

SP MEDIKAL NEWS

Second newsletter

by SP Medikal San. Ltd

Already a second newsletter just to keep you informed about the latest events, news and products.

We accomplished a lot in only a few months and our goal has been achieved i.e. to be ready and present with a full product line of CSSD consumables at the start of Medica -Düsseldorf.

We have to thank our raw material suppliers who have been supportive by any means and costs to make it possible.

Currently we are producing not only to fill up our stocks but also to supply and deliver the incoming orders and prepare for upcoming orders.

At this moment SP Medikal is having exclusive distributing contracts in South America, Europe, Middle East and South East Asia.

The outcome of Medica - Düsseldorf will learn us whether we can reach a distribution network which covers more than thirty countries by the end of this year.

We opened a Facebook account to inform our staff and customers about news, upcoming events and product related information.

Just find SP Medikal and click the 'like' button and you will get our updates, news etc. automatically.



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SP MEDIKAL'S NEW CATALOGUE

At Medica we presented the complete product range through a comprehensive catalogue in English.

All product groups are displayed in a logical order and the pictures give a good impression on the actual products.



If you want to receive our catalogue, both as printed version or pdf-file, please send your inquiry to

marketing@spmedikal.com.

CUSTOMIZED INDICATOR LABELS

Sometimes labels are a big challenge.

One telephone call from a customer asking for a customized label can keep you busy for a few hours to a few days.

Developing a new label with new materials and of course delivery should be yesterday.

We have set up a good cooperation with our suppliers for the cutting tools, cliché and label stock materials in order to be as flexible and quick as possible.

We will provide a solution which cover your needs for any material, indicator, shape or lay-out

If you have a requirement please address yourself to info@spmedikal.com



SP MEDIKAL AT MEDICA 2011



From 16. till 19. November 2011 SP Medikal participated the Medica exhibition in Düsseldorf - Germany for the first time and presented the Sterintech™ product range on our 40 square meter stand.

With the words of one of our customers

'now you are in the race'

it was a good exhibition for us thanks to you. Overall we have had visitors from 65 countries and by this we want to thank all of you coming to see us and giving us all these opportunities to extend our network.



NEW ARRIVALS @ SP MEDIKAL

Since our first Newsletter we have been adding a few new products. These are:

- Moving Front Integrator class 5
- SCBI for Plasma (Ampoule)
- Plasma Indicator Strip
- Tyvek Sterilization Rolls
- Container Filters
- Digital Incubator for Steam,EO, Plasma
- Seal Checker

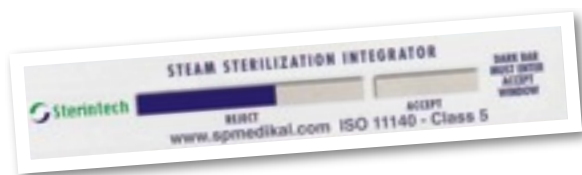
As we were too busy to arrange all the developments, testing, lay-outs, sample productions and stocking we are behind in creating product related documentation for all of them.

Please check our website regularly in order to download the new pdf-files for these products.



MOVING FRONT INTEGRATOR CLASS 5

One of the new arrivals we added to our product range is the Moving Front Integrator. An ISO 11140 class 5 integrator which offers much more information to the end-user about the cycle parameters than Chemical indicators can do.



Calibrated and validated to serve both 121 °C - 20 min. and 134 °C - 3,5 min. cycles the Moving Front Integrator have been tested extensively in a BIER Vessel in order to check the performance of its functioning compared to biological indicators.

It passed all tests with a glance.

The Moving Front Integrator is based upon an ink which is solid in room temperatures.



When the Integrator is placed in a sterilizer together with the load and sterilization conditions are met the ink is changing from solid into a liquid which is slowly absorbed by a strip over time.

Depending on time, presents of steam and temperature the blue colored ink is moving and at 134°C - 2,5 minutes (or 121°C - 15 minutes) it starts to reach the ACCEPT window. With a safety margin it is performing likewise a biological indicator but gives you a direct result after the sterilization cycle.

SP MEDIKAL REGISTERED AT GMDN

These days Medical Device Regulators may specify the use of the GMDN to their specific country or region.

For example, regulators in the European Economic Area (EEA), request the use of GMDN to support the Conformity Assessment process required for CE marking.

The Regulators in other countries are beginning to require the use of the GMDN Code in their medical device registration process.

The Global Medical Device Nomenclature (GMDN) is a system of internationally agreed descriptors used to identify medical device products.



The GMDN Database lists all the terms, which are currently available to name and describe medical devices, although new terms are regularly issued to cope with new medical devices innovations.

SP Medikal has been registered since November of 2011 in order to be able to register itself in a number of countries.

For more information pls use the following link: www.gmdnagency.com

BATCH CONTROL HELIX TEST: CLASS 2 VERSUS CLASS 5

Many customers are asking us why we are having the class 2 indicator in our Batch Control Helix Test in stead of the class 5 or class 6 as other suppliers are selling.



The reason is simply and given by the ISO 11140 standard definitions.

A class 5 integrator is tested by a CIER vessel for compliancy testing to the ISO 11140.

But solely as an indicator strip. The Helix device is not taken into consideration.

Consecutive our customers are using the indicator strip only in combination with the Helix PCD. Which is at least remarkable.

A class 2 indicator is tested in combination with the Helix PCD however and as such it is making a lot more sense as the ISO 11140 compliancy is now based upon the actual product which is used by our customers.

HEALTH , ENVIRONMENT, SAFETY & HAZARDS

SP Medikal products including Biological Indicators and Chemical Indicators are manufactured by using non-pathogenic organisms or materials which are not toxic or hazardous in nature.



Our products do not pose harm to the user's safety and as such a Material Safety Data Sheet (MSDS) is not required per International standards.

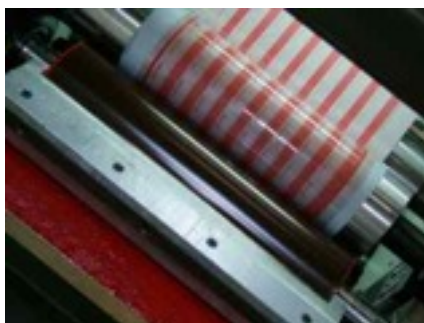
In ordinary use of our biological products, spores would not be directly contacted. However only in order to protect the integrity of the product rather than as a user safety precaution.



Actual contact with the spores due to damaged packaging or incident would not be harmful to the user's safety.

Direct contact with our non-biological products such as the Chemical Indicators and Customized 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.



Confirmations related to chemical indicators:

- All chemical indicator inks used for our production are water-based inks
- Chemical indicators neither contain heavy metals nor toxic substances
- All chemical indicator inks are registered under REACH.
- Our label material is not containing Natural Rubber Latex.

General and product related Certificates are available.

Calendar

of relevant exhibitions

January 2012

Arab Health - Dubai - U.A.E.

April 2012

Expomed Istanbul 2012

November 2012

Medica - Düsseldorf - Germany

October 2013

14th WFHSS Congress - Istanbul

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