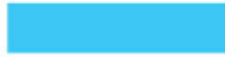


TECHNICAL DATA SHEET

STEAM HELIX TEST STRIP (CLASS 2)

- PRODUCT CODE** : **IS2410**
- RELATED STANDARDS** : PMSSteriTest Helix indicator is classified as Class 2 according to ISO 11140-1 standard. CE marking is not applicable for Helix product, because this product is not considered a medical device under the clause of the MDR (EU) 2017/745 Medical Device Regulation.
- INTENDED USE** : PMSSteriTest Helix indicator test strips are designed for air removal and steam penetration capability in pre-vacuum steam sterilizers. They provide immediate visual evidence of inadequate air removal or air leak, vacuum pump failures.
- OPERATION CONDITIONS** : PMSSteriTest Helix test strips are designed to operate at steam cycle 134°C - 3,5 minutes conditions.

Before Sterilization



After Sterilization



- CHEMICAL COMPOSITION** : The sterilization indicator ink used for 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, which should be taken into account according to EC directives.
- PRODUCT SPECIFICATIONS** : Each bag contains 250 pieces Helix indicator strips. The indicator is printed as rectangle and it is temperature and steam concentration sensitive.
- PACKAGING** : 200 pieces in cardboard.



PMSSteriTest™