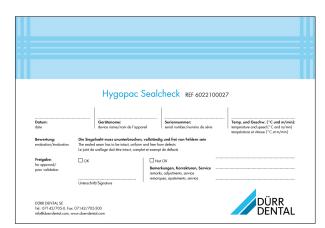
Product information Hygopac Sealcheck



6022100027 Hygopac Sealcheck 250 pieces

Product specification

- Control sheet for operational qualification of the sealing process and verification of the following sealing quality parameters:
 - o Intact seal seam along the complete sealing area
 - o No channels along length and open seam
 - o No punctures or tears to seam
 - o No delamination or peeling of sealing material
- The blue colour of the laminate is changing to a darker blue under the sealing area
- The industrial fabricated seal seams on both sides of the Hygopac Sealcheck are references for an intact, acceptable seal seam
- For documentation fill in, sign and file the Hygopac Sealcheck
- The Hygopac Sealcheck can also be used for the peeltest (to verify the tensile strength in comparison with the industrial fabricated seal seam) and for the dye penetration / ink test for seal seam integrity
- In case of defects corrective actions adjustments have to be implemented and the test should be repeated until the acceptable result is achieved

Norms

In accordance with ISO 11607-2:2006

Informationen

- The Hygopac Sealcheck is a ready to use test designed for daily operational qualification of the sealing process
- This part of the ISO 11607 establishes the requirements for the development and validation of packaging processes for medical products, which are sterilized in a sterile barrier system The validation shall include at a minimum, an installation qualification, an operational qualification, and a performance qualification
- Operational qualification in sealing process is to obtain and document evidence that the sealer operates within predetermined limits when used in according with its operational procedures
- The critical sealing parameters are temperature, time/speed and pressing force
- These parameters have to be adjusted as per the manufacturer's instructions for the packaging material

Information regarding the sealing temperature

Set the temperature of the sealing device to 165 °C-190 °C

Technical Data

 The Hygopac Sealcheck is constructed of medical grade paper (70g/m²) and a multiply PET/PP-plastic laminate (12/40 microns)

Storage recommendations and shelf life

- Storage in original, closed transport carton, in dry and clean conditions
- Temperature: + 15° C bis + 25° C
- Protect from direct sunlight and excessive moisture
- Relative humidity: 35% 50% RH
- The recommended "Best before" date and the manufacturing date are stated on the carton label
- The shelf life is event-related

