

TECHNICAL DATA SHEET

STEAM EMULATING INDICATOR (CLASS 6)

PRODUCT CODE : **IS2601**

RELATED STANDARDS : PMSSteriTest Steam Emulating Indicator is classified as Class 6 according to ISO 11140-1 standard. CE marking is not applicable for indicator products, because this product is not considered a medical device under the clause of the EC-directive 93/42/EEC

INTENDED USE : PMSSteriTest Steam Emulating Indicators are cycle verification indicators that confirm the presence or absence of specific time and temperature parameters during a cycle. The products allows the end user to identify incorrect packaging, load problems and sterilization failures.

OPERATION CONDITIONS : Steam Emulating Indicators are designed operate at steam cycle 134°C - 3,5 minutes or 121 °C - 15 minutes operation conditions.

Before Sterilization



After Sterilization



CHEMICAL COMPOSITION : The sterilization indicator ink used for printing contains following components in ppm levels.

Water 35% (CAS # 7732-18-5)

Diacetone Alcohol 3% (CAS # 123-42-2)

Proprietary Mixture 62% (CAS # N/A)

Contains no substance classified as hazardous, which should be taken into account according to EC directives.

PRODUCT SPECIFICATIONS : Each box contains 250 pieces indicator printed carton sheets having size 25 mm x 60 mm. The indicator is printed as rectangle and it is temperature, time and steam concentration sensitive.

PACKAGING : 48 pieces in cardboard.



PMSSteriTest™