



安庆市宜人纸塑包装材料有限公司

"YOU CAN TRUST YIPAK"

ANQING YIPAK PACKAGING MATERIAL CO., LTD



**EC DECLARATION OF CONFORMITY**  
(Regarding Medical Device Regulation (2017/745))



**Manufacturer:**

**Name:** Anqing Yipak Packaging Material Co., Ltd.

**Address:** No. 10, Liuji Industrial Park, Development Zone, Anqing, Anhui, China

**EC REP:**

**Name:** Shanghai International Holding Corp. GmbH (Europe)

**Address:** Eiffestrasse 80, 20537 Hamburg, Germany

**Products:**

Product Name	Basic UDI code
Flat Sterilization Roll	697025684000189
Gusseted Sterilization Roll	69702568400028B
Self-Seating sterilization Pouch	69702568400038D
Heat-sealing Sterilization Pouch	69702568400048F
Gusseted Heat-Sealing Sterilization Pouch	69702568400058H
Tyvek Sterilization Roll	69702568400068K
Tyvek Sterilization Pouch	69702568400078M
Sterilization Paper Bags	69702568400088P
Nonwoven Wrapping Material	69702568400098R
Sterilization Wrapping Paper	69702568400108A
Sterilization Indicator Tapes	69702568400118C
Sterilization Indicator Strip	69702568400128E
Bowie-Dick Test Pack	69702568400138G
Dental Cotton Roll	69702568400148J

**Type:** See Annex of details

**Classification:** Class I, According to EU Medical Device Regulation (2017/745), Rule 1, Annex VIII

Anqing Yipak Packaging Material Co., Ltd. declares that products above mentioned meet the requirements of Medical Device Regulation and the following harmonized standards:

EN 868 part 2, 3 & 5

EN ISO 11607-1:2017

EN 550

EN 552

EN 556

EN ISO 11140-1,4,5

BP2012

EN ISO 14971:2012

EN ISO 15223-1:2016

EN1041:2008

EN ISO 10993-1:2018

EN ISO 10993-5:2009

No.10, Liuji Industrial Park, Development Zone, Anqing, Anhui China.

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EN ISO 10993-10:2013

Under Quality System conforming to ISO 9001:2016  
ISO 13485:2016

**Signature:** Mr. Long Sheng

**Position/Title:** General Manager

**Date:** April. 14th, 2021

**Anqing Yipak Packaging Material Co., Ltd.**

A handwritten signature in black ink, appearing to be the name "Long Sheng" in a cursive style.





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# Annex

NO.	Product Name	Model No.	Product Size	Packing Quantity
1.	平面灭菌卷袋 Flat Sterilization Roll	YFSR60-050	50mm*200m	12rolls/carton
		YFSR60-055	55mm*200m	10rolls/carton
		YFSR60-075	75mm*200m	8rolls/carton
		YFSR60-100	100mm*200m	6rolls/carton
		YFSR60-120	120mm*200m	4rolls/carton
		YFSR60-125	125mm*200m	4rolls/carton
		YFSR60-150	150mm*200m	4rolls/carton
		YFSR60-200	200mm*200m	2rolls/carton
		YFSR60-250	250mm*200m	2rolls/carton
		YFSR60-300	300mm*200m	2rolls/carton
		YFSR60-350	350mm*200m	2rolls/carton
		YFSR60-380	380mm*200n	2rolls/carton
		YFSR60-400	400mm*200m	2rolls/carton
		YFSR60-450	450mm*200m	2rolls/carton
		YFSR60-500	500mm*200m	2rolls/carton
		YFSR60-550	550mm*200m	2rolls/carton
		YFSR60-600	600mm*200m	2rolls/carton
		YFSR70-050	50mm*200m	12rolls/carton
		YFSR70-055	55mm*200m	10rolls/carton
		YFSR70-075	75mm*200m	8rolls/carton
		YFSR70-100	100mm*200m	6rolls/carton
		YFSR70-120	120mm*200m	4rolls/carton
		YFSR70-125	125mm*200m	4rolls/carton
		YFSR70-150	150mm*200m	4rolls/carton
		YFSR70-200	200mm*200m	2rolls/carton
		YFSR70-250	250mm*200m	2rolls/carton
		YFSR70-300	300mm*200m	2rolls/carton
		YFSR70-350	350mm*200m	2rolls/carton
		YFSR70-380	380mm*200n	2rolls/carton
		YFSR70-400	400mm*200m	2rolls/carton
YFSR70-450	450mm*200m	2rolls/carton		
YFSR70-500	500mm*200m	2rolls/carton		
YFSR70-550	550mm*200m	2rolls/carton		
YFSR70-600	600mm*200m	2rolls/carton		



