	±2 mm	Visual	Each printed roll
Print Image	pcs	Artwork and readable	Visual	Each printed roll

Sterilization Efficacy Validation Test

Sterilization efficacy validation tests are used to determine the efficiency of medical sterilization packaging systems by processing them in a sterilizer validated to a sterility assurance level (SAL). Packaging are expected to meet the SAL at half cycle exposure time. On this report, Sterilization efficacy of STERIS Sterilization Tyvek® Pouches were determined by the overkill method per AAMI and ISO guidelines. STERIS Sterilization Tyvek® Pouches were processed in the STERIS V-PRO 1 Plus Lumen sterilization cycle which is validated to a SAL of 10-6 Geobacillus stearothermophilus spores. The SAL was achieved by inoculating of these spores in the most difficult locations to sterilize and sealing them within STERIS Sterilization Tyvek® Pouches. The pouches were processed at one-half the expected full cycle exposure time. Following exposure, the biological indicators were aseptically transferred to culture media and incubated as required. With this test method, sterilization was accomplished by demonstrating that a minimum 10-6 Geobacillus stearothermophilus spores were successfully killed in half cycle.

Bioburden Properties

The term bioburden is used to describe the population of viable microorganisms present on or in product and/or a sterile barrier system. STERIS Sterilization Tyvek® Pouches & Reels have been tested for bioburden after manufacturing process according ISO (11737-1) standard by an independent and

accredited test laboratory every 3 months. STERIS Sterilization Tyvek® Pouches & Reels are produced in a controlled and clean environment and provide a safe and effective barrier against microorganism by no bacteria growth.

Microbial Barrier Properties

STERIS Sterilization Tyvek® Pouches & Reels are proven and effective microbial barriers. Tyvek sterilization packaging have been tested for determining the microbial barrier properties following exposure to ASP, Sterrad 100NX at Standard Cycle by an external and accredited laboratory in the USA.

Tyvek sterilization packaging samples have been subjected to an aerosol of spores after exposure to Sterrad 100NX Standard Cycle sterilization process. Each packaging sample was loaded with stainless steel coupons, a biological indicator (BI) and a chemical indicator (CI). Following the exposure to microbial aerosol challenge, the BI's and stainless-steel coupons were aseptically transferred to culture media and incubated as required.

Following the full incubation period, negative test samples were inoculated with spores and incubated for forty-eight (48) hours per USP for growth promotion. The presence of growth verified the media could still support growth of a low number of challenge organism and that bacteriostatic substances did not inhibit growth.

- The test sample coupons demonstrated no growth following incubation of test samples.
- All positive controls were positive for growth
- All negative and environmental controls were negative for growth

STERIS Sterilization Tyvek® Pouches & Reels **are an effective microbial barrier following ASP, Sterrad 100NX, Standard Cycle.**

TEST RESULTS

Sample ID		Pouch # 1	Pouch # 2	Pouch # 3
LOT: 2213	1	N	N	N
	2	N	N	N
	3	N	N	N
	4	N	N	N
	5	N	N	N
	BI	N	N	N
Environmental Control – TSB 131209-1		N	N	N
Negative Control – TSB 131209-1		N	N	N
Positive Control –CycleSure BI		P	P	P
Negative Verification – LA12		P	P	P

Cytotoxicity Testing

Cytotoxicity testing is crucial to ensure biocompatibility of medical devices. This involves extracting leachable materials from the device or components and analyzing the leachable extracts for potentially harmful chemicals or cytotoxicity. STERIS Sterilization Tyvek® Pouches & Reels have been tested using MEM Elution Cytotoxicity Assay per USP and ISO methods after being processed in athe STERIS

V-Pro 1 Plus lumen sterilization cycle by an external and accredited laboratory in the USA.
After being exposed to V-PRO 1 Plus Lumen Sterilization, L929 mammalian fibroblast cells samples were plated, incubated and extracted within MEM Elution fluid for 24±2 hours. Following incubation, cell culture medium was aspired, and test samples were plated in triplicate with L929 cells and incubated for 48±2 hours. Following the full incubation period, the test samples met the USP and ISO 10993-5 requirements and STERIS Sterilization Tyvek® Pouches & Reels proved its non-toxicity.

STERIS Sterilization Tyvek® Pouches & Reels **are non-toxic following STERIS, V-PRO 1 Plus, lumen sterilization.**

Product Burst Test

Burst testing provides a quick means of assessing tendencies for a pouch to fail when it is exposed to a pressure differential. Pressure differentials may occur within a package during different situations, such as sterilization and transportation and it is important to ensure that the package can maintain integrity and therefore sterility throughout all reasonable circumstances. With this test, burst value of STERIS Sterilization Tyvek® Pouches & Reels was assessed per ASTM F1140.

