## Technical Data Sheet

Product name:

# Type 5 Steam Integrator with note area


Product reference:

☑ 105.203.0500 Type 5 Steam Integrator

Applicable standards:

☑ ISO 11140-1 : 2014
☑ ISO 15223-1
☑ ISO 13485

**Content:**



**Attachment(s):**

☑ A Certificate of conformity


SP Medikal San. Ltd. Şti.
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IBAN: TR36 0006 2000 4370 0009 0896 01
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## 1 Introduction

The Integrator is used as a indicator placed inside packs to detect sterilization conditions have been met at that particular place. It cannot serve to release loads and serve acknowledgement of proper sterilization to Operating Room staff.

## 2 Description

The Integrator is designed and based upon the ISO 11140 part 1 standard. The Integrator indicators are turning into their end-color when the combination of sterilization temperature, holding time and saturated steam presence have been sufficient. As such the Integrator can detect following problems:

✦- Sterilization temperature too low
✦- Sterilization temperature too high
✦- Sterilization holding time too short
✦- Sterilization holding time too long
✦- Insufficient steam penetration in loads (at the spot where the indicator is placed)

After opening the pack at the operating room and evaluating the color of the indicators to meet the reference color the Integrator can be stored or evidence can be recorded in the patient file. There is no legal need to store the Integrator as long as the result is recorded and signed for in the operating file or patient file.

The Integrator is changing color from initial color (blue) into its end color pink. (refer to REF color on the integrator). The indicators are calibrated upon the following temp/time combinations:

134ºC - 3,5 min / 121ºC - 15,0 min

**Lay-out of the Integrator**


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## 3 Confirmation to standards

The Sterintech™ Type 5 Integrator is compliant to the following standard:

**Chemical Indicator: ISO 11140-1: 2014 Type 5**

Pls refer to the attached Certificate of Conformity.

## 4 Raw Materials

The Sterintech™ Type 5 Integrator is 70 x 30 mm (LxW) and consisting out of the following materials:

- Carrier: Self-Adhesive Paper 170 gr/m²
- Inks: Indicator Ink: Waterbased, non solvent, non-toxic, non-heavy metals
  Lacquer: Waterbased, non-solvent, non-toxic
- Box: Carton
- Box Label: Not applicable
- Manual: Not applicable

## 5 Quality assurance

The Sterintech™ Type 5 Integrator are produced in accordance with our ISO 13485 based procedures. All working instructions and checking methods are laid-down in our Quality Assurance system which is audited twice a year internally and once year by external auditors.

All products produced by SP Medikal are traceable by lot numbers. Production files are recorded and kept for 10 years and by these every product can be traced and linked to raw materials used for the production of the product.

Re-call procedures are forming a part of our quality manual.

## 6 Packaging

The Sterintech™ Type 5 Integrator are packed in a carton box as specified under 4) 'Raw Materials' with the following dimensions: 75 x 140 x 33 mm (L x W x H). Each carton contains 500 pieces.

## 7 Storage conditions

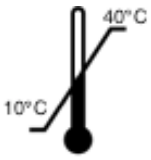
On each box the storage conditions are mentioned which guarantees the product specifications within the expiry time. Claims of non-performance of the product are subject to registered storage conditions. SP Medikal is guaranteeing the performance of the products within the specified Expiry time unless the packaging was opened or damaged.

## 8 Explanation of Symbols

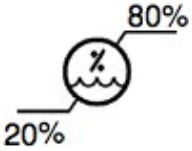
The following storage conditions symbols (ISO 15223-1) are used on the box:

Keep dry and away from fluids

Protect against UV light




Store at specified temperatures




Store at specified relative humidity

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## 9 Manufacturer's declaration

To the best of our knowledge there are no bleeding / staining effects or releases of toxic substances in the quantities which can cause a health hazard or hazard to the goods during sterilization.

The Sterintech™ Type 5 Integrator are produced and packed in a climate controlled production room which has been designed based upon the GMP guidelines at the following location by:

SP Medikal San Ltd. Sti.
Deliklikaya Mah. Cubuklu Cad. 39
Arnavutköy Istanbul
Turkey

# Certificate of Conformity

We, SP Medikal San Ltd Sti., represented by undersigned, herewith declare that the

Sterintech™ Type 5 Integrator with:

**- REF.: 105.203.0500 STEAM 134ºC - 3,5 min / 121ºC - 15 min**

have been tested in a CIER-Vessel at an independent Laboratory based upon the requirements as per ISO 11140 part 1.

We herewith confirm that the Integrator are designed and compliant to the following standard:

Chemical Indicator: ISO 11140-1, 2014:
**'Sterilization of health care products**
**Chemical indicators -- Part 1: 'General requirements'**

Based upon these tests the chemical indicator is Classified as Type 5

Chemical and Biological Indicators are not listed as a Medical Device in the MDD.

2 January 2021

Seda Kücükyilmaz
Quality Department

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Managing Partner

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