

## Technical Data Sheet

Product name:

## Labelgun labels



Product reference:

- 602.xxx.9000 2 Line label gun labels
- 603.xxx.9000 3 Line label gun labels
- 604.xxx.9000 3 Line label gun labels

Applicable standards:

- ISO 11140-1
- EN 980
- ISO 13485

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## 1 Introduction

The Sterintech™ 2 and 3 line label gun labels are designed to be used in conjunction with the Sterintech™ label guns and provide in a documentation, registration and traceability of sterilization packaging by applying a label with relevant process data on each and every packaging before or after sterilization.

The 2 and 3 Line label gun Labels are available in labels with colors only, color and indicator combination and labels indicator only.

Indicators on the labels are available for STEAM, EO , FORM and Plasma sterilization cycles.

## 2 Description

As per Medical Device Directive all Medical Devices (incl. wrapped instrument trays) need to be provided with the following data on the outside of the pack:

- Sterilization Date
- Expiry Date
- Sterilization art
- Lot number
- Chemical Indicator (as proof that item has been processed)

The 2 and 3 line label gun Labels are providing all these data on a small label only. Both label gun labels are coming as piggy-back label only. The reason for that is that the data printed by the label gun on the label gun label can be used for traceability purposes by glueing the top part of the label into the patient's file at the operating room.

The Sterintech™ 2 and 3 line label gun label materials are characterized by the following:

- Compatible to STEAM, FORM, EO and Plasma sterilization methods
- Compliant to standard ISO 11140-1 (Class 1)

The reference numbers are giving details about size and quantity per unit as follows:

Example: 602.xxx.9000 : 2 Line Label gun label, quantity per unit is 9000 labels

Example: 603.xxx.9000 : 3 Line Label gun label, quantity per unit is 9000 labels

### 3 Lay-outs (2 line label gun labels)

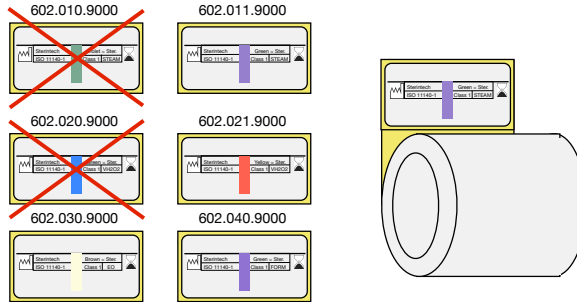
#### Sterintech design sheet for labels

16.6.2011 rev A

11.7.2011 rev B

02.1.2012 rev C

Product: 2 line label gun label (piggy back) with Indicator



Label dimension: 34 x 17mm  
Overall dimension: 36 x 19 mm  
Material: Piggy back, see spec  
Qty: 16 (h) x 6 (w) labels  
3 Cutting tools, one from bottom (T)  
3 Cliche, 1. black, 2. Indicator, 3. lacquer covering indicator  
Position of lines and text: see sample

#### Sterintech™ design sheet for labels

22.6.2011 rev A

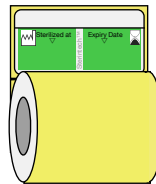
05.7.2011 rev B

03.2.2012 rev C

Product: 2 line piggy back label gun label COLORED



Label dimension: 34 x 17mm  
Overall dimension: 36 x 19 mm  
Material: Piggy back, see spec  
Qty: 16 (h) x 6 (w) labels  
3 Cutting tools, one from bottom (T)  
Position of lines and text: see sample

