



ISTITUTO SERVIZI  
EUROPEI TECNOLOGICI

**ISET S.r.l.**

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## CERTIFICATE OF COMPLIANCE

Certificado de Conformidade - Сертификат соответствия - Konformitätserklärung

**1) APPLICANT:**

Anqing Tianrun Paper Packaging Co.,Ltd.  
East of Jingshi Road,South of weilu Road,Daqiao  
Development Area,Anqing City,Anhui province,China

**2) CERTIFICATE NO.:**

IT050944TR150817S

**TCF(S) NO.:**

TCF(14)-250-MDD

**3) WITH REFERENCE TO EC DIRECTIVE APPLIED:**

Medical Device Directive 93/42/EEC

**HARMONIZED STANDARDS APPLIED:**

EN ISO 11607-1:2009,EN 868-5-2009,  
EN ISO 10993-1:2009,EN ISO10993-5:2009,  
EN ISO 10993-10:2010,EN ISO15223:2012,  
EN ISO 14971:2012,EN ISO 14155-1:2009

**4) CERTIFICATION ISET MARK:**

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**5) PRODUCT CHARACTERISTICS:** Medical Packaging Material

**MODEL(S):**Medical Paper,Medical Dialysis Paper, Medical Film, Medical Composite Film,  
Medical Sterilization Pouch,Medical Sterilization Roll,Medical PE Pouch,Easy-Peel Pouch,  
Sticher Paper Pouch,Tyvek Pouch,Tyvek Roll,Medical Paper-Plastic Pouch, Medical Crepe Paper,  
Medical Indicator Tape/Strip/Label,BD Test Pack, Dental Bib,Non-Woven Fabric.

**REMARK:** CE marking and EC declaration are duties of the manufacturer before the putting into service of its product on market. The verification has been carried out on voluntary application of the manufacturer based only on the documents prepared and provided by the manufacturer itself. The manufacturer is responsible to maintain the internal production control to ensure the compliance of the product. ISET declines any liability with reference to any other document, product or test report that hasn't been submitted to evaluation.

**6) DATE OF ISSUE:** 17/08/2015

**DATE OF EXPIRE:** 16/08/2020

**CERTIFICATION MANAGER:**

  
