

SP MEDIKAL NEWS

Sixth newsletter

by SP Medikal San. Ltd

A little later than planned for we proudly present you our sixth Newsletter. We waited a while to be able to write about the latest developments about our product range as well as the latest news about our company.

As a result of our increasing business SP Medikal expanded its production by adding more staff. We want to keep our delivery times at around two weeks.

As per June 2013 SP Medikal has established a second












company under the name of SP International in order to deal more effectively with the increasing amounts of customers and orders in the international market place.

As of 1st of July all export deliveries will be completed under the new company name.

SP International is a full daughter company of SP Medikal.

Please feel free to suggest us any subjects for our next edition.

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SP International

A NEW STERINTECH CLASS 4 PRODUCT

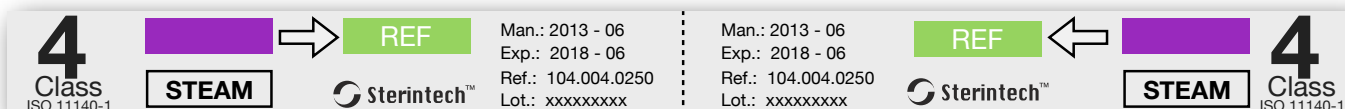
As a result for many requests for a long strip Class 4 Steam Indicator strip which can be divided into two smaller indicator strips, SP Medikal developed the product as shown here.

We have used our standard steam ink as basis for this class 4 product i.e. violet to green color change.

To check the right end-color we printed a color reference on the strip.

For ordering information and pricing please feel free to contact us at the following email address:

info@spmedikal.com



It is coming as a 20 cm long strip with a width of 25 mm.

The product will be on stock as from end of June 2013.

IMPROVEMENT SCBI PLASMA

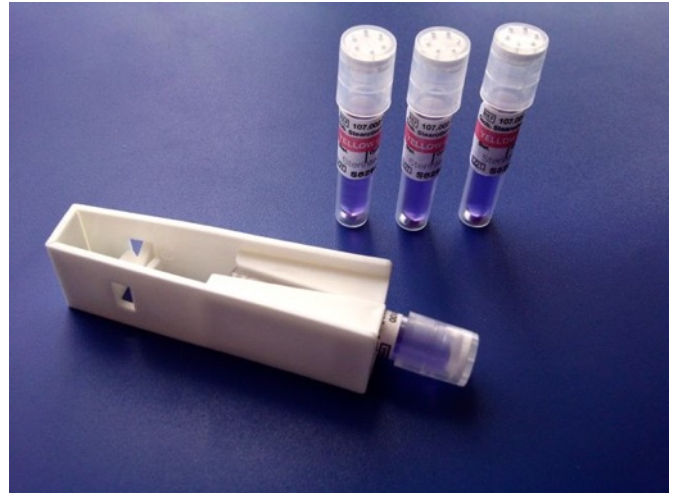
The Sterintech SCBI Plasma have been improved over the last few months and are now characterized by:

- Chemical indicator is the standard one we use for all plasma labels and printed on Tyvek.
- The new vial is reduced in diameter to fit into incubators with smaller diameters
- The fluid inside the ampoule is increased to compensate the evaporation during the incubation
- The carrier is now made of stainless steel in stead of plastic
- The cap is having 6 holes in the top to let plasma penetrate more easily.
- The filter in the cap is made of Tyvek.

VH2O2

For crushing the vial before incubation we do have added a plastic tool i.e. called crusher. It is available as an additional tool.

We decide it not to include in every box as once a hospital is having a crusher there is no need to give one with every supply of new SCBI.



A new technical file has been created for those SCBI's. You may require your copy through sending an email to info@spmedikal.com



IN MEMORIAM

The beginning of 2013 was starting with the news that Mr. Husein Er, managing director and partner of Hijyen Medikal, died in a German Hospital as a result of a heart attack.

We lost a great expert in the field of cleaning and disinfection as well as a colleague who worked hard to build-up Hijyen Medikal over the past years.

Our thoughts are with the family, relatives and friends of Mr. Er.

HAI AND ANTI-BIOTIC RESISTANCE

The World Economic Forum 2013, for the first time in history, is warning for the increasing numbers of bacterias now immune for even the strongest / latest antibiotics.

A few points from their report:

the use of antibacterial and antimicrobial compounds (antibiotics) – may no longer be readily available in the near future

human innovation may no longer be outpacing bacterial mutation.

are we in danger of returning to a pre-antibiotic era in which a scratch could be potentially fatal?

