

Instruction for use (IFU Steam Indicator 1-2023 version A)

This direction for use is applicable for the following Sterintech™ products:

Steam indicator:

104.003.0500 Type 4 Steam Indicator
104.004.0250 Type 4 Long strip with steam indicator
104.304.0250. Type 4 Long strip with steam indicator Self Adh.

Warnings:

Upon receipt of goods please check whether the package was undamaged and ensure you about the expiry date of the materials.

Introduction:

This Indicator is composed of a special paper strip and a special indicating steam ink which is turning into end color under steam sterilization conditions. The Indicator was developed based upon the use of non- toxic, heavy metal free inks. For more details please refer to the technical data sheet.

The Steam Indicator is giving a conclusion on the sterility of the container or pouch and its content.

Use recommendations:

This Steam Indicator can be used inside pouches, trays and baskets wrapped in sterile barrier systems, as well as inside instrument containers to check on local steam sterilization conditions.

Intended use:

This Indicator is recommended for the monitoring of Steam sterilization cycles.

Warning:

Do not use this Indicator in other type of sterilization cycles with a different SV.

Any serious incident that has occurred in relation to the Indicator should be reported to the manufacturer.

Instructions for use:

Place the Indicator inside the pouch, pack, basket, tray or container together the materials which will be sterilized.

Keep the Indicator away from the bottom of the object to prevent condensate to effect the results.

In rigid systems, as containers, place the indicator in each corner, or at least in two diagonally opposite corners to assure that steam has reached the most critical points at those places. Place pouches sideways / vertically in order to avoid the plastic film side to block the paper back side which might influence the effectiveness of the sterilizing agent.

Results interpretation:

If the indicator changes to the reference end color printed on the product, it indicates that the process reached the condition and the sterilization process was successful. If one or more sterilization parameters were not accomplished the indicator is not reaching its full end color. In the latter case the materials / instruments cannot be considered sterile and must be processed again.

Storage conditions:

Please take into consideration the storage conditions provided for at the box label of the product . Only in case the storage conditions were met, SP Medikal guarantee products compliance to standard within the expiry date.

Do not expose the Steam Indicators to sterilizing agents or other chemical products of any kind.

Compliance to standards:

The Indicators are compliant to standard ISO 11140 - 1: 2014.

Technical Data Sheet:











For these products technical data sheets are available in which reference to standards, packaging, certificates etc. are enclosed.


This Direction for use may be changed in the future.

Shelf life:

The indicators have a limited shelf life from manufacturing date, when stored in the recommended conditions. The manufacturing and expiry date as well as lot number are indicated on the packaging label. Do not use the indicators after the expiry date. After use, the indicator will maintain its color for a period of 5 years if stored under the given storage conditions.

Symbols declarations:

	Manufacturing date		Keep dry
	Manufacturer		Keep away from sunlight
	Reference number		Temperature limits
	Lot number		Relative Humidity limits
	Expiry Date		Warning sign

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