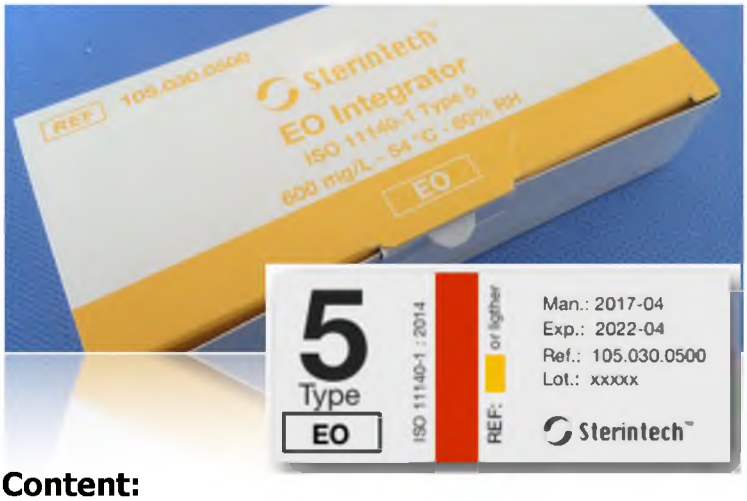
Technical Data Sheet

Product name:

EO integrator



Product reference:

☑ 105.030.0500 EO Integrator

Applicable standards:

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

Content:

Attachment(s):

☑ A Certificate of conformity

SP Medikal San. Ltd. Şti.
Deliklikaya Mah. Cubuklu Cad. No: 39
Arnavutköy-İstanbul/TÜRKİYE
C.o.C. Reg. No:76183

Tel : +90-212-613 80 54
Fax : +90-212-613 80 55
Email: info@spmedikal.com
Web : www.spmedikal.com

Bank: Garanti Bank - Istanbul - TURKEY
(EUR) Account No. : 9089601
(US$) Account No. : 9089602
VAT: Bayrampaşa - 781 046 3595

BIC : TGBATRIS Branch No.: 437
IBAN: TR36 0006 2000 4370 0009 0896 01
IBAN: TR09 0006 2000 4370 0009 0896 02

1 Introduction

The Sterintech™ EO 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 Sterintech™ EO Integrator designed and based upon the ISO 11140 part 1 standard.
The EO Integrator indicators are turning into their end-color when the combination of sterilization temperature, holding time and Ethylene-Oxide concentration have been sufficient.
As such the EO Integrator can detect following problems:

- ✦- Sterilization temperature too low
- ✦- Sterilization temperature too high
- ✦- Sterilization holding time too short
- ✦- Too low concentration of Ethylene-Oxide
- ✦- Insufficient Ethylene-oxide 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 indicator to meet the reference color the EO Integrator can be stored or evidence can be recorded in the patient file. There is no legal need to store the EO Integrator as long as the result is recorded and signed for in the operating file or patient file.

The Sterintech™ EO Integrator is changing color from initial color (see below) into yellow. The indicator are calibrated upon the following combinations:

- 600 mg/l EO concentration at 54°C - 60% RH

Lay-out of the Sterintech™ EO Integrator

SP Medikal San. Ltd. Şti.
Deliklikaya Mah. Cubuklu Cad. No: 39
Arnavutköy-İstanbul/TÜRKİYE
C.o.C. Reg. No:76183

Tel : +90-212-613 80 54
Fax : +90-212-613 80 55
Email: info@spmedikal.com
Web : www.spmedikal.com

Bank: Garanti Bank - Istanbul - TURKEY
(EUR) Account No. : 9089601
(US$) Account No. : 9089602
VAT: Bayrampaşa - 781 046 3595

BIC : TGBATRIS Branch No.: 437
IBAN: TR36 0006 2000 4370 0009 0896 01
IBAN: TR09 0006 2000 4370 0009 0896 02

3 Confirmation to standards

The Sterintech™ EO Integrator is compliant to the following standard:

Chemical Indicator: ISO 11140-1 Type 5

Pls refer to the attached Certificate of Conformity.

4 Raw Materials

The Sterintech™ EO Integrator is 55 x 25 mm (LxW) and consisting out of the following materials:

- Carrier:	Paper 200 gr/m²	(Self-Adhesive version : 180 gr/m²)
- Indicators:	Indicator Ink,	Waterbased, non solvent, non-toxic, non-heavy metals
- Box:	Carton	
- Box Label:	Not applicable	
- Manual:	Not applicable	

5 Quality assurance

The Sterintech™ EO Integrators 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™ EO Integrators are packed in a carton box as specified under 4) 'Raw Materials' with the following dimensions: 63 x 130 x 28 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:

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

SP Medikal San. Ltd. Şti.
Deliklikaya Mah. Cubuklu Cad. No: 39
Arnavutköy-İstanbul/TÜRKİYE
C.o.C. Reg. No:76183

Tel : +90-212-613 80 54
Fax : +90-212-613 80 55
Email: info@spmedikal.com
Web : www.spmedikal.com

Bank: Garanti Bank - Istanbul - TURKEY
(EUR) Account No. : 9089601
(US$) Account No. : 9089602
VAT: Bayrampaşa - 781 046 3595

BIC : TGBATRIS Branch No.: 437
IBAN: TR36 0006 2000 4370 0009 0896 01
IBAN: TR09 0006 2000 4370 0009 0896 02

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™ EO Integrators 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