SP MEDIKAL NEWS

Fifth newsletter

by SP Medikal San. Ltd

Another year, another booth. It is Medica time !!!

A 50 sqm big booth was our showroom for only 4 days.

We feel blessed by the many visitors who came and visited us at our booth in Hall 12 F07.

Having all our products at display we received visitors from over 50 different countries.

We do hope, despite the economic situation, we again will gain a few distributors.

For those of you who couldn't attend, this Newsletter has all the latest information about our products and company.

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

In this Edition:

THANK YOU !!

SP MEDIKAL STAND DESIGN MEDICA - GERMANY 2012

Sterintech™

SMS NON-WOVENS - BLUE

Through a close co-operation with our French raw material supplier we were able to launch SMS Non-Woven sterile barrier materials as from this November.

Due to our big national market (Turkey) we have the capability to produce quantities efficiently. This will benefit our export markets by our competitive pricing.

The SMS Non-Woven materials are compliant to all international standards and are coming packed in a plastic bag which is on its turn packed into a carton box to give the best protection to the materials to environmental conditions wherever on the world.

The SMS Non-Woven are supplied in the standard sizes but when a customer needs a specific dimension we can produce these bespoke products as well.

A new technical file has been created for those SMS materials. You may require your

SP MEDIKAL WEBSITE FOR MEMBERSHIPS ONLY

Changing specifications, new products, new standards, remarks and comment by end-users. All of these are keeping us busy on a weekly basis and every time one of each of those changes are having an effect on the content of our technical files, our manuals (DFU's) and/or certificates of conformity.

It is too hard to keep record of who of our distributors and customers has received what and which status the document had at that time.

However there is a big need for our contacts to have the latest version of our technical files.

To publicize all these to any visitor to our website is not the best idea as we do not want to assist our competition.

To offer a solution we created a membership only part in our website which you can only enter through username and password log-in.

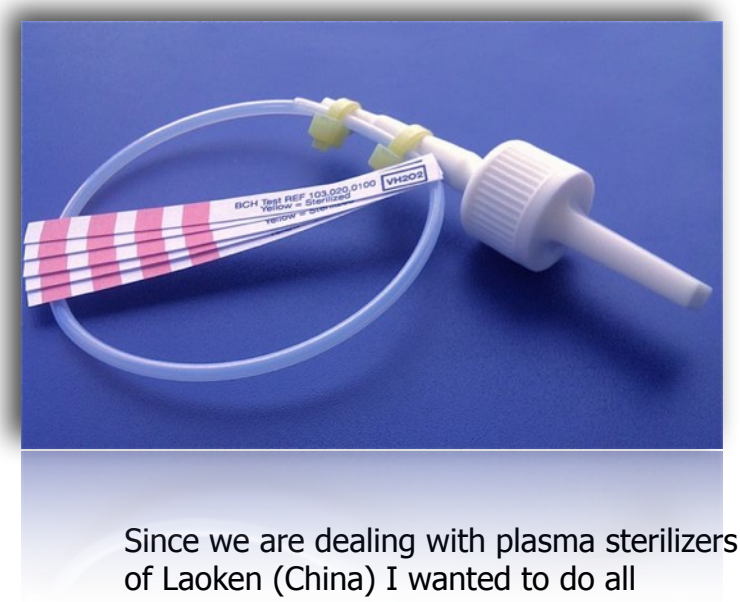
We will be uploading all documents during December. If you want to become member and receive your password and username please send us an email to

info@spmedikal.com

PS: you may like us at Facebook to get automatic smaller news feeds the moment they take place. Please click the following link SP on Facebook and click on the like symbol.

PLASMA STERILIZATION

Building up my know-how and initial first experiences in the field of sterilization in The Netherlands where the Ministry of Health was blocking J&J to supply 5 plasma sterilizers free of charge to five hospitals was giving me a very critical attitude towards plasma sterilization. In the beginning nobody else than the manufacturer himself could validate the equipment, there were no biological indicators not chemical indicators to test the performance of first plasma sterilizers.



Since we are dealing with plasma sterilizers of Laoken (China) I wanted to do all necessary tests to be convinced of the effectiveness of plasma sterilization.

