Technical Data Sheet

Product name: **Seal Checker**

Product reference:

- ☑ 909.001.0250 Seal Checker

Applicable standards:

- ☑ ISO 11607 - 2 / ISO 868 part 3
- ☑ EN 980
- ☑ ISO 13485

Content:

Attachment(s):

- ☑ A Certificate of conformity
- ☑ B Examples of seal checker results

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1 Introduction

The ISO 11607 - 2 is describing the IQ,OQ and PQ procedures which are applicable to Medical Heat sealers. For Operational Qualification (OQ) and daily testing of your sealing device in accordance with EN ISO 11607-2 the Sterintech™ Seal Checker can be used as a indicator placed in between the layers of medical pouches and seal it. By its unique printed pattern of the black area the inspection of the seal and the detection of minor or bigger problems are easily detected.

2 Description

The Sterintech™ Seal Checker is designed and based upon the ISO 11607- part 2 and EN 868 - part 3 standard.

Guidelines of the DGSV and WFHSS are advising to test each medical heat sealer at the beginning of the day after the heat sealer has heated up. Based upon the initial test the heat sealer can be released for the day.

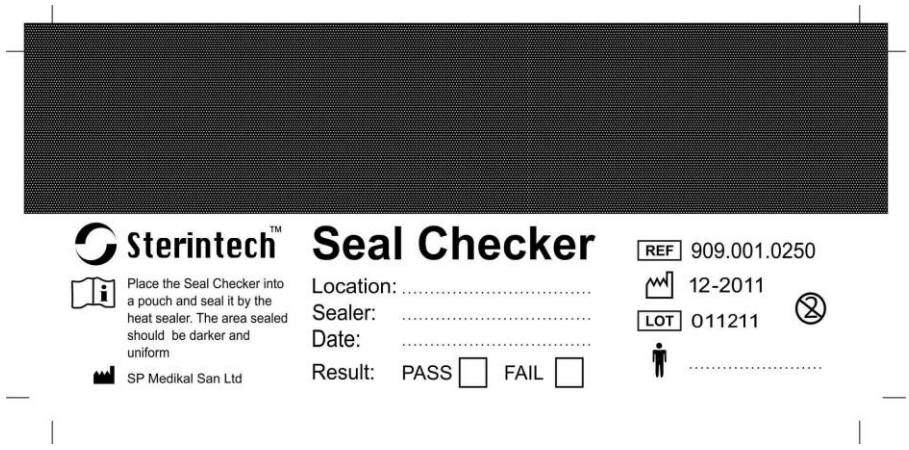
The Sterintech™ Seal Checker is a perfect aid in testing the medical heat sealer and to record the test data for each machine and each day.

The Seal Checker is used as a sheet which is placed in between the layers of a medical pouch with the face up to the laminate side of the pouch. The combination is then heat sealed after which one can read the test results quite easily.

As such the Seal Checker can display the following heat sealer problems:

✦- Sealing temperature too low
✦- Sealing pressure too low
✦- Interruptions in the seal

Lay-out of the Sterintech™ Seal Checker



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3 Confirmation to standards

The Sterintech™ Seal Checker is compliant to the following standard:

Procedure: **ISO 11607 - 2**
Materials: **ISO 868 - 3**

Pls refer to the attached Certificate of Conformity.

4 Raw Materials

The Sterintech™ Seal Checker is 175 x 75 mm (LxW) and consisting out of the following materials:

- Paper: 60 gr/m², Medical Grade
- Inks: Waterbased, non solvent, non-toxic, non-heavy metals

- Box: Carton
- Box Label: Vellum, Non-latex adhesive
- Manual: On product - not applicable

5 Quality assurance

The Sterintech™ Seal Checkers are produced in accordance with our ISO 13485 based and certified procedures. All working instructions and checking methods are laid-down in our Quality Assurance system which is audited twice a year internally and once year by external auditors.

All products produced by SP Medikal are traceable by lot numbers. Production files are recorded and kept for 5 years and by these every product can be traced and linked to raw materials used for the production of the product.

Re-call procedures are forming a part of our quality manual.

6 Packaging

The Sterintech™ Seal Checkers are packed in a carton box as specified under 4) 'Raw Materials' with the following dimensions: 180 x 80 x 25 mm (L x W x H). Each carton contains 250 pieces.

7 Storage conditions

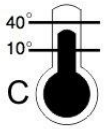
On each box label the storage conditions are mentioned which guarantees the product specifications within the expiry time. Claims of non-performance of the product are subject to registered storage conditions. SP Medikal is guaranteeing the performance of the products within the specified Expiry time unless the packaging was opened or damaged.

8 Explanation of Symbols

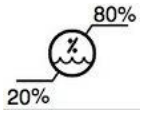
The following storage conditions symbols (EN 980) are used on the box:

Keep dry and away from fluids

Protect against UV light



Store at specified temperatures



Store at specified relative humidity

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9 Manufacturer's declaration

Interfering substances or conditions and release of toxic substances.

On this date there are no known interfering substances or conditions that are affecting the performance of the indicators as long as they are stored as per required storage conditions.

To the best of our knowledge there are no bleeding / staining effects or releases of toxic substances in the quantities which can cause a health hazard or hazard to the goods during sterilization.

The Sterintech™ Seal Ckecker are produced and packed in a climate controlled production room which has been designed based upon the GMP guidelines at the following location by:

SP Medikal San Ltd. Sti.
Topçular Mahallesi
Incirlik Sokak
Ertas Is Merkezi , No.: 5/65 Kat : 2
RamiSequential / Eyüp Istanbul
Turkey

Certificate of Conformity

We, SP Medikal San Ltd Sti., represented by undersigned, herewith declare that the

Sterintech™ Seal Checker with:

- REF.: 909.001.0250 SEAL CHECKER

are designed and compliant to the following standard:

Test requirements: ISO 11607-2, 2006:
Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

Materials: EN 868-3, 2009
Packaging for terminally sterilized medical devices. Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5). Requirements and test methods

Based upon these standards the Seal Checker can be used as a daily test for Medical Heat Sealers to release the heat sealer to be used during the day. Next to that the Seal Checker can be used for the operational qualification(OQ) as required per ISO 11607 - 2. Operational qualification (OQ) requires proof of (1) intact seal for a specific seal width, (2) No open channels of open seals, (3) No punctures or tears in seals, (4) No material de-lamination or separation

Seda Kücükyilmaz
Quality Department

Peter M. den Uil (B. Sc.)
Managing Partner

1st February 2012

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Attachment B: Examples of seal checker results
Good Seal result: straight and coherent seal lines.
Low temperature result: Lines are not coherent, bottom line is fluctuating in thickness

Transport disturbed while sealing. Wrinkles and folds in seals

Folded material leads to leaks: Happens when packed goods are too big for bag.

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