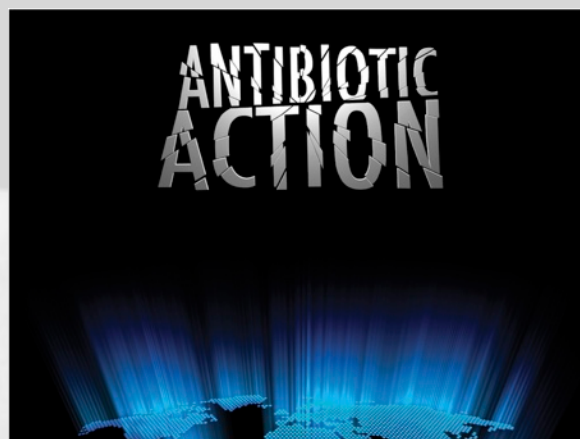
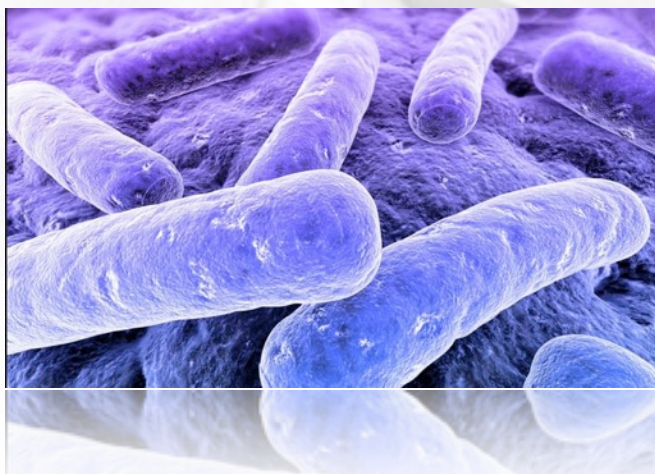
Others like microbiologist Professor Laura JV Piddock, Chair in Public Engagement and Professor of Microbiology, University of Birmingham is not only warning but started a website to get some attention for the subject.

Pls support this initiative by signing up at <http://antibiotic-action.com>

Even the G8 meeting held on 12th of June 2013 is issuing a special statement about it. You may read that here:

www.gov.uk/government/news/g8-science-ministers-statement

What we are seeing currently is that governments are starting to worry about the anti-biotic resistance of bacteria's as the numbers are starting to get terrifying.



Why is SP Medikal so interested in distributing this subject ?

Because most of the anti-biotic resistant bacteria's are found inside Hospitals and when you define the pre-cleaning department of the CSSD as the most dirtiest place inside the Hospital, you, our customers, are coming more and more in contact with these bacteria's

Just a few numbers from the USA:

- Each year 2.0 million people acquire a HAI
- About 105.000 of them are dying as a result

The CDC (USA) estimates that healthcare acquired infections cost hospitals in the United States between \$35.7 and \$45 billion annually.

For the first time ever the European community is paying 190 million Euro to pharmaceutical companies to start developing new antibiotics as the interest to do so by pharmaceutical companies is very limited. From 16 new antibiotics registered in between 1984 and 1987 to 2 new antibiotics registered over a same period of time in 2008 - 2012.

With the words of Prof. Paddock:

"If we don't sort out the problem of antibiotic resistance then the wonderful medical advances that we take for granted now... they're not going to be possible" in the near future

We feel it as our duty to increase Sterility Assurance as part of our contribution to fight against increasing numbers of HAI.

SEMINAR IN LITHUANIA

In cooperation with the KVK in Lithuania, SP Medikal presented a 6 hour long presentation in two cities in Lithuania in March 2013.

In Vilnius over 55 heads of CSSD attended the seminar whereas in Klaipedia there were more than 75 attendants.

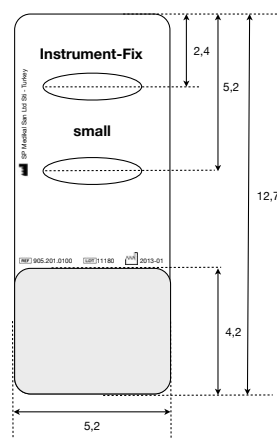
Doctor epidemiologist Ramutė Budginaitė was giving a lecture about the new Hygiene standards in Lithuania whereas Peter M. den Uil spoke about HAI in combination with Sterility Assurance in practice.

It was a great experience and a successful seminar thanks to a.o. our distributor.

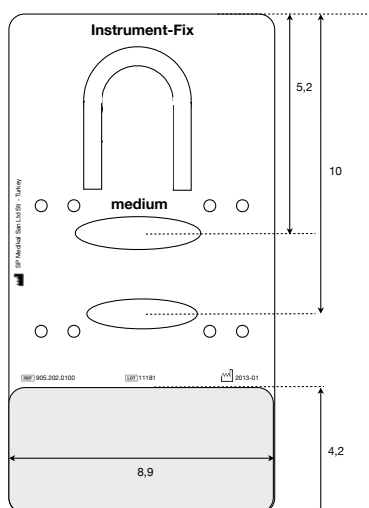


INSTRUMENT FIX

The request from a few of our distributors for an fixture to secure sharp instruments in their pouches has lead to the development of four different dimensions of Instrument-Fix. The Instrument Fix is a card which can hold scalpels, scissors and other sharp instruments where the sharp part is protected by a PP pocket.