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2.	立体灭菌卷袋 Gusseted Sterilization Roll	YGSR60-075	75mm*100m	8rolls/carton
		YGSR60-100	100mm*100m	6rolls/carton
		YGSR60-120	120mm*100m	4rolls/carton
		YGSR60-125	125mm*100m	4rolls/carton
		YGSR60-150	150mm*100m	4rolls/carton
		YGSR60-200	200mm*100m	2rolls/carton
		YGSR60-250	250mm*100m	2rolls/carton
		YGSR60-300	300mm*100m	2rolls/carton
		YGSR60-350	350mm*100m	2rolls/carton
		YGSR60-380	380mm*100m	2rolls/carton
		YGSR60-400	400mm*100m	2rolls/carton
		YGSR60-450	450mm*100m	2rolls/carton
		YGSR60-500	500mm*100m	2rolls/carton
		YGSR60-550	550mm*100m	2rolls/carton
		YGSR70-075	75mm*100m	8rolls/carton
		YGSR70-100	100mm*100m	6rolls/carton
		YGSR70-120	120mm*100m	4rolls/carton
		YGSR70-125	125mm*100m	4rolls/carton
		YGSR70-150	150mm*100m	4rolls/carton
		YGSR70-200	200mm*100m	2rolls/carton
		YGSR70-250	250mm*100m	2rolls/carton
		YGSR70-300	300mm*100m	2rolls/carton
		YGSR70-350	350mm*100m	2rolls/carton
		YGSR70-380	380mm*100m	2rolls/carton
		YGSR70-400	400mm*100m	2rolls/carton
		YGSR70-450	450mm*100m	2rolls/carton
YGSR70-500	500mm*100m	2rolls/carton		
YGSR70-550	550mm*100m	2rolls/carton		
3.	特卫强卷袋 Tyvek Sterilization Roll&Pouch	YTR-050	50mm*100m	12rolls/carton
		YTR-075	75mm*100m	8rolls/carton
		YTR-100	100mm*100m	6rolls/carton
		YTR-120	120mm*100m	4rolls/carton
		YTR-125	125mm*100m	4rolls/carton
		YTR-150	150mm*100m	4rolls/carton
		YTR-200	200mm*100m	2rolls/carton
		YTR-250	250mm*100m	2rolls/carton
		YTR-300	300mm*100m	2rolls/carton
		YTR-350	350mm*100m	2rolls/carton
		YTR-380	380mm*100m	2rolls/carton
		YTR-400	400mm*100m	2rolls/carton
		YTR-450	450mm*100m	2rolls/carton
		YTR-500	500mm*100m	2rolls/carton
		YTR-550	550mm*100m	2rolls/carton
YTR-600	600mm*100m	2rolls/carton		
4.	自封灭菌袋 Self-sealing Sterilization Pouch	YSP-057130	57mm*130mm	200pcs/box, 30boxes/carton
		YSP-090165	90mm*165mm	200pcs/box, 20boxes/carton
		YSP-070260	70mm*260mm	200pcs/box, 15boxes/carton
		YSP-090230	90mm*230mm	200pcs/box, 15boxes/carton
		YSP-090260	90mm*260mm	200pcs/box, 10boxes/carton
		YSP-135280	135mm*280mm	200pcs/box, 10boxes/carton
		YSP-135283	135mm*283mm	200pcs/box, 10boxes/carton
		YSP-140280	140mm*280mm	200pcs/box, 10boxes/carton
		YSP-160200	160mm*200mm	200pcs/box, 10boxes/carton
		YSP-190360	190mm*360mm	200pcs/box, 5boxes/carton
		YSP-190380	190mm*380mm	200pcs/box, 5boxes/carton