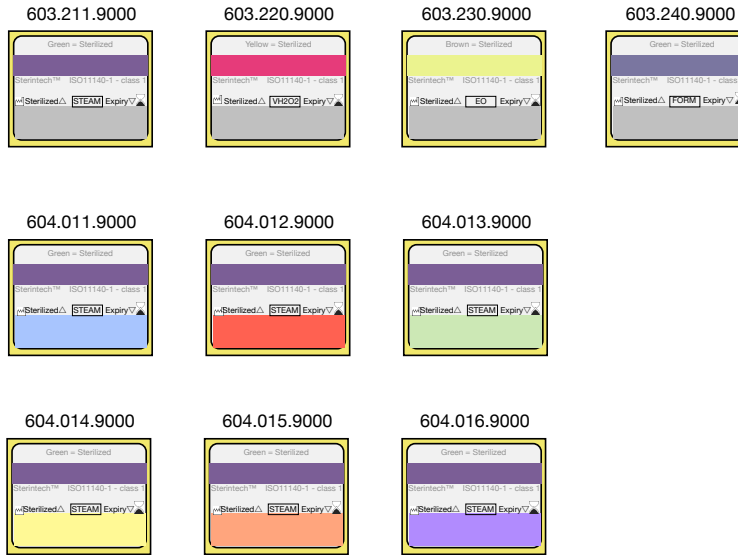


### 3 Lay-outs (3 line label gun labels)

#### Steritech™ design sheet for labels

24.04.2012 Rev A

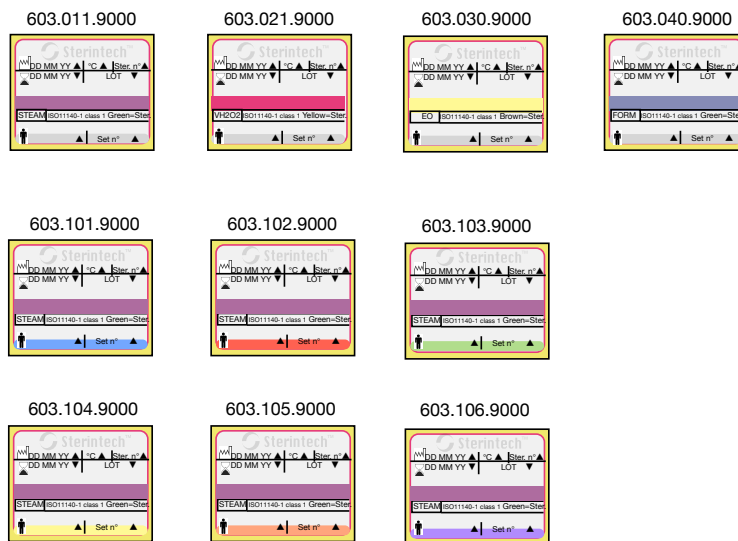
Product: 3 line label gun label with indicator and color



#### Steritech™ design sheet for labels

24.04.2012 Rev A

Product: 3 line label gun label with indicator and color - SP Design



#### 4 Raw Materials

The Sterintech™ Label gun label materials consists out of the following materials:

- Top Material (1x)

72 gr/m<sup>2</sup>, white, machine finished label material. Excellent performance with all kinds of printing equipment incl. thermo-transfer printing.

( in case of a Plasma label the top material is made out of 55 gr/m<sup>2</sup> (150um) Tyvek )

- Glue (2x)

Permanent acrylic based adhesive. High tack and outstanding peel adhesion on both polar and non-polar surfaces. It is resistant to light, heat and ageing. Max. service temperature: 150 degrees Celsius. Comply with recommendation FDA 21 CFR 175.105 (Adhesives).

- Liner (2x)

60 gr/m<sup>2</sup>, White , supercalendered glassine

- |              |                         |
|--------------|-------------------------|
| - Box:       | Carton                  |
| - Box Label: | Vellum , non latex glue |
| - Manual:    | Not Applicable          |

The inks used for text and indicator printing are all water-based, non-toxic inks.

#### 5 Quality assurance

The Sterintech™ Label gun labels 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 5 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™ 2 and 3 Line label gun labels are packed in a carton box as specified under 4) 'Raw Materials' . Each carton is designed to fit the proper size and quantities of the product and is carrying all product related details on a box label.

## 7 Storage conditions

On each box the storage conditions are mentioned which guarantees the product specifications within the expiry time.

The properties of label gun label materials are not altered in a significant proportion, if stored under the recommended conditions (refer to box label on the product).