Starting with indicators strips only, followed by SCBI's and indicator labels I finally was ready to test the plasma sterilizers with a Helix PCD.

All plasma sterilizer manufacturers are having lots of restrictions written in their operating manuals ranging from materials which cannot be sterilized by plasma to the limitations of inner diameter and length of narrow lumen instruments.

The overall restriction for single open end tubes with a diameter of > 1 mm is 30 cm.

Beyond the 30 cm of tube plasma sterilizer manufacturers do not guarantee effective penetration of the sterilant to the very end of the closed lumen.

Therefor we couldn't start with our standard PCD with 1,5 mtr length of tube but did all our testing with a 30 cm long tube PCD.

We are still pioneering as there is no standard likewise for Steam chemical indicators. No classification yet know or given by any standard. It is once again proving that plasma sterilization has just started to develop.

After a few months of testing and with the help of the technical people at Laoken we have now a Helix PCD with chemical indicator that detect failures during the sterilization cycle. We have been able to test the device and indicators in various fault conditions of the plasma sterilization. The Plasma PCD is able to pick up following faults.

Failures picked up by Plasma PCD:

★ Too less Plasma sterilant
★ Failure to reach deep vacuum
★ Too less penetration in lumen
★ Overloading sterilizer

VH2O2

We will start production this month. List price will be Euro 65,00 per set with 100 indicators. Order / product reference number is 103.020.0100. The color change of the indicator is from red to yellow.

Standard	Status	Remark	Name
Chemical Indicators			
EN 867-1: 1997	Withdrawn 2006	Replaced by ISO 11140-1 : 2005	Non-biological systems for use in sterilizers. General requirements
EN 867-2: 1997	Withdrawn 2006	Replaced by ISO 11140-1 : 2005	Non-biological systems for use in sterilizers. Process indicators (Class A)
EN 867-3: 1997	Withdrawn 2007	Replaced by ISO 11140-3 : 2007	Non-biological systems for use in sterilizers. Specification for Class B indicators for use in the Bowie and Dick test
EN 867-4: 2001	Withdrawn 2007	Replaced by ISO 11140-4 : 2007	Non-biological systems for use in sterilizers. Specification for indicators as an alternative to the Bowie and Dick test for the detection of steam penetration
EN 867-5: 2001	Valid		Non-biological systems for use in sterilizers. Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S
ISO 11140-1: 2005	Valid	Applicable for class 1 to 6	Sterilization of health care products -- Chemical indicators -- Part 1: General requirements
ISO 11140-2: 1998	Not applicable	Replaced by ISO 18472:2006	Sterilization of health care products -- Chemical indicators -- Part 2: Test equipment and methods
ISO 11140-3: 2007	Valid	Applicable for BD test sheets	Sterilization of health care products -- Chemical indicators -- Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
ISO 11140-4: 2007	Valid	Applicable for BD EN 285 (7 kilo)	Sterilization of health care products -- Chemical indicators -- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration
ISO 11140-5: 2007	Valid	Applicable for BD AAMI (4 kilo)	Sterilization of health care products -- Chemical indicators -- Part 5: Class 2 indicators for Bowie and Dick-type air removal tests
ISO 11140-6	Under development		Sterilization of health care products -- Chemical indicators -- Part 6: Class 2 indicators and process challenge devices for use in performance testing of steam sterilizers
Biological Indicators			
EN 866-1: 1997	Withdrawn 2006	Replaced by ISO 11138-1 : 2006	Biological systems for testing sterilizers and sterilization processes. General requirements
EN 866-2: 1998	Withdrawn 2006	Replaced by ISO 11138-2 : 2006	Biological systems for testing sterilizers and sterilization processes. Particular systems for use in ethylene oxide sterilizers
EN 866-3: 1997	Withdrawn 2006	Replaced by ISO 11138-3 : 2006	Biological systems for testing sterilizers and sterilization processes. Particular systems for use in moist heat sterilizers
EN 866-4: 1999	Withdrawn 2012	Replaced by ISO 11138-4 : 2006	Biological systems for testing sterilizers and sterilization processes. Particular systems for use in irradiation sterilizers
EN 866-5: 2000	Withdrawn 2006	Replaced by ISO 11138-5 : 2006	Biological systems for testing sterilizers and sterilization processes. Particular systems for use in low temperature steam and formaldehyde sterilizers
EN 866-6: 2000	Withdrawn 2006	Replaced by ISO 11138-4 : 2006	Biological systems for testing sterilizers and sterilization processes. Particular systems for use in dry heat sterilizers
ISO 11138-1: 2006	Valid	Published 2006	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
ISO 11138-2: 2006	Valid	Published 2006	Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 11138-3: 2006	Valid	Published 2006	Sterilization of health care products -- Biological indicators -- Part 3: Biological indicators for moist heat sterilization processes
ISO 11138-4: 2006	Valid	Published 2006	Sterilization of health care products -- Biological indicators -- Part 4: Biological indicators for dry heat sterilization processes
ISO 11138-5: 2006	Valid	Published 2006	Sterilization of health care products -- Biological indicators -- Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
ISO 11138-6	Under development		Sterilization of health care products -- Biological Indicators -- Part 6: Biological indicators for hydrogen peroxide vapour sterilization processes
Packaging			
EN 868-1: 1997	Withdrawn 2006	Replaced by ISO 11607-1 : 2006	Packaging materials and systems for medical devices which are to be sterilized. General requirements and test methods
EN 868-2: 2009	Valid	Published 2009	Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods
EN 868-3: 2009	Valid	Published 2009	Packaging for terminally sterilized medical devices. Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) Requirements and test methods
EN 868-4: 2009	Valid	Published 2009	Packaging for terminally sterilized medical devices. Paper bags. Requirements and test methods
EN 868-5: 2009	Valid	Published 2009	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods
EN 868-1: 2009	Valid	Published 2009	Packaging for terminally sterilized medical devices. Paper for low temperature sterilization processes. Requirements and test methods
ISO 11607-1: 2006	Valid	Published 2006	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2: 2006	Valid	Published 2006	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
Status of this list:	**01 Nov 2012**	**Published by**	**SP Medikal Sti Ltd. For inquiries and / or questions please contact Mr. Peter M. den Uil , B.Sc. Managing Partner at SP Medikal : info@spmedikal.com**

