



Hans J. Michael GmbH



Ecolab Contamination Control, a worldwide provider of leading products and services for the control of microbial contamination in the cleanroom environment, has launched a unique product which will revolutionise the process of transfer disinfection within the pharmaceutical industry.

New product from Ecolab Contamination Control set to revolutionise the transfer disinfection process



Klercide Sporicidal Alcohol from Ecolab Contamination Control will revolutionise the process of transfer disinfection.

Klercide Sporicidal Alcohol has all the positive features of an alcohol-based disinfectant, including a low surface tension which improves product contact. It also has a 'flash off' time of just two minutes and minimal residues, which combined with sporicidal properties, significantly enhances its efficacy.

Critically, Klercide Sporicidal Alcohol will minimise the risk of introducing spores to the manufacturing process during transfer disinfection; a process which has long posed a significant challenge to hospital pharmacies and pharmaceutical manufacturers alike.

It is exactly what the pharmaceutical industry and hospitals have been waiting for and has been specifically developed to address a long standing need to provide a sterile sporicidal product with the key characteristics of alcohol for the transfer disinfection process.

This is in line with recent regulatory guidelines, including GMP Annex 1 and PIC/S P1007-6 which states that 'Sporicidal agents should be used wherever pos-

sible but particularly for spraying in components and equipment in aseptic areas.'

In the past, water based sporicides have been used which cause significant wetting, a feature not recommended for transfer disinfection. This can also increase the risk of inadequate product contact, leading to poor practical performance. It can also increase process time or require transfer to take place while the items are still wet. Water based sporicides also result in pooling which can significantly reduce material compatibility and increase the likelihood of residue build-up.

The consequences of inadequate transfer disinfection where spores evade the disinfection process are extremely serious.

This is a view supported by Good Manufacturing Practice (GMP), which states: 'Transfer of materials into and out of the cleanroom is one of the greatest potential sources of contamination,' (GMP Annex 1).

Klercide Sporicidal Alcohol is manufactured in Ecolab Contamination Control's own purpose built cleanroom and is supported by the firm's Process Match assurance mark to highlight that the manufacturing processes match those of its customers. It is also fitted with the patented SteriShield Delivery System (SDS), the only fully validated trigger spray system on the market, which ensures the integrity of the product is protected throughout its entire use.

By using Klercide Sporicidal Alcohol customers will improve their processes and deliver contamination control without compromise.



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New product from Ecolab Contamination Control set to revolutionise the transfer disinfection process	1
Particle Measuring Systems Completes ISO/IEC 17025 Assessment with Zero Deficiencies	3
Systec & Solutions extend international operations	3
Precision control with astounding speed	4
Cherwell highlights new cleanroom decontamination system at Pharmig	5
Maximum safety at lower cost	6
Cherwell strengthens team with Microbiology Product Specialist appointment	7

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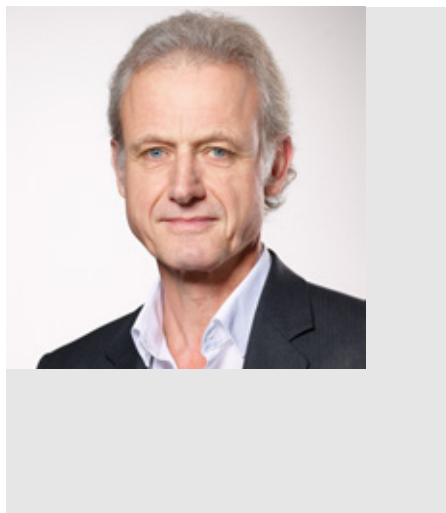
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Dear readers, dear subscribers,

now it's January 2016 and we have a lot of interesting news and a lot of interesting events for your appointment calendar.

So the amount of the German and the international newsletters is constantly growing. We hope, we can give you with this information a good help for your daily work and your planning tasks.

Yours sincerely

 Reinhold Schuster



The map shows where the readers of the cleanroom online newsletter are coming from: if you want to get in contact with these readers please contact us.



NEW

If you click at this sign in the pdf-document you will easily get more information in the internet

Accredited calibrations for select products can now be conducted at the corporate headquarters with the latest international standard.

Particle Measuring Systems Completes ISO/IEC 17025 Assessment with Zero Deficiencies



Particle Measuring Systems (PMS) is pleased to announce certification of ISO/IEC 17025, accredited by A2LA, for the performance of ISO/IEC 17025 Accredited Calibrations. This accreditation provides PMS with the ability to offer globally recognized ISO/IEC 17025 accredited calibrations for critical instruments at our Boulder service center. The vigorous ISO assessment took place November 4th and 5th, 2016.