Product Ageing Studies

Product ageing studies have been conducted to establish the product shelf life of STERIS Sterilization Tyvek® Pouches & Reels. Data obtained from these studies is based on conditions that simulate the effects of aging on the material and its properties. These product ageing studies consist of two parts; accelerated ageing and natural ageing for verification of shelf life under 'real-time' ageing conditions.

Accelerated Ageing

STERIS Sterilization Tyvek® Pouches & Reels have a product shelf life of 3 (three) years under recommended storage and handling conditions. Accelerated ageing study valid for 3 years has been applied according ASTM F1980 to ensure highest quality and to determine the product shelf life. Accelerated aged products have been tested for their product properties internally at the laboratory.

Natural (Real Time) Ageing

Natural ageing is essential for verification of test results obtained after accelerated ageing. STERIS Sterilization Tyvek® Pouches & Reels are stored under controlled and monitored environment and product physical property tests applied in a 6, 12, 18, 24 and 36 monthly period.
All data resulting from the testing have been evaluated and kept under record. The test results verify the shelf life of 3 (three) years for STERIS Sterilization Tyvek® Pouches & Reels under recommended storage conditions.

Product Packaging

The product packaging of STERIS Sterilization Tyvek® Pouches & Reels consists of three packaging types; the inner packaging, the outer packaging and the transport packaging. Each packaging is done after the final product quality control by trained personnel and by use of proper selected materials to ensure protection from dust and moisture during transportation and storage.

The inner packaging of Tyvek sterilization pouches is done in bundles of 250 pieces and wrapped with PP film. Tyvek Sterilization reels of 70 meter lengths are placed in PE bags single or in groups depending

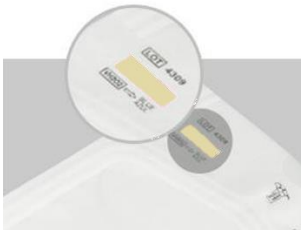
on the reel width.

For outer packaging of the products, double wall corrugated cardboard boxes as shipping cartons are used. The double wall corrugated structure provides higher protection against any kind of damages during transportation and handling.

The transport packaging as the final stage prior shipment, is done by use of 4way wooden and heat treated (according ISPM-15) pallets. Proper placed shipping cartons are wrapped with PP film for protection against dust and moisture and secured with edge protections and 12m wide PET belts.

LOT Number

STERIS Sterilization Tyvek® Pouches & Reels have a LOT number printed on the Tyvek bottom web. The LOT number allows the traceability of the product during the manufacturing process.

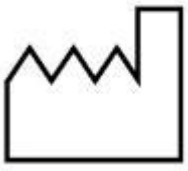


The LOT number is coded as follows:
LOT WWYY
- WW = Week of the year
- YY = Year of manufacturing

Expiry Date / Shelf Life

The shelf life of STERIS Sterilization Tyvek® Pouches & Reels is 3 (three) years after manufacture date under recommended storage and handling conditions.

The product must be used within 3 years from date of manufacture. The expiry date, as well as the manufacture date are printed on the product traceability labels and the shipping carton label.

 Manufacture Date Symbol
Dd.MM.yy

 Expiry Date Symbol
Dd.MM.yy

Storage Conditions

STERIS Sterilization Tyvek® Pouches & Reels need to be stored under following recommended storage conditions to ensure optimum product quality, microbial properties and expiry date.

Storage conditions are printed on each shipping carton labels and are also available at product related instructions for use.

- Stored in original packaging
- Stored under controlled temperature (max. 35°C)
- Stored under controlled humidity (max. %70 Relative Humidity)
- Stored protected from direct sunlight, moisture and excessive airflow

Product Traceability Label

Each Tyvek sterilization reel and pouch bundle is attached with a label including important product and manufacturing information. These labels are essential for product traceability and must be keep safe in case of any product related subjects. Each product traceability label contains following details;

- Product Item Code (Ref.)
- Lot Number
- Manufacture Date
- Expiry Date
- Machine No
- Roll / Pouch Bundle No
- Product specific barcode

6.5 Shipping Carton Label

Each shipping carton is attached with a label including essential product information and traceability data. Each label contains following details;

- Brand
- Product description
- Product Dimension
- Product Item Code
- Quantity

- Manufacture Date
- Expiry Date
- Lot Number
- Recommended storage conditions
- Product Barcode
- Manufacturer contact details
- CE Mark