

PRODUCT SPECIFICATIONS

Title: SPSmedical Steam Indicator Dot Label

1. Scope and Classification

1.1 Scope - This specification covers a steam indicator label consisting of a paper label printed with a reactive ink designed to visually demonstrate exposure to steam sterilization conditions.

1.2 Classification - The following items are included in this specification:

<u>Part No.</u>	<u>Catalog No.</u>	<u>Description</u>
5097	SBD-038	3/8" steam indicator dot label, 2000/roll

2. Application Documents

- ANSI/ASQC Z1.4 - 1993
- Inspection Checklist

3. Requirements

3.1 Physical Properties

3.1.1 Paper - The paper stock used in the manufacture of the labels shall be a pliable stock with a 40 lb. face liner.

3.1.2 Adhesive - The adhesive shall be compounded for high temperature applications. The adhesive shall leave no residue when removed from muslin but will adhere to indicator tape and peel pouches.

3.1.3 Indicator Ink

3.1.3.1 Reactive Ink - The ink used in the steam indicator shall be a blue color in its unreacted form. They shall be manufactured in accordance to specified ink formulation and manufacturing procedures.

3.2 Description - Each label shall be a 3/8" circle being printed with chemically reactive ink. The printing configuration and legends on the label shall conform to artwork provided by SPSmedical.

3.3 Performance - The product shall meet the performance requirements identified beginning in section 4.5.1 of this product specification.

3.4 Workmanship - Workmanship shall be first quality throughout. Labels shall be free from performance and cosmetic defects. (See Table III for defect classifications.)

4. Quality Assurance Provisions

4.1 Certificates - Certificates from the manufacturer of each product component shall be required at the discretion of SPSmedical upon request. The certificates shall be signed by a responsible employee of the manufacturer.

4.2 Product Release/Acceptance is based on successful passage of all specified tests. If any test is not satisfactory, the production represented by the samples shall be segregated and quarantined. Further testing shall be performed as required to determine the appropriate disposition of the product.

4.3 Product Sampling - Sample sizes shall be in accordance with ANSI/ASQC Z1.4-1993 unless otherwise specified.

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4.5.2 Steam Hospital Sterilizer - Take samples of unprocessed labels and place them onto Aesculap container locks. Attach labels to Aesculap Steri containers and place in hospital size sterilizer.

<u>Parameter</u>	<u>Conditions</u>
Chamber temperature	270° ± 5°F (132 ± 2°C)
Exposure time	4 min.
Dry Time	20 min

4.7 Expected Test Results:

4.7.1 Complete Reaction Test - (4.5.1) The reactive ink shall have turned brown/dark brown.

4.7.2 Complete Reaction Test - (4.5.2) The reactive ink shall have turned brown/dark brown.

5. Packing and Labeling

5.1 Unit Packaging The unit package shall be 2,000 labels/ roll. Each roll is labeled with lot #, storage conditions and expiration date.

5.2 Intermediate Package Ten rolls of labels shall be placed in a bag and the twist tied closed.

5.3 Packing Shipping containers shall meet specifications for interstate commerce and shall be sized and packed to provide even load distribution and freedom from shifting of contents.