



ARJOWIGGINS

**TECHNICAL INFORMATION NOTICE**  
**TO Nan Tong Fuhua Medical Packing Co.,LTD**

**Address :** 1#A Area XinKai industrial Park,  
XinFu Road ,  
Nan Tong Development Zone,  
Jiangsu Province  
CHINA

The porous product hereafter :

**PRODUCT DESIGNATION**

**ETHYPEL KF 60GSM**

**CODE**

**0850000**

complies with the EN ISO 11607-Part 1 requirements : *Packaging for terminally sterilized medical devices - Part 1 requirement for materials, sterile barrier systems and packaging systems*, when :

- used according following sterilization method :
  - o Ethylene oxyde (54°C / 90min)
  - o Gamma ray (25kGy)
- within 5 years after its manufacturing date,
- with stockage according to the following conditions
  - o Stored in the original packaging (protective polyethylene wrapper)
  - o Stored in a cool, dry location away from strong sunlight or UV light (30 to 60% relative humidity; 50 to 104°F / 10 to 40°C)
  - o Use the earliest materials received first

Forming and sealing process have to be evaluated downstream since material is a coating base.

This information is based on our current knowledge. It applies to the sole product individually referred to herein.

Friday, 16 May 2008  
Regulatory Affairs Coordinator,

**JM GAILLARD**