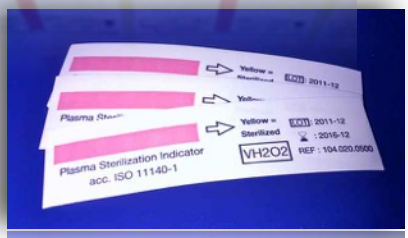
We would like to share this information with you:

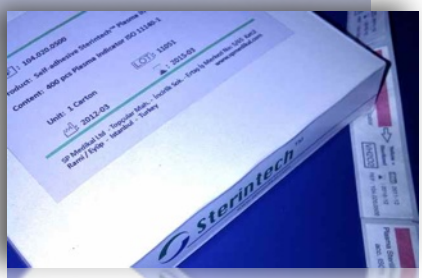
An overview of standards which are used in our daily work was requested by one of our distributors. Standards are still changing rapidly and we will keep it up todate over time and publish it every year from now on.

ALL OUR PLASMA PRODUCTS

By now we have completed our product range for plasma sterilization. An overview by means of pictures:

- SMS Non-Woven Sterile Barrier
- Batch Control Helix Test
- Self-contained Biological Indicator
- In-pack indicator strips
- Self-adhesive indicator strip
- Tyvek sterilization rolls
- Plasma tape with indicator
- Label gun labels for 2 & 3 Line label guns
- Computer labels (Tyvek) with indicator





NEW ARRIVALS @ SP MEDIKAL

Since the fourth Newsletter the following products have been launched.

- Blue Masking Tape with High Tack
- Stainless steel (SS) Helix for Batch Control (max. 5000 cycles)
- Sticky Mats

PRODUCTION PICS

Calendar

of relevant exhibitions

November 2012

Medica - Düsseldorf - Germany ✓

November 2012

13th WFHSS Congress - Japan ✓

January 2013

Arab Health - Dubai

October 2013

14th WFHSS Congress - Istanbul

Contact details

SP MEDIKAL SAN LTD

Adress:
Topcular Mahallesi
Incirlik Sokak
Ertas Is Merkezi 5/65
Kat: 2 Rami / Eyüp
Istanbul - Turkey

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

Skype: spmedikal