Technical Data Sheet – HALYARD* sterilization wrap – H100

Description:

- HALYARD* Sequential Sterilization wrap H100
- HALYARD ONE-STEP* Sterilization wrap H100
- HALYARD* QUICK CHECK* Sterilization wrap H100

Dimensions:

Sequential		*One-Step*		*Quick Check*		*Size*
Ref	*QTY/ case*	*Ref*	*Appl / case*	*Ref*	*Appl / case*	
10712	1000					30 x 30 cm
10715	1000					38 x 38 cm
10718	1000			34156	480	45 x 45 cm
10720	1000	12720	480	34192	480	50x 50 cm
10724	500	12724	240	34178	240	60 x 60 cm
10730	300	12730	144	34176	144	76 x 76 cm
10736	300	12736	144	34194	144	91 x 91 cm
10740	250	12740	120	34200	120	101 x 101 cm
10745	250	12745	120			114 x 114 cm
10748	250	12748	120	34161	120	121 x 121 cm
10754	100	12754	96			137 x 137 cm
10772	100					137 x 182 cm

Indication: HALYARD sterilization wrap is a disposable packaging material intended for use in the sterilization of medical products and for the maintenance of their sterility until use of the products.

Composition: SMS Non-Woven (polypropylene)
Does not contain natural rubber latex. Does not contain DEHP.

Properties: Two sheets of 35.6g/m^2 (total 71.2g/m^2). ONE-STEP* and QUICK CHECK* is thermally sealed on the edges.
Melting point: 150°C. Treated with an anti-static treatment.
Can be safely incinerated. Under proper combustion conditions, it burns to give water vapour, carbon dioxide and some ash residue. The generated heat is approximately the same as that from home heating oil.
The product is classified as a class 1 product in terms of flammability (National Fire Prevention Association) i.e. slow burning fabric which have a flame spread time of 20 seconds or more.

Sterilization: Product is delivered non-sterile

Compatibility sterilisation modalities: Pre-vacuum steam sterilisation (4 minutes – 132°C; 30 minutes – 135°C)
Gravity steam sterilisation: 121°C – 30 minutes
Gas plasma sterilisation including:

- STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® 100S, STERRAD®100 FLEX scope, STERRAD®100 NX (EXPRESS, FLEX, Standard, Duo), STERRAD® NX (Advanced cycle, Standard cycle).
- STERIS® V-PRO 1 , STERIS® V-PRO 1 Plus, STERIS® V-PRO maX
- Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Cycle

Formaldehyde

Packaging: See table above for quantities per shipping case. Products are place within polyethylene bags.
Bar coding: GS1-128 symbology, linear, on shipping case and polyethylene bags.

Manufacturing: Non-woven manufactured in the USA. Product assembled in the USA or Mexico.

Regulatory Information: Product CE-marked as per 93/42/EEC Directive on Medical Devices. Class of the device: I
H100 sterilization wrap was tested as a Barrier System in accordance to EN ISO 11607 and is compatible with EN 868-2. Results are listed in the attached table.

Storage information: Store in a dry and cool place, away from intense sources of heat.

Shelf life: None specified

Parameter	*Test Method*	*Standard reference*	*Unit*	*Requirements*	*Results*[1]
		EN ISO 11607 - 1			
Microbial barrier (BFE)	ASTM F2101-07	5.2.3.	%		98.9
MPI testing steam[2]	LexaMed	5.2.3.	-	-	1 year: pass
MPI testing Sterilucent[2]	Cfr brochure HC465	5.2.3.			180 days: pass
Final pack test	TNO	5.2.3.	%	Max 99.9%	>99.9%
Gelbo lint testing	Inda Standard Test IST 160.1 (01)	5.1.7d	Avg. # of particles >10µM	-	3
Colour leach	ISO 6588 hot extraction	5.1.7a	-	-	No leach
pH	ISO 6588, hot extraction method	5.1.7f	-		5 - 8
Sodium Chloride content	ISO 9197-1, hot extraction method	5.1.7f	%		<0.005
Sodium Sulphate content	ISO 9198, hot extraction method	5.1.7f	%		<0.005
Fluorescence	DIN 58953-6: 1987	5.1.7f	-		Absence of fluorescence

Parameter	*Test Method*	*Standard reference*	*Unit*	*Requirements*	*Results*[1]
		EN 868-2			
Drapeability	ISO 9073-9	4.2.1.7	%	Informative	80.66
Tear resistance dry MD	EN21974 (ISO 1974)	4.2.2.3.1	mN	>750	3200
Tear resistance dry CD	EN21974 (ISO 1974)	4.2.2.3.1	mN	>1000	5202
Burst strength dry	ISO 2758	4.2.2.3.2	kPa	>130	270
Burst strength wet	ISO 3689	4.2.2.3.3	kPa	>90	277
Hydrostatic Head	IST 80.4 INDA	4.2.2.3.5	mbar	Under revision	59.5
Tensile strength dry MD	EN ISO 1924 – 2	4.2.2.3.6.	kN	>1.0	1.89
Tensile strength dry CD	EN ISO 1924 – 2	4.2.2.3.6.	kN	>0.65	1.13
Elongation MD	EN ISO 1924 – 2	4.2.2.3.4	%	>5%	30.8
Elongation CD	EN ISO 1924 – 2	4.2.2.3.4.	%	>7%	23.4
Tensile strength wet MD	ISO 3781	4.2.2.3.7.	N/m	>750	2199
Tensile strength wet CD	ISO 3781	4.2.2.3.7.	N/m	>500	1038
Air permeability	ISO 9237		cfm	>10	26.8

[1]Results valid for HALYARD* Sequential (2 layers), HALYARD ONE-STEP* and HALYARD* QUICK CHECK* (1 application = 2 layers).

[2]MPI testing includes handling, distribution and storage.