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 or stored under different conditions than stipulated.

## 8 Explanation of Symbols

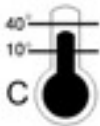
The following storage conditions symbols (EN 980) are used on the box:



Keep dry and away from fluids



Protect against UV light



Store at specified temperatures



Store at specified relative humidity

## 9 Manufacturer's declaration

The Sterintech™ 2 and 3 Line label gun label materials 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.  
Topçular Mahallesi  
İncirlik Sokak  
Ertas İş Merkezi , No.: 5/65 Kat : 2  
Rami / Eyüp İstanbul  
Turkey

The production is based upon our quality management in accordance with ISO 13485

## 10 Hazard, Safety and Health

Sterintech products, including Biological Indicators and Chemical Indicators as well as self-adhesive labels are manufactured using non-pathogenic organisms or materials which are not toxic or hazardous in nature.

The products do not pose harm to the user's safety thus a Material Safety Data Sheet (MSDS) is not required.

Direct contact with our non-biological products such as the Chemical Indicators and customized self-adhesive indicator labels poses no harm to the user's safety.

In summary, Biological Indicators and Chemical Indicators manufactured by SP Medikal San Ltd represent no health hazard and do not fit into any other class of physical hazard for which a MSDS would be required.

Use of a MSDS format to convey this information could obscure the essentially harmless nature of these products and as such is not issued by SP Medikal San Ltd.

## Certificate of Conformity

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

Sterintech™ 2 Line label gun indicator labels and 3 Line label gun indicator labels (with ref. nr. 602.xxx.9000, 603.xxx.9000 and 604.xxx.9000) and their raw materials have been selected to fulfill the general requirements of various sterilization applications and in case of steam sterilization application have been tested in a CIER-Vessel based upon the requirements as per ISO 11140 part 1.

We herewith confirm that the Sterintech™ 2 Line and 3 Line label gun indicator labels are designed and compliant to the following standard:

Chemical Indicator: **ISO 11140-1, 2005:**  
**'Sterilization of health care products**  
**Chemical indicators -- Part 1: 'General requirements'**

Based upon tests as per the above-mentioned standard chemical indicator is classified as class 1

The label material and indicator ink comply to REACH guidelines. Any of the raw materials we use do not contain Natural Rubber Latex and are non-toxic as well as heavy metal free.

Indicators exposed to sterilization conditions and have reached their end-color can be kept for record for a period of 10 years when stored under the storage conditions as displayed on our box label / carton.

Label gun labels are not listed as Medical Device.

21st Mai 2012



Seda Kücükylmaz  
Quality Department



Peter M. den Uil (B. Sc.)  
Managing Partner



Attachment B: ISO 13485 certificate



**Attachment C: External laboratory test results**

Product:	Two line label gun label C2-170SP
Art.No.:	602.011.9000
Batch No.:	11047
Date:	03.04.2012



121°C 3 min	
121°C 10 min	
134°C 0,5 min	
134°C 2 min	
134°C 3,5 min	
132°C 2,6 min	
Operation Date / Sign: 03.04.2012 Schmidt	
Review and Release Date / Sign: 03.04.2012 H. H.	

Original:  
erg. 03.04.12. B



Registered as:  
Compliance Advice and Services  
in Microbiology GmbH  
at Amtsgericht Köln, HRB 31628  
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Account:  
Kreissparkasse Koeln  
SWIB/BIC: COKSDE 33  
Account-No.: 0 158 006  
IBAN: DE18 37050299 C

Product:	Three line label gun label C2-171SP
Art.No.:	603.011.9000
Batch No.:	11048
Date:	03.04.2012



121°C 3 min	
121°C 10 min	
134°C 0,5 min	
134°C 2 min	
134°C 3,5 min	
132°C 2,6 min	
Operation Date / Sign: 03.04.2012 Schmidt	
Review and Release Date / Sign: 03.04.2012 H. H.	

Original:  
erg. 03.04.12



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