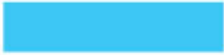





TECHNICAL DATA SHEET

BOWIE&DICK TEST PACK

- PRODUCT CODE** : **BD 3090**
- RELATED STANDARDS** : PMSSteriTest Bowie Dick Test Packs fulfill the performance requirements of ISO 11140-4. Indicator used is classified as Type 2 according to ISO 11140-1 standard. CE marking is not applicable for indicator products, because this product is not considered as medical device under the clause of the Medical Device Regulation (EU) 2017/745.
- INTENDED USE** : Bowie Dick Test Packs are designed for daily monitoring of air removal and steam penetration in pre-vacuum steam sterilizers. The Bowie-Dick test packs provide immediate visual evidence of inadequate air removal or air leak , vacuum pump failures, presence of non-condensable gases, high temperature, steam penetration, wet steam problems.
- OPERATION CONDITIONS** : Bowie Dick Test Packs are designed to operate in pre-vacuum steam sterilizers at 134 °C 3,5 minutes and 121 °C 15 minutes operation conditions. The color change should be checked with the sheet in the back of packaging to show if the parameters have been reached
- | <u>Before Sterilization</u> | <u>After Sterilization</u> |
|---|---|
|  |  |
|  |  |
- CHEMICAL COMPOSITION** : The sterilization indicator used in printing contains following components in ppm levels.
- | | | |
|--------------------|---------|--------------------|
| Isopropyl Acetate | % 15-20 | (CAS # 108-21-4) |
| Isopropyl Alcohol | % 15-20 | (CAS # 67-63-0) |
| Glycol Ether | % 1-5 | (CAS # 107-98-2) |
| Lead Carbonate | % 15-20 | (CAS # 1319-46-6) |
| Barium Thiosulfate | % 5-10 | (CAS # 35112-53-9) |
- Contains no substance classified as hazardous in concentrations, which should be taken into account according to EC directives.
- PRODUCT SPECIFICATIONS** : 95 mm x 125 mm white filling paper, 1 indicator printed test sheet in middle and 1 indicator printed control paper. Indicator printed test carton sheet is covered by film.
- PACKAGING** : 48 pieces in cardboard.



PMSSteriTest™