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		YSP-200320	200mm*320mm	200pcs/box, 5boxes/carton
		YSP-200360	200mm*360mm	200pcs/box, 5boxes/carton
		YSP-230395	230mm*395mm	200pcs/box, 5boxes/carton
		YSP-300420	300mm*420mm	200pcs/box, 5boxes/carton
		YSP-305430	305mm*430mm	200pcs/box, 5boxes/carton
		YSP-360360	360mm*360mm	200pcs/box, 5boxes/carton
		YSP-400400	400mm*400mm	200pcs/box, 3boxes/carton
		YSP-400535	400mm*535mm	200pcs/box, 2boxes/carton
		YSP-420600	420mm*600mm	200pcs/box, 2boxes/carton
		YSP-500630	500mm*630mm	200pcs/box, 2boxes/carton
5.	热封灭菌袋 Heat-sealing Sterilization Pouch	YFP/YGP/YTP-075260	7.5cm*26cm	6000pcs/carton
		YFP/YGP/YTP-080250	8cm*25cm	6000pcs/carton
		YFP/YGP/YTP-080120	8cm*12cm	6000pcs/carton
		YFP/YGP/YTP-1015	10cm*15cm	6000pcs/carton
		YFP/YGP/YTP-1025	10cm*25cm	4000pcs/carton
		YFP/YGP/YTP-1020	10cm*20cm	6000pcs/carton
		YFP/YGP/YTP-1215	12cm*15cm	6000pcs/carton
		YFP/YGP/YTP-1518	15cm*18cm	4000pcs/carton
		YFP/YGP/YTP-1520	15cm*20cm	4000pcs/carton
		YFP/YGP/YTP-1530	15cm*30cm	2000pcs/carton
		YFP/YGP/YTP-2025	20cm*25cm	2000pcs/carton
		YFP/YGP/YTP-2030	20cm*30cm	2000pcs/carton
		YFP/YGP/YTP-2040	20cm*40cm	1600pcs/carton
		YFP/YGP/YTP-2526	25cm*26cm	2000pcs/carton
		YFP/YGP/YTP-2535	25cm*35cm	1600pcs/carton
		YFP/YGP/YTP-2530	25cm*30cm	1600pcs/carton
		YFP/YGP/YTP-3040	30cm*40cm	1000pcs/carton
		YFP/YGP/YTP-3045	30cm*45cm	1000pcs/carton
		YFP/YGP/YTP-3050	30cm*50cm	800pcs/carton
		YFP/YGP/YTP-3060	30cm*60cm	600pcs/carton
		YFP/YGP/YTP-3550	35cm*50cm	800pcs/carton
		YFP/YGP/YTP-3545	35cm*45cm	800pcs/carton
		YFP/YGP/YTP-4050	40cm*50cm	800pcs/carton
		YFP/YGP/YTP-4055	40cm*55cm	500pcs/carton
		YFP/YGP/YTP-4060	40cm*60cm	500pcs/carton
		YFP/YGP/YTP-4550	45cm*50cm	500pcs/carton
YFP/YGP/YTP-4560	45cm*60cm	500pcs/carton		
YFP/YGP/YTP-5060	50cm*60cm	500pcs/carton		
YFP/YGP/YTP-5070	50cm*70cm	500pcs/carton		
6.	医用皱纹纸 Sterilization Wrapping Paper	YCP-20	20cm*20cm	4000pcs/carton
		YCP-30	30cm*30cm	2000pcs/carton
		YCP-35	35cm*35cm	2000pcs/carton
		YCP-40	40cm*40cm	1000pcs/carton
		YCP-45	45cm*45cm	1000pcs/carton
		YCP-50	50cm*50cm	1000pcs/carton
		YCP-60	60cm*60cm	500pcs/carton
		YCP-75	75cm*75cm	250pcs/carton
		YCP-80	80cm*80cm	250pcs/carton
		YCP-90	90cm*90cm	250pcs/carton
		YCP-100	100cm*100cm	250pcs/carton
		YCP-120	120cm*120cm	200pcs/carton
		YCP-120140	120cm*140cm	200pcs/carton
		YCP-120160	120cm*160cm	200pcs/carton
		YCP-120180	120cm*180cm	200pcs/carton
		YCP-140	140cm*140cm	200pcs/carton