Design Instrument Fix small and medium - Version A



The whole thing can be pouched and sealed easily and secures that steam sterilization can be effectively taking place without a risk that the film or paper of the pouch is being punctured by the sharp edges.

A real additional safety feature for situations where sterilized instruments are transported over many different departments.

The Instrument Fix is coming in four different sizes i.e.

REF: 905.201.0100	Instrument-Fix - Small	80 x 140 mm	Unit: 100 pieces
REF: 905.202.0100	Instrument-Fix - Medium	89 x 165 mm	Unit: 100 pieces
REF: 905.203.0100	Instrument-Fix - Large	100 x 198 mm	Unit: 100 pieces
REF: 905.204.0100	Instrument-Fix - X-Large	125 x 256 mm	Unit: 100 pieces

For additional information please ask us for the technical file, leaflet or pricing by email.

LABEL MATERIAL STATEMENTS

Food contact statement for adhesive

The adhesives comply with European food regulation 1935/2004/EC, with the German Recommendation (BfR) XXI and with FDA § 175.105. It also meets the demands of the limit values laid down in 10/2011/EU. It further complies with DIN ISO 3826.

In accordance with the requirements of relevant EU food regulations, the adhesives may safely stand in direct contact with dry, moist and non-fatty foodstuffs.

Statement on the Heavy Metals

No heavy metals are used in the by SP Medikal selected label materials. Our products comply with the Packaging and Packaging Waste Directive 94/62/EC, US CONEG Model Toxics legislation and Directive 2000/53/EC on end-of life vehicles, in relation to the various heavy metals paragraphs.

Statement on the RoHS

To the best of our knowledge, all SP Medikal products currently in production are in compliance with the requirements of the European Union Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, also known as "RoHS".

The six restricted substances listed in Annex 2 of 2011/65/EU are randomly tested of these products measured levels of the regulated substances significantly below the set maximum concentration limits.

The restricted substances involved and their maximum concentration values by weight are: Lead (0, 1 %), Mercury (0,1 %), Cadmium (0,01 %), Hexavalent chromium (0,1 %), Polybrominated biphenyls (PBB) (0,1 %) and Polybrominated diphenyl ethers (PBDE) (0,1 %).

REACH legislation

REACH legislation (Registration, Evaluation, Authorisation and restriction of Chemicals) has been in force since 2006. It means that industry now has a greater legal responsibility for managing risk from chemicals, and especially from substances of very high concern (SVHCs).

From the very beginning, SP Medikal has worked hard to comply with all relevant aspects of this regulation to avoid disruption of the manufacture and supply of its products, collaborating with all suppliers to maintain compliance now and in the future.

Statement on the compostability and bio-degradability of packaging: EN13432 standard

European Standards for Compostable Packaging, EN13432, require packaging to be compostable and bio-degradable under industrial composting conditions.

All paper used in our label materials are viewed as chemically unmodified paper materials, coming from a natural origin, so they can be accepted as biodegradable without testing.

Presence of Latex

To the best of our knowledge all label materials and their adhesives are manufactured without using any of natural latex, as is the case with the formulations of the participating materials and components nor as ingredient in the materials used in the applied manufacturing process.



REGISTRATION

Time is flying and the deadline for the registration for the conferences and accommodation with discounted pricing is coming soon.

July 31st is the last day to benefit reduced pricing.

In the meantime the WFHSS has not only updated the speakers and congress program on their website but also a full range of other activities is offered through the website.

From day trips to all kinds of activities around the venue.

The venue of the congress is beautiful. It is a perfect location for such an important event.

We can make the reservations for accommodation for our distributors and their guests. We only need to know this within 14 days which means 7th of July. Please let us have your reactions as quickly as possible as otherwise it will be too hard to get proper accommodations etc.

We hope that we may welcome a good number of our international customers.



THE HOLY BELIEVE IN BIOLOGICAL INDICATORS

Biological Indicators are being used in almost all countries we serve as a sterilization monitoring aid.

When you ask people what the BI is monitoring, they do not know exactly and none is realizing that the BI is killed within only 30 to 40 seconds at 134° C

Sometimes when our class 5 or class 6 Integrators/Emulators are showing a problem in sterilization conditions people tend to say:

"But the BI is always killed as we do not see any outgrowth after incubation"

If SP Medikal would make a chemical indicator which is turning into end-color within 30 seconds at 134°C that Chemical Indicator would be leading to a pass always as well.

We would like to emphasize that a class 5 or class 6 Chemical indicator is a more accurate way of monitoring your Holding time than any Biological indicator.

Therefore differences in results can differ in between the Biological and Chemical indicators.

For more detailed information please feel free

Calendar

of relevant exhibitions

November 2013

14th WFHSS Congress - Antalya

November 2013

Medica - Düsseldorf - Germany

January 2014

Arab Health - Dubai - UAE

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PRODUCTION PICS

