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.

Technical Specifications

ANSI/AAMI/ISO-11140-1:2005/(R)2010 and EN ISO 11140-1:2005 *Sterilization of healthcare products-Chemical indicators-Part 1: General requirements* defines performance requirements and classification of chemical indicators.

3M™ Comply™ Lead Free Indicator Tapes for Steam Sterilization: Class 1: Process indicator as classified by ANSI/AAMI/ISO 11140-1:2005/(R)2010 and EN ISO 11140-1:2005.

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°C.
b) 2 minutes at 134°C°C.

Specifications

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

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.

Intended Use

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.

Precautions

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.

Accessories/ Attachments

3M™ Indicator Tape Dispensers are available in two models for dispensing sterilization indicator tape.

Safety

This product contains dry natural rubber.

Environment/Disposal

Consult the Material Safety Data Sheet (MSDS).

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.

3M
Health Care
3M Center Building 275-4W-02
St. Paul, MN 55144-1000
USA
1 800 228-3957
www.3M.com/healthcare

©Mar2011