

Instructions For Use



EN INSTRUCTIONS FOR USE

REF BM33002560 - AP | Seal Check 175mm

REF BM33002561 - AP | Seal Check NW Polyolefin fabric 175mm

Intended use

The Seal Check is intended to be used as verification tool to verify the sealing quality performed by a sealing machine. By inserting the Seal Check into the pouch/reel and by performing a seal, a clear indication of the seal quality will appear as result of the contrast pattern of the Seal Check. The width of the Seal Check is 175mm which ensures a complete coverage of the sealing wheel. All relevant information such as sealing machine number, location, date and results can be noted on the Seal Check.

Instruction for use of the product

- Perform a Seal Check at the start of each day for each heat sealer and if changing between different process (e.g. film/paper seal pouches and reels to film/polyolefin fabric (Tyvek®) and vice versa).
- Start the sealing machine and let it reach the operating temperature as per compliance with your facility/department policy for heat sealing for the specified materials and conform the materials manufacturer's instructions.
- Include the Seal Check into a suitable width of pouch/reel (min. 180mm width). Ensure that the edge of the contrast pattern is parallel to the edge of the pouch/reel on the side of where the seal takes place.
- Seal the pouch/reel by performing the heat sealing process.
- Evaluate the result of the test by checking the seal on the contrast pattern.
- Use the "Product result references" from this Instruction For Use to see if a Pass or Fail can be evaluated. If a Pass, then the cycle/test was successful. If a Fail, then the cycle/test was unsuccessful. The heat sealing system should be checked / maintained on its performance!

Intended users

- For professional use only!
- Central Sterile Services Department (CSSD) employees assigned for handling sterilization control products and ancillary products.
- Other professionals assigned for handling sterilization control products and ancillary products.

Indications and contra-indications

Use the product conform the information on the label. Do not use for any other purposes than indicated on the label or as specified under "Intended use".

User specifications

Handle, process and dispose in compliance with your facility/department policy and validated processes for sterilization. Use in compliance with the indicated standards which apply for this product (see Declaration of Conformity).

Standard process values

Heat sealing in compliance with your facility/department policy for heat sealing for the specified materials and conform the materials manufacturer's instructions.

Disposal information

Dispose in compliance with your facility/department policy for disposal of all sterilization packaging.

Residual risks

Risks if reused could be an incorrect representation of the tested cycle.

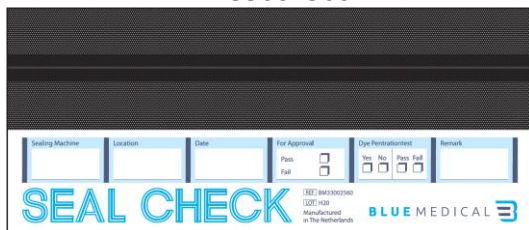
Do not use if any unexpected abnormalities appear in or on the product, such as, but not limited to inequalities in structure and/or color.

Avoid handling that could cause damage to the product or its properties.

Product result references

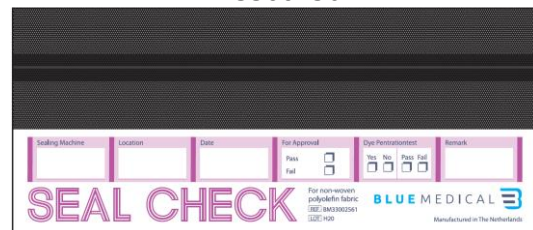
Only a clear, straight and complete seal present a Pass. The showed Fail results are indications only. The extent of the presence of the incorrect seal can deviate from the patterns below but will still indicate a Fail.

