### 3M™ Comply™ 1322 and 1355 Lead Free Indicator Tapes for Steam Sterilization

#### Technical Data Sheet

**Product Description**

Comply 1322 and 1355 indicator tapes are designed for use with steam sterilization as a method of securing packs and identifying processed from unprocessed items. The 1322 tape can be used with both disposable and reusable wraps. The 1355 tape is used with disposable wraps only.

**Composition**

The 1322 and 1355 indicator tapes have similar construction. The same indicator ink chemistry is used for both products. The products differ in their paper backing color and adhesive. The Comply 1322 indicator tape is made up of the following components:

- **Paper backing**: The backing is a beige colored crepe paper (1322) or a blue colored crepe paper (1355), approximately 5 mils thick. The backing conforms easily to the contours of the packs, yet allows the tape to stretch as the pack expands during sterilization. This stretch helps minimize bundle popping (i.e., tape lifting, curling, or falling off).

- **Steam chemical indicator**: The tape is printed with a broken diagonal pattern of off-white chemical indicator stripes. The chemical indicator lines will show a visual color change from off-white/tan to dark-brown/black when exposed to a steam sterilization process.

- **Coating**: The coating is applied to the non-adhesive side of the crepe paper to allow the indicator tape to unwind easily but yet not interfere with the tape adhering to wraps.
**Pressure sensitive adhesive**

The 1322 tape adhesive is an aggressive, pressure-sensitive dry natural rubber adhesive designed to adhere to a variety of wraps, including treated and untreated woven, treated and untreated non-woven, paper and paper/plastic wraps in order to secure the pack during steam sterilization. The 1355 tape adhesive has been optimized for disposable wraps. After sterilization, the tape is designed to remove easily and cleanly from treated and untreated woven wraps. Remove tape section from reusable treated or untreated woven fabrics prior to laundry to prevent adhesive gumming that can occur during laundry procedures.

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**Technical Specifications**


Indicator shall not show the endpoint color after exposure to saturated steam for:
- a) 3 minutes at 121°C
- b) 30 seconds at 134°C.

Indicator shall show the endpoint color when after exposure to saturated steam for:
- a) 10 minutes at 121°C
- b) 2 minutes at 134°C.
Specifications

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Typical Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width</td>
<td>12 mm 18 mm 24 mm 48 mm</td>
</tr>
<tr>
<td>Length</td>
<td>55 m (60 yd).</td>
</tr>
<tr>
<td>Color change 3M release standard. Testing done on each lot of product.</td>
<td>Vacuum-assisted steam sterilizer: Complete color change when exposed to 132°C/270°F for 3 minutes sterilization, 1 minute dry time</td>
</tr>
<tr>
<td>Unwind (ability of tape to unwind from roll)</td>
<td>&gt; 29 ounces/in</td>
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<tr>
<td>Adhesion to glass (ability of tape to adhere)</td>
<td>&gt; 30 oz/in</td>
</tr>
</tbody>
</table>

Regulatory

FDA Classification: Comply chemical indicators are among devices identified as chemical sterilization process indicators. The classification of these products is set forth in the Code of Federal Regulation (CFR), Title 21, Chapter 1, Part 880, Subpart C, Section 880.2800 (b).

3M has taken steps necessary to comply with all applicable regulations for medical devices as outlined in CFR 21:

**Part 801 Labeling**
3M has a review system which assures compliance with this section.

**Part 803 Medical Device Reporting**
3M has a medical device reporting policy in place which assures compliance with the Medical Device Reporting regulations.

**Part 807 Establish Registration, Device Listing and Pre-market Notification Procedures**
3M™ Comply™ 1322 and 1355 Lead Free Indicator Tapes for Steam Sterilization are manufactured in a facility.
registered with the FDA (Establishment No. 1000283504). 3M has taken necessary steps to assure that this product is listed with the FDA as required by Part 807, Subpart B, Section 807.20 through 807.39, and Subpart C, Section 807.40. These products are in compliance with the Premarket Notification as required by Part 807, Subpart E, Section 807.81 through 807.100.

### Part 820 Quality System Regulation

These devices are manufactured in a facility which operates in compliance with FDA’s Medical Device Quality System Regulation.

These products are manufactured under a 3M quality system registered to ISO 9001:2000 and ISO 13485:2003 standards.

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Use the steam indicator tape on the outside of each package except when an internal chemical indicator is visible to demonstrate that packs have been exposed to the sterilization process and to distinguish between processed and unprocessed packs. Use a piece(s) of tape on the outside of the pack that is long enough to secure the pack. The 1322 tape is designed to secure packs wrapped with treated and untreated woven, treated and untreated non-woven, paper and paper/plastic wraps. The 1355 tape is designed to secure disposable wraps.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precautions</td>
<td>Do not use with dry heat, ethylene oxide, or other low temperature sterilization processes. DO NOT use the steam indicator tape to secure packs wrapped with barrier treated woven polyester fabrics. Potential problems may occur with marginal adhesion and/or adhesive residue.</td>
</tr>
<tr>
<td>Accessories/Attachments</td>
<td>3M™ Indicator Tape Dispensers are available in two models for dispensing sterilization indicator tape.</td>
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<tr>
<td>Safety</td>
<td>This product contains dry natural rubber.</td>
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<tr>
<td>Environment/Disposal</td>
<td>Consult the Material Safety Data Sheet (MSDS).</td>
</tr>
</tbody>
</table>
**Storage and Shelf Life**

Store in a dry (<50% relative humidity) condition at room temperature [15-30°C (59-86°F)]. Store away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents.

After use the indicator will not change visually within 6 months when stored at above conditions.

When stored at above recommended conditions, Comply 1322 and 1355 indicator tapes for steam sterilization have an 18 month shelf life from the date of manufacture. The expiration date is printed on the inside core of each roll of tape.

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