



## Compliance Report

**Applicant:** Anqing Yipak Packaging Material Co., Ltd.  
**Address:** NO.13, Liuji Industrial Park, Development Zone, Anqing, Anhui, China.

**Product:** Sterilization Pouches and Reels with Chemical Indicator (Steam/EO/Form) for Single Use, Steam-Sensitive Tapes, Steam-Sensitive Strips, Bowie-Dick Test Pack, Sterilization Paper Bags with Process Indicator for Single Use, Creped Wrapping Paper, Nonwoven Wrapping Material, Tyvek Pouches and Reels with Chemical Indicator(Plasma/EO) for Single Use, Dental Bibs

**Type:** See annex for details

**Product Classification:** Class I

**The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).**

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

No. **02474**

Initial Issue Date: **28 Jan 2016**

*Tony Chen*

General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.



## Annex to Report (No. 02474 )

Anqing Yipak Packaging Material Co., Ltd.

Product Name	Type
Sterilization Pouches and Reels with Chemical Indicator (Steam/EO/Form) for Single Use	57mmx135mm,70mmx260mm,90mmx260mm, 90mmx165mm,135x280mm,140mmx305mm, 190mmx360mm,190mmx380mm,305mmx430mm, 50mmx100mm,100mmx150mm,100mmx200mm, 150mmx250mm,250mmx370mm According to the customer request.
Steam-Sensitive Tapes	12mm × 50m,19mm × 50m,25mm × 50m
Steam-Sensitive Strips	15mmx100mm
Bowie-Dick Test Pack	125mmX115mm
Sterilization Paper Bags with Process Indicator for Single Use	90mmx50mmx150mm,90mmx50mmx250mm, 110mmx45mmx190mm,190mmx65mmx330mm, 90mmx50mmx170mm,100mmx50mmx170mm, 110mmx30mmx190mm,140mmx50mmx330mm, 140mmx75mmx250mm,180mmx95mmx380mm, 250mmx100mmx380mm,300mmx60mmx530mm, 75mm × 150mm,100mm × 200mm, 100mm × 250mm,115mm × 200mm, 115mm × 245mm,150mm × 250mm, 150mm × 280mm,200mm × 330mm, 230mm × 280mm,230mm × 380mm, 250mm × 320mm,300mm × 390mm, 300mm × 450mm According to the customer request

This annex is only valid if attached to the report mentioned above.



**Annex to Report (No. 02474 )**

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

Product Name	Type
Creped Wrapping Paper	30*30cm,40*40cm,45*45cm,50*50cm,60*60cm, 75*75cm, 90*90cm,100*100cm,120*120cm According to the customer request
Nonwoven Wrapping Material	30*30cm,40*40cm,45*45cm,50*50cm,60*60cm, 75*75cm, 90*90cm,100*100cm,120*120cm According to the customer request
Tyvek Pouches and Reels with Chemical Indicator (Plasma/EO) for Single Use	75mm×100m,100mm×100m,150mm100m, 200mm×100m,250mm×100m,300mm100m, 350mm×100m,400mm×100m,75mmx70m, 100mmx70m,150mmx70m,200mmx70m, 250mmx70m,300mmx70m,350mmx70m,400mmx70m According to the customer request
Dental Bibs	330mmx450mm

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