



Reach Global India Pvt. Ltd.

TDS No.:

RGI/TDS/RPTS01

Rev. No.:

00

Technical Data Sheet (TDS)

Effective Date:

23.09.2021

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### Sterilization Heat Seal Pouch - Tyvek Paper

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<b>PRODUCT NAME</b>	RPT
<b>RELATED STANDARDS</b>	EN868-5 and ISO11607-1
<b>INTENDED USE</b>	Sterilization pouches as a packaging solution for sterilization applications, ensure the protection of the medical device against contamination with bacteria and chemicals from the time of sterilization until use of the sterile medical device.
<b>INSTRUCTION TO USE</b>	Seal the pouch properly from and after sterilization peel off from thumb notch. Do not use if found open Do not sterilize two times Store in dry place
<b>OPERATION CONDITIONS</b>	Sterilization Pouch is designed to use for steam sterilization at 121°C for 20 minutes and 134 °C for 5 minutes and 55°C -480min for ETO sterilization. Sterilization cycle for product is completed when chemical indicators Shows color change Pink Color to Cocoa and Blue color to Yellow/Brown

#### RAW MATERIAL SPECIFICATIONS:

	Properties	Unit	Results
Tyvek Paper	Material	NA	High density spun-bound polyethylene
	Type	visual	Uncoated
	color	visual	white
	Grammage	g/m <sup>2</sup>	75
	Thickness	Mm	0.22

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Office No. 1&2, Wing A, Sai Raj Regency, Pimple Saudagar, Pune - 411 027, Maharashtra, India.

+91 20 2740 9487 | info@orohealthcare.com | Customer Care No: +91 93707 88850/52/55 | www.orohealthcare.com

CIN U 74900PN2012PTC145221 GST: 27AAGCR1308D1ZS



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### RAW MATERIAL SPECIFICATIONS:

	Properties	Unit	Results
Tyvek Paper	Tensile Strength MD	N/15 mm	NLT 40
	Tensile Strength MD	N/15 mm	NLT 40
	Tensile Strength CD	N/15 mm	NLT 20
	Seal Strength MD	N/15 mm	NLT 1.50
	Seal Strength CD	N/15 mm	NLT 1.50
	PET-CPP Film	Color	Visual
Grammage		g/m <sup>2</sup>	48-57
Thickness		mm	0.08
Bond Strength		g/15mm	350-370
Peel Strength		g/15mm	400
Pantone ink	Color	NA	Blue
	Solvent	NA	Water based
	Toxicity	NA	Non toxic
Indicator Ink	color	NA	Pink coloured Blue Colored
	Solvent	NA	Water based
	Toxicity	NA	Non toxic

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**PRODUCT SPECIFICATIONS:**

<b>Description</b>	Sterilization heat seal Pouch
<b>Material Composition</b>	Tyvek paper and PET-CPP Film
<b>Testing Frequency</b>	Every lot
<b>Test Method</b>	EN868-5

Sr. No	Parameters	Specification
1.	length	As per below chart
2.	Width (mm)	As per below chart
3.	Heat seal width	10 mm
4.	Repeat length	As per width of pouch
5.	Indicator length x width	22 mm x 5mm
6.	Intensity of tearing	NLT 1.5 N
7.	Eye-mark	3mm x 15mm
8.	Thumb notch	16mm x 8mm

**Size of heat-Seal pouch:**

Sr. No.	Length x Width (mm)
1	50mm x 205mm
2	50mm x 220mm
3	57mm x 100mm
4	57mm x 125mm
5	60mm x 130mm
6	60mm x 330mm
7	70mm x 225mm
8	75mm x280mm
9	90mm x 165mm
10	90mm x 260mm

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Sr. No.	Length x Width (mm)
11	100mm x 130mm
12	100mm x 150mm
13	100mm x 280mm
14	100mm x 330mm
15	134mm x 283mm
16	135mm x 280mm
17	150mm x 180mm
18	150mm x 275mm
19	190mm x 360mm
20	200mm x 280mm
21	220mm x 340mm
22	250mm x 300mm
23	250mm x 340mm
24	250mm x 400mm
25	260mm x 400mm
26	330mm x 395mm
27	330mm x 410mm
28	330mm x 450mm
29	400mm x 500mm

**PACKING AND STORAGE:**

Packaging Flow	Sterilization heat seal pouch have tertiary packing LD polythene bag –Mono box-outer carton
Packing condition	200 pouch/ Mono box Outer box packaging changes as per size of pouch
Storage	Store in cool and dry place
Expiry	Three years from the date of Manufacture

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