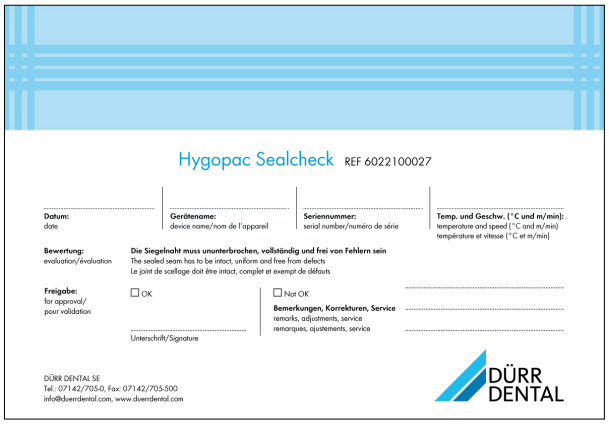
Product information Hygopac Sealcheck


Hygopac Sealcheck REF 6022100027

Datum: date

Gerätename: device name/nom de l'appareil

Seriennummer: serial number/numéro de série

Temp. und Geschw. (°C und m/min): temperature and speed (°C and m/min) température et vitesse (°C et m/min)

Bewertung: evaluation/évaluation

Die Siegelnaht muss ununterbrochen, vollständig und frei von Fehlern sein
The sealed seam has to be intact, uniform and free from defects
Le joint de scellage doit être intact, complet et exempt de défauts

Freigabe: for approval/ pour validation

☐ OK ☐ Not OK

Unterschrift/Signature

Bemerkungen, Korrekturen, Service remarks, adjustments, service remarques, ajustements, service

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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

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

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