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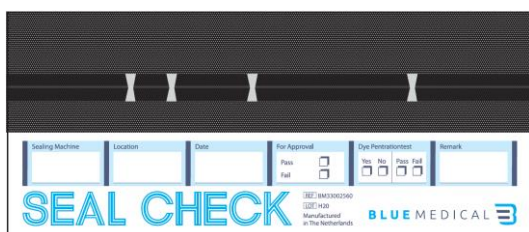


Pass

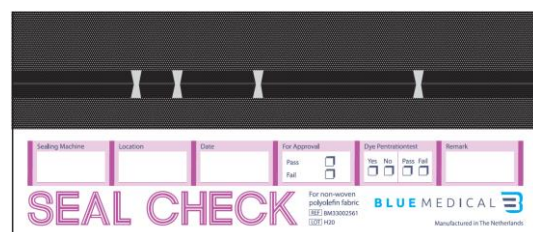
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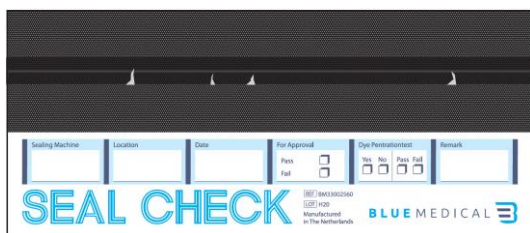
Pass



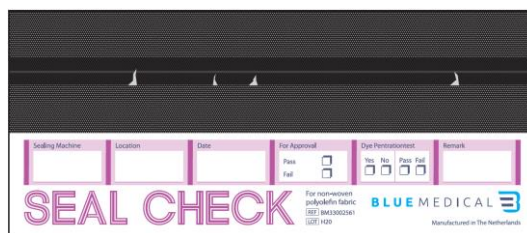
Fail!
Channel building.



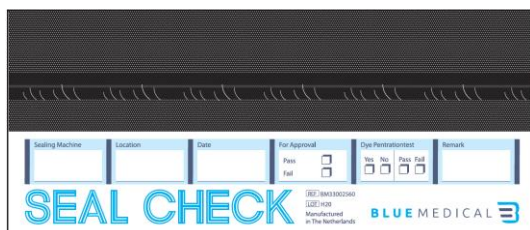
Fail!
Channel building.



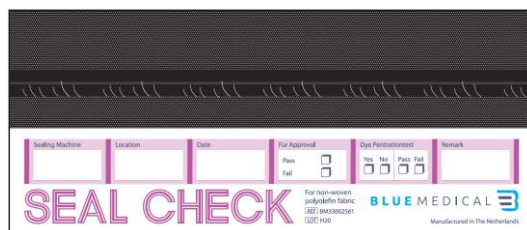
Fail!
Tearing.



Fail!
Tearing.

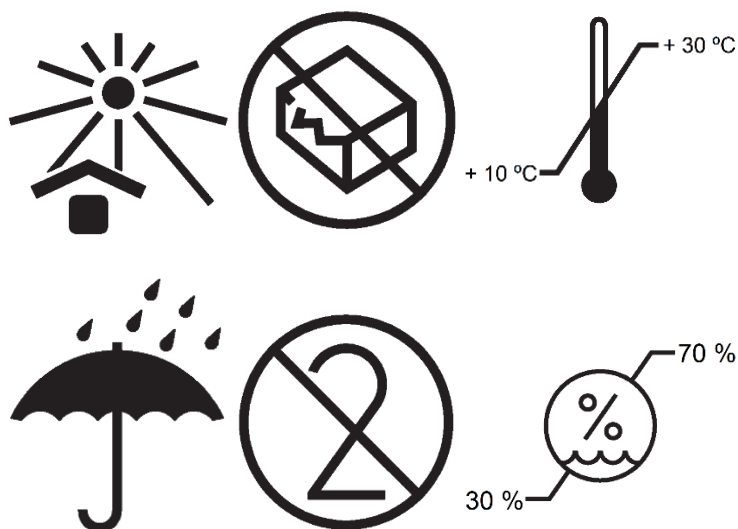


Fail!
Pressure or temperature wrong.



Fail!
Pressure or temperature wrong.

Notice: any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



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This Instructions for use is issued under the sole responsibility of Blue Medical B.V.. We hereby declare that the Instructions for use specified above meets the indicated standards. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Ms. Monique Buijsman
Operations Manager

Place, date (dd.mm.yyyy) of issue and version:

Zaandam, 08.03.2021, V1