Upon completion of the evaluation, it was determined that PMS passed with zero deficiencies. "Most initial assessments are completed with an average of eight to ten deficiencies, that we passed with none is a testament to the high standards at which we hold our employees and our operations. The assessor noted Particle Measuring Systems' excellence in all areas as the key factor in achieving zero deficiencies upon evaluation, and also stated that this is an extremely rare accomplishment," said Kathy Campitelli, Director of Engineering at Particle Measuring Systems.

"Particle Measuring Systems has been an ISO 9001 certified facility since 1998. ISO 17025 accreditation was the next step in ensuring we could meet the full requirements of our customers," said John Mitchell, President of Particle Measuring Systems, "Our next step will be to immediately pursue the same ISO accreditation at our relevant international locations including Denmark, Italy, Germany, China, Singapore, and Taiwan."

About Particle Measuring Systems

A global technology leader in the microcontamination monitoring industry, PMS, a Spectris company, is the inventor of laser particle counting and the largest particle counter manufacturer in the world. Regardless of industry or monitoring requirements, PMS helps manufacturers measure what matters.



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Since 1 November 2015 Systec & Solutions GmbH have been working with a new sales partner in the Netherlands – Verduyn bv.

Systec & Solutions extend international operations



Image Rights: Systec & Solutions GmbH

With more than 65 years of experience in the fields of automation, processing, packaging and robotics, Verduyn will be able to make a valuable contribution towards strengthening the international sales structure. Like Systec & Solutions, the company specializes in supplying to the pharmaceutical and foodstuffs industries and will act as a local representative to provide on-the-spot service for customers in the Netherlands.



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Electromotive process control valves

Precision control with astounding speed

The advantages of electromotive actuators are receiving more attention in process automation. As simple, smart systems they offer diverse opportunities for process optimisation. With the Type 3360/3361 electromotive seat valves Bürkert offers a complete process control valve that sets new standards with respect to performance, reliability and cost-effectiveness. Potential uses for the new valves include applications with stringent requirements for control accuracy and process stability, as well as applications in which operation without a compressed air system is advantageous.

The special feature of the new Bürkert product family is its performance, which is comparable to that of pneumatic actuators. With a control speed of 6 mm/s and a closing time of less than four seconds Bürkert has improved the previous weak point of many electromotive process control valves, which have control speeds of only 0.1 ... 3 mm/s. The Type 3360/3361 valves allow adjustment of the control speed to the requirements of the customer's specific application, in addition to definition of the stroke and closing limits and soft approach of end positions. Another positive feature of the electromotive valves compared to pneumatic, spring-balanced actuators is that they travel to the desired position virtually without delay and without overshooting and remain stable regardless of the media pressure. In case of a power outage the safety position can be approached via the optional SAFEPOS energy storage pack. In addition, the possibility of emergency manual movement also exists. In view of the trend toward "Industry 4.0" the Bürkert Type 3360/3361 valves fulfil the increasing customer requirements with respect to the diagnosis of process and valve data as well as the capability of optimal integration in a central company network.

Application focuses and customer benefits

Bürkert's development of the electromotive process control valves is intended for applications in which the use of compressed air is not desired or not possible. Examples of such applications include large-area storage systems with long distances to the single valves, as well as systems for mobile, decentralised water treatment. Another customer benefit is to be found in applications with stringent requirements for control accuracy and speed, together with minimal dead time, such as in engine test rigs. The electromotive process control valves are ideal for the precise control of the media temperature by means of heat exchangers in modern food and beverage systems. In such applications, the customer benefits in particular from the actuator surface, which is designed based on hygienic criteria in accordance with the EHEDG Guideline. Harsh environments are no problem for the robust body with protection type IP65 / IP67, which also features an easy-to-clean and closed design.

With respect to cost-effectiveness users benefit from low energy costs and savings throughout the entire system. Lower energy costs because no expensive compressed air is needed. With respect to the overall system, use of the new process control valves can eliminate the need for a compressed air system entirely, reduce the load on such a system or allow it to be retrograded. IP control cabinets as well as pneumatic control lines in the field are likewise unnecessary.

Technical data and features

For the market launch the new Bürkert process control valves are available as an angle seat valve (Type 3360) and a globe valve (Type 3361) in diameters from DN15 to DN50. They can be used with gases, liquids and steam and are designed for media temperatures from -10 to 185 °C. The maximum operating pressure is 16 bar. The connection options are flange, sleeve, weld-on and clamp. The Kvs values extend from 0.1 to 37 m³/h. A voltage of 24 V DC is needed for the electric power supply. Following the market launch, continuous expansion of the new electromotive process control valves is planned. Future developments will be a process controller, membrane valves, a connecting diameter up to DN 100, an open/close solution and connection to other field bus systems in addition to Ethernet, Profinet and Modbus.

For uncompromising communication capabilities the motorised process control valves feature the Efficient Device Integration Platform (EDIP), developed by Bürkert to open the way for