Halyard Sterilisationsvlies Sequential einlagig H100

pure¹¹-Nr.: 1114318, Marke: Halyard

Eigenschaften

- Breite in mm: 910 mm
- Länge in mm: 910 mm
- Material Packmittel & Entsorgungsbeutel: SMS
- Farbe: Blau
- Geeignet zur Dampf- oder EO-Sterilisation
- Marke: Halyard
- Flächengewicht in g/m²: 71,2 g/m²

Empfohlene Reinraumklassen

ISO 5 | 6 | 7 | 8 | 9

GMP A/B | C | D

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Material

-

Verpackung

- 300STK

Produktvarianten

pure[11]-Nr.: 1114318, Halyard Sterilisationsvlies Sequential einlagig H100

Abmessungen: 91x91cm; Farbe: Blau / VE: 300STK

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TECHNICAL DATA SHEET
HALYARD* Sterilisation Wrap – H100

CE

Description:

- HALYARD* Sequential Sterilisation wrap H100
- HALYARD* QUICK CHECK* Sterilisation wrap H100

Dimensions:

Sequential		*Quick Check**		*Dimensions*
Ref	*QTY/ 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	34192	480	50x 50 cm
10724	500	34178	240	60 x 60 cm
10730	300	34176	144	76 x 76 cm
10736	300	34194	144	91 x 91 cm
10740	250	34200	120	101 x 101 cm
10745	250			114 x 114 cm
10748	250	34161	120	121 x 121 cm
10754	100	34172	96	137 x 137 cm
10772	100			137 x 182 cm

Indication: HALYARD sterilisation wrap is a disposable packaging material intended for use in the sterilisation 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). QUICK CHECK* is thermally sealed on the edges.
Melting point: 150 - 180°C. Treated with an anti-static treatment.
Recycle, landfill or incinerate based upon state and local regulations. Recycle non-soiled wraps only.
The wrap is composed of polypropylene plastic which has a plastics recycling code of “5”.

Sterilisation: Product is delivered non-sterile

Compatibility sterilisation modalities: Pre-vacuum Steam (4 minutes – 132°C; 30 minutes – 135°C)
Gravity Steam: 121°C – 30 minutes
Compatible with EO sterilization
Compatible with gas plasma sterilization (STERRAD®, STERIS®, Sterilucent™)

Packaging: See table above for quantities per shipping case. Products are placed within polyethylene bags. Bar coding: GS1-128 linear or 2D on shipping case and polyethylene bags.

Manufacturing: Non-woven manufactured in the USA. Product assembled in the USA and in China.

Regulatory Information: Product CE-marked as per Medical Device Regulation MDR 2017/745. Class of the device: I H100 sterilisation wrap was tested as a Barrier System in accordance with EN ISO 11607-1:2020 and EN 868-2:2017. Results are listed in the attached table.

Storage information: Store in a clean, dust free location and away from fluorescent or ultraviolet light. Refer to EN ISO 11607 Packaging for terminally sterilized medical devices and/or local guidelines.

Shelf life: 5 years as of manufacturing date

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]	Validation per LexaMed Laboratories and, HighPower Validation Labs	5.2.3.	-	-	1 year: pass
MPI testing EtO, VH_2O_2, Gas H_2O_2, or VHP[2]	LexaMed Laboratories and, HighPower Validation Labs	5.2.3.			1 year: 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 6588-2 hot extraction	5.1.7a	-	-	No leach
pH	ISO 6588-2, hot extraction method	5.1.7f	-		5 - 8
Sodium Chloride content	ISO 9197, hot extraction method	5.1.7f	%		<0.05
Sodium Sulphate content	ISO 9198, hot extraction method	5.1.7f	%		<0.25
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	4.2.1.8	%	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	EN 20811	4.2.2.3.5	mbar	Document	77.4
Tensile strength dry MD	EN ISO 1924 – 2	4.2.2.3.6.	kN/ m	>1.0	2.48
Tensile strength dry CD	EN ISO 1924 – 2	4.2.2.3.6.	kN/ m	>0.65	1.31
Elongation MD	EN ISO 1924 – 2	4.2.2.3.4	%	>5%	31.2
Elongation CD	EN ISO 1924 – 2	4.2.2.3.4.	%	>7%	32.1
Tensile strength wet MD	ISO 3781	4.2.2.3.7.	N/m	>750	2437
Tensile strength wet CD	ISO 3781	4.2.2.3.7.	N/m	>500	1466
Air permeability	ISO 9237	4.2.2.4.6.	Cfm/ft^2	>10 (< 20 mm/s)	23.05

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

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