

TECHNICAL DATA SHEET

HALYARD* Sterilisation Wrap – H100



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/m² (total 71.2g/m²). 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®, Steriluent™)

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 11607-1 Packaging for terminally sterilized medical devices and/or local guidelines.

Shelf life:

5 years as of manufacturing date

<i>Parameter</i>	<i>Test Method</i>	<i>Standard reference</i>	<i>Unit</i>	<i>Requirements</i>	<i>Results¹</i>
		EN ISO 11607 - 1			
Microbial barrier (BFE)	ASTM F2101-07	5.2.3.	%		99.6 ³
MPI testing steam ²	Validation per LexaMed Laboratories and, HighPower Validation Labs	5.2.3.	-	-	1 year: pass
MPI testing EtO, VH ₂ O ₂ , Gas H ₂ O 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	-	3.1 ³
Colour leach	ISO 6588-2 hot extraction	5.1.7a	-	-	No leach ³
pH	ISO 6588-2, hot extraction method	5.1.7f	-		6 - 7 ³
Sodium Chloride content	ISO 9197, hot extraction method	5.1.7f	%		<0.05 ³
Sodium Sulphate content	ISO 9198, hot extraction method	5.1.7f	%		<0.25 ³
Fluorescence	DIN 58953-6: 1987	5.1.7f	-		Absence of fluorescence ³

<i>Parameter</i>	<i>Test Method</i>	<i>Standard reference</i>	<i>Unit</i>	<i>Requirements</i>	<i>Results¹</i>
		EN 868-2			
Drapeability	ISO 9073-9	4.2.1.8	%	Informative	84.99 ³
Tear resistance dry MD	EN21974 (ISO 1974)	4.2.2.3.1	mN	>750	4354 ³
Tear resistance dry CD	EN21974 (ISO 1974)	4.2.2.3.1	mN	>1000	5202 ³
Burst strength dry	ISO 2758	4.2.2.3.2	kPa	>130	298 ³
Burst strength wet	ISO 3689	4.2.2.3.3	kPa	>90	305 ³
Hydrostatic Head	EN 20811	4.2.2.3.5	mbar	Document	98.1 ³
Tensile strength dry MD	EN ISO 1924 – 2	4.2.2.3.6	kN/m	>1.0	2.24 ³
Tensile strength dry CD	EN ISO 1924 – 2	4.2.2.3.6	kN/m	>0.65	0.96 ³
Elongation MD	EN ISO 1924 – 2	4.2.2.3.4	%	>5%	33.8 ³
Elongation CD	EN ISO 1924 – 2	4.2.2.3.4	%	>7%	33.5 ³
Tensile strength wet MD	ISO 3781	4.2.2.3.7	kN/m	>750	2.30 ³
Tensile strength wet CD	ISO 3781	4.2.2.3.7	kN/m	>500	0.96 ³
Air permeability	ISO 9237	4.2.2.4.6	cfm or L/m ² /s	Informative	29.64 or 150.46 ⁴

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

²MPI testing includes handling, distribution and storage.

³Data on File. Test data generated by Centexbel Laboratories, Inc.

⁴Data on file. Physical Property Data, ISO 9237:1995 Textiles Determination of the permeability of fabrics to air Claim #08265.