Main information

Description

This Technical and Compliance File relates to Sterilization Indicators (which come from our supplier 3000278) which is called below as “product”.

Quality Management System

Südpack Medica SAS complies with the requirements of ISO 9001:2015, ISO 13485:2016 and ISO 15378:2017.

Responsibilities

The information contained herein is based on the confirmations of the suppliers, chemical, physical and biological studies and our present state of knowledge. Users should consider these data only as a supplement to other information. A legally obligatory warranty of certain information as well as suitability for the specific application cannot be derived from this declaration. The determination of the specific suitability of this product for individual applications is the sole responsibility of the purchaser.

Applications

- This product reacts to all critical sterilization parameters.
- It has an excellent for record keeping, results will not revertor bleed.
- Instantly recognizable symbol “OK” is formed by ink and color reference.
- Best in class ink provides an unwavering diagnostic tool.
- Easy to read results: distinct color change to brown/black

Fail: Any incomplete change or non-uniformity in color indicates a fail result.

Pass: A solid black arrow and K indicate that sterilization parameters have been met. On 8” OK Strip, the indicator dot will also be solid dark brown/black.

Compatibility with sterilization

This product is suitable with the following sterilization method:

- Steam 121 °C (250°F) and 134°C (273°F)

REACH

REACH is the Regulation, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1St June 2007 to streamline and improve the former legislative framework on chemicals of the European Union (UE). Manufacturers and importers of chemicals and also all users are required to manage the risks that chemicals may pose to the health and the environment.

Südpack Medica SAS has the status if a Downstream User, has determined that the supplied articles do not requires any registrations/pre-registration with the ECHA, since there is no "international release" of chemical substances.

Based on information available from our raw material suppliers and at our current levels of knowledge, none substances or candidate substances of very high concern as published on the draft list issued by ECHA are present at 0,1% weight by weight.

Last update: ECHA - Candidate List of SVHC 23.01.2024

https://echa.europa.eu/candidate-list-table

If in future a new candidate material in the products we deliver to you be included at concentrations above 0.1% (w/w), we will voluntarily provide information under Article 33 of our legal and comply with REACH delivery.

Safety Data Sheet

As this product complies with REACH Regulation EC 1907/2006 (see above), it is considered non-hazardous and does not require a safety data sheet.

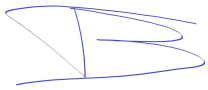
Validity of this Technical and Compliance File

This declaration is given in good faith and to the best of our current knowledge, according to our supplier's declaration. It doesn't release from the responsibility to check the suitability of packaging material for the proposed application.

This declaration is valid for 18 months after the date as stated on the top of this page only and expires thereafter, without any further notice being required. Furthermore, any information of this declaration may be subject to change at any time.

Technical Description – Sterilization Indicators (3000278)				
Strips	**Description**	**Type**	**Length**	**Packaging**
OK	Long indicator for use in large trays to ensure adequate steam throughout pack. Indicator dot imprint on the distal end of the 8” strip permits a secure sterile presentation.	Type 4 Chemical Indicator	8” (20 cm)	250/Per Box
SHORT OK	Ideal for small packs or placed in multiple locations in the tray.	Type 4 Chemical Indicator	4” (10 cm)	250/Per Box

Revision history		
Version	**Date**	**Subject of the review**
1	05/04/2024	Creation of the document. This document cancels and replaces the following documents: • Statement “REACH”

Signature
 Thomas BAZIN, Responsable Qualité Système 2024.04.05 14:17:16 +02'00'