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		YCP-140160	140cm*160cm	100pcs/carton
		YCP-140180	140cm*180cm	100pcs/carton
7.	医用包装无纺布 Nonwoven Wrapping Material	YSM-20	20cm*20cm	2000pcs/carton
		YSM-30	30cm*30cm	2000pcs/carton
		YSM-35	35cm*35cm	2000pcs/carton
		YSM-40	40cm*40cm	1000pcs/carton
		YSM-45	45cm*45cm	1000pcs/carton
		YSM-50	50cm*50cm	500pcs/carton
		YSM-60	60cm*60cm	500pcs/carton
		YSM-75	75cm*75cm	250pcs/carton
		YSM-80	80cm*80cm	250pcs/carton
		YSM-90	90cm*90cm	250pcs/carton
		YSM-100	100cm*100cm	250pcs/carton
		YSM-120	120cm*120cm	200pcs/carton
		YSM-140	140cm*140cm	200pcs/carton
		YSM-120140	120cm*140cm	100pcs/carton
		YSM-120160	120cm*160cm	100pcs/carton
		YSM-120180	120cm*180cm	100pcs/carton
		YSM-140160	140cm*160cm	100pcs/carton
		YSM-140180	140cm*180cm	100pcs/carton
8.	灭菌指示胶带 Sterilization Indicator Tape (Steam, ETO gas, Plasma, formaldehyde)	YST-1250	12mm*50m	1roll/bag, 76rolls/carton
		YST-1850	18mm*50m	1roll/bag, 48rolls/carton
		YST-1950	19mm*50m	1roll/bag, 48rolls/carton
		YST-2250	22mm*50m	1roll/bag, 36rolls/carton
		YST-2550	25mm*50m	1roll/bag, 36rolls/carton
		YST-1255	12mm*55m	1roll/bag, 76rolls/carton
		YST-1855	18mm*55m	1roll/bag, 48rolls/carton
		YST-1955	19mm*55m	1roll/bag, 48rolls/carton
		YST-2255	22mm*55m	1roll/bag, 36rolls/carton
		YST-2555	25mm*55m	1roll/bag, 36rolls/carton
		YET-1250	12mm*50m	1roll/bag, 76rolls/carton
		YET-1850	18mm*50m	1roll/bag, 48rolls/carton
		YET-1950	19mm*50m	1roll/bag, 48rolls/carton
		YET-2250	22mm*50m	1roll/bag, 36rolls/carton
		YET-2550	25mm*50m	1roll/bag, 36rolls/carton
		YET-1255	12mm*55m	1roll/bag, 76rolls/carton
		YET-1855	18mm*55m	1roll/bag, 48rolls/carton
		YET-1955	19mm*55m	1roll/bag, 48rolls/carton
		YET-2255	22mm*55m	1roll/bag, 36rolls/carton
		YET-2555	25mm*55m	1roll/bag, 36rolls/carton
		YPT-1250	12mm*50m	1roll/bag, 76rolls/carton
		YPT-1850	18mm*50m	1roll/bag, 48rolls/carton
		YPT-1950	19mm*50m	1roll/bag, 48rolls/carton
		YPT-2250	22mm*50m	1roll/bag, 36rolls/carton
		YPT-2550	25mm*50m	1roll/bag, 36rolls/carton
		YPT-1255	12mm*55m	1roll/bag, 76rolls/carton
		YPT-1855	18mm*55m	1roll/bag, 48rolls/carton
		YPT-1955	19mm*55m	1roll/bag, 48rolls/carton
		YPT-2255	22mm*55m	1roll/bag, 36rolls/carton
		YPT-2555	25mm*55m	1roll/bag, 36rolls/carton
		YFT-1250	12mm*50m	1roll/bag, 76rolls/carton
		YFT-1850	18mm*50m	1roll/bag, 48rolls/carton
		YFT-1950	19mm*50m	1roll/bag, 48rolls/carton
YFT-2250	22mm*50m	1roll/bag, 36rolls/carton		
YFT-2550	25mm*50m	1roll/bag, 36rolls/carton		



