

# SP MEDİKAL NEWS

## Third newsletter

by SP Medikal San. Ltd

After the wintertime the spring and summertime is welcomed by many people. These seasons are giving energy and motivation.

After some visits this spring in Asia we would like to activate a campaign to promote the Helix devices.

During some training we were highlighting the bene-

fits of the Helix device as batch monitoring device but also the big advantages when compared to detection possibilities of CI and BI's.

They are huge !!

You will find a list of these on page 3 of this publication.

Hope it contribute to your understanding.

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- Biological Indicators
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## ISO 13485 CERTIFICATION

It has been party time at SP Medikal since the day of our external audit.

Achieved in less then a year we proudly presented our ISO 13485 certification in March 2012.

The external audit did cover all our area's from production to sales and after sales services.

We realize that this is only a small step in our future of quality management and getting our products registered in the various markets.



## TECHNICAL BULLETIN

We do not like to speak about our competitors products as all of us manufacturers have deserved a place in the market.

But our German competitors are not sharing this opinion.

They think that they should assist their customers by writing statements and letters about our products with the only purpose to win a contract or tender.

Our technical bulletin will give technical information based upon our tests, our

findings, our experiences and our customer reviews.



Just to help you understand our products better and have an answer to those who are questioning our products.



You may request your copy by sending a mail to [info@spmedikal.com](mailto:info@spmedikal.com)

## SP MEDIKAL AT EXPOMED 2012 - ISTANBUL - TURKEY

From 12. till 15. April 2012 the Sterintech products were on display at the stand of our sister company Sterilizasyon Medikal.

Mainly a Turkish national exhibition we still had a good number of international visitors coming from surrounding countries showing their interest in our S.A.P.'s



## FIELD EXERCISE

February 2012 was an introduction of our products into the Indonesian and Malaysian



markets. Next to an intensive training of our new partners staff for two days we made a number of visits to hospitals which



learned us a few more things about how training and proper equipment and consumables can make a difference in sterility assurance programs.

We are thankful for the hospitality shown by our hosts as well as the exchange of experiences during the visits.

## HELIX VERSUS SCBI & IN-PACK INDICATORS

Helix devices as batch monitoring compared to other CI's and BI's are proven to be more valuable to get the information about your sterilization cycle.

If only you see the detection possibilities of Helix devices it will show you the reason why we make these kind of statements.

Problems occurring during sterilization	SCBI	Helix	In-Pack indicators
- Sterilization temperature too low	V	V	V
- Sterilization holding time too short	<b>Z-value !</b>	V	V
- Steam presence	V	V	V
- Insufficient vacuum in depth and in number	X	V	<b>Only when packed</b>
- Insufficient air removal from hollow A devices	X	V	X
- Insufficient steam penetration in hollow A	X	V	X
- Leakage of piping / valves / door seals	<b>Only big volume</b>	V	<b>Only big volume</b>
- Detection of presence of small volume inert gas in steam.	X	V	X
- Detection of excessive amounts of condensate	X	V	X
Immediate cycle verification ?	<b>NO</b>	<b>V</b>	<b>NO</b>

## BIOLOGICAL INDICATORS

In Hospitals the use of Biological indicators is mainly determined by history and education. It varies a lot. Sometimes they are used once a week, once a day, every cycle or only when implants are sterilized. There is no general rule.

But surprisingly most of staff are only concerned about the population and read this on the certificate of analysis. But in fact the Z-value is more important to have a reasonable killing time.

An example of data found in a typical certificate of analysis:

$P_0 = 2.6 \times 10^6$  (Accuracy: 50-300%)  
 $D_2 = \text{D-Value at } 121^\circ\text{C (T}_2) = 1,8 \text{ min.}$   
 $Z = 10^\circ\text{C}$

When you want to calculate the theoretical killing time at your sterilization temperature the following calculation is applicable:

$D_1 = \text{D-Value at } 134^\circ\text{C (T}_1) \text{ calculated:}$

$$D_1 = D_2 \times 10^{E((T_2-T_1)/Z)}$$

$$D_1 = 0,090213 \text{ min}$$

Theoretical Kill time  $134^\circ\text{C:}$

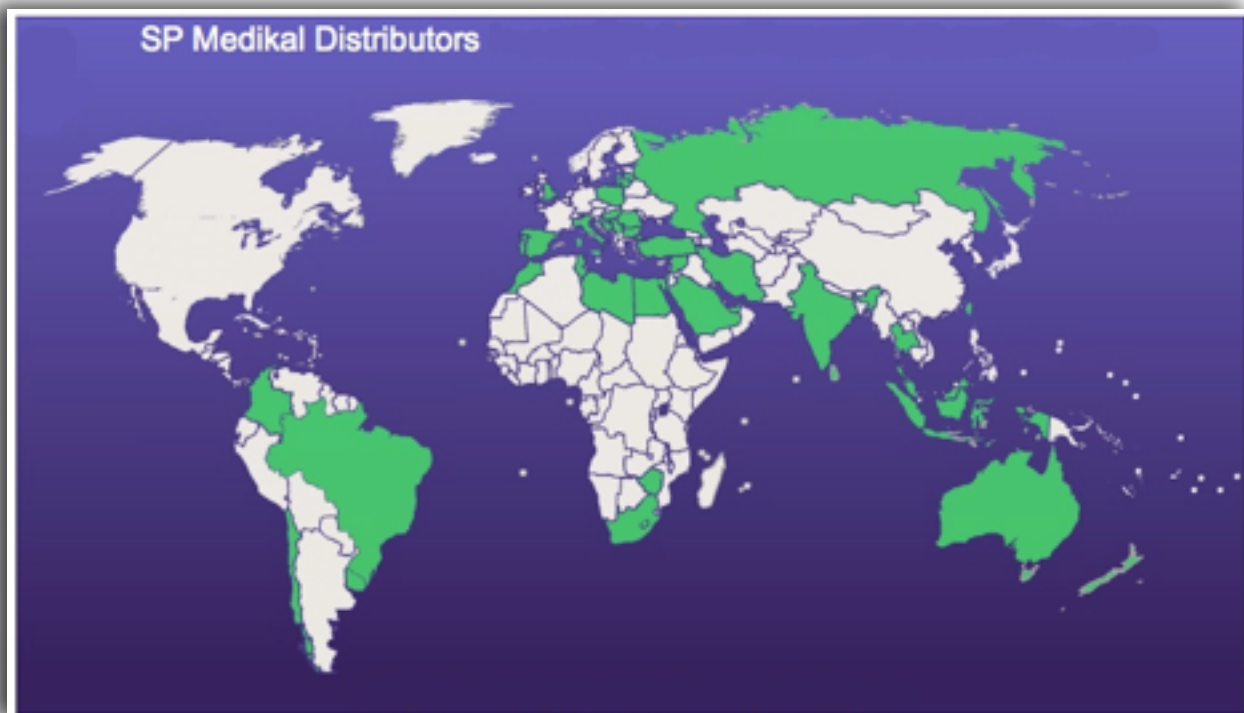
$$(\text{Log}_{10}P_0+1) \times D_1 = \text{less then 1 minute}$$

Mind you !!

After one minute of exposure to steam the BI is killed.

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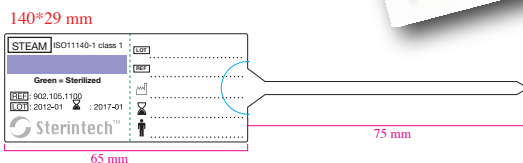
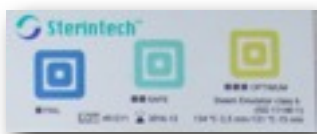
## YOU FIND OUR PRODUCTS AND SUPPORT IN THE FOLLOWING COUNTRIES



### NEW ARRIVALS @ SP MEDIKAL

Since the second Newsletter the following products have been launched.

- Container Seal, self-adhesive with pin
- Instrument protector tips
- Sequential Integrator 134°C 3,5 min - ISO 11140-1 Class 5
- Biological Indicator Plasma (SCBI)



### EXTERNAL LABORATORY TESTING

Our steam indicator class 1 has been tested by the German based Microbiological Laboratory Compliance. The result:

Our ISO 11140-1 class 1 is proven to be a real class 1 product. Check by yourself !!!

Product:	Three line label gun label CL-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 Schmid
Review and Release Date / Sign	03.04.2012 UH

134°C 0,5 min	
134°C 2 min	
134°C 3,5 min	
132°C 2,6 min	

Original:   
e.g. 03.04.12

Registered as:  
Compliance Advice and Services  
in Microbiology GmbH  
at: Amtsgerecht Köln, HRB 31628  
Managing Directors:  
Dr. Klaus Haberer, Karl-Heinz Schöhlein  
VAT-No.: DE 202547548

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Account:  
Kreissparkasse Koeln  
SAB/BIC: COKSDE 33  
Account No.: 0 158 006 008  
IBAN: DE18 2512 0299 0158006008

## PRODUCT PICS



**TWO LINE LABEL GUN & STEAM LABEL**



**BOWIE DICK HELIX TEST**



**THREE LINE LABEL GUN & STEAM LABEL**

## Calendar

of relevant exhibitions

### May 2012

Africa health - South-Africa

### November 2012

Medica - Düsseldorf - Germany

### November 2012

13th WFHSS Congress - Japan

### October 2013

14th WFHSS Congress - Istanbul

## Contact details

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