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		YFT-1255	12mm*55m	1roll/bag, 76rolls/carton
		YFT-1855	18mm*55m	1roll/bag, 48rolls/carton
		YFT-1955	19mm*55m	1roll/bag, 48rolls/carton
		YFT-2255	22mm*55m	1roll/bag, 36rolls/carton
		YFT-2555	25mm*55m	1roll/bag, 36rolls/carton
9.	灭菌指示卡 <b>Sterilization Indicator Strip (Steam, ETO gas, Plasma, formaldehyde)</b>	YSIS-15100	15mm*100mm	200pcs/box, 100boxes/carton
		YSIS-18105	18mm*105mm	200pcs/box, 100boxes/carton
		YSIS-15802	15mm*80mm*2	250pcs/box, 40boxes/carton
		YSIS-151002	15mm*100mm*2	250pcs/box, 40boxes/carton
		YSIS-20107	20mm*107mm	200pcs/box, 100boxes/carton
		YSIS-2070	20mm*70mm*2	200pcs/box, 100boxes/carton
		YSIS-2075	20mm*75mm	200pcs/box, 100boxes/carton
		YEIS-15100	15mm*100mm	200pcs/box, 100boxes/carton
		YEIS-18105	18mm*105mm	200pcs/box, 80boxes/carton
		YEIS-15802	15mm*80mm*2	250pcs/box, 40boxes/carton
		YEIS-151002	15mm*100mm*2	250pcs/box, 40boxes/carton
		YEIS-20105	20mm*105mm	200pcs/box, 100boxes/carton
		YEIS-2075	20mm*75mm	200pcs/box, 100boxes/carton
		YPIS-15100	15mm*100mm	200pcs/box, 100boxes/carton
		YPIS-18105	18mm*105mm	200pcs/box, 80boxes/carton
		YPIS-15802	15mm*80mm*2	250pcs/box, 40boxes/carton
		YPIS-151002	15mm*100mm*2	250pcs/box, 40boxes/carton
		YPIS-20105	20mm*105mm	200pcs/box, 100boxes/carton
		YPIS-2075	20mm*75mm	200pcs/box, 100boxes/carton
		YFIS-15100	15mm*100mm	200pcs/box, 100boxes/carton
		YFIS-18105	18mm*105mm	200pcs/box, 80boxes/carton
		YFIS-15802	15mm*80mm*2	250pcs/box, 40boxes/carton
		YFIS-151002	15mm*100mm*2	250pcs/box, 40boxes/carton
		YFIS-20105	20mm*105mm	200pcs/box, 100boxes/carton
YFIS-2075	20mm*75mm	200pcs/box, 100boxes/carton		
10.	<b>Bowie-Dick 测试包</b> <b>Bowie-Dick Test Pack</b>	YBD-115125	115mm*125mm	1pc/bag, 100pcs/carton
11.	<b>牙科垫 Dental Bibs</b>	YDB-3345	33cm*45cm	125pcs/bag, 500pcs/carton
12.	灭菌纸纸袋 <b>Sterilization Paper Bags</b>	YPB-090150 A	90*50*150mm	1000pcs/ctn
		YPB-090250 B	90*50*250mm	1000pcs/ctn
		YPB-110190 C	110*30*190mm	1000pcs/ctn
		YPB-140250 D	140*75*250mm	1000pcs/ctn
		YPB-140330 F	140*50*330mm	500pcs/ctn
		YPB-140360 G	140*50*360mm	500pcs/ctn
		YPB-180380 H	180*95*380mm	500pcs/ctn
		YPB-100150 J	100*50*150mm	1000pcs/ctn
		YPB-250380 L	250*100*380mm	250pcs/ctn
		YPB-190330 P	190*65*330mm	500pcs/ctn
		YPB-110190 Q	110*45*190mm	1000pcs/ctn
13.	牙科棉卷 <b>Dental Cotton Roll</b>	YCR-0838	8mm*38mm	50pcs/band, 20bands/bag, 24bags/ctn
		YCR-1038	10mm*38mm	50pcs/band, 20bands/bag, 24bags/ctn
		YCR-1238	12mm*38mm	50pcs/band, 20bands/bag, 24bags/ctn

We not only offer above mentioned sizes, we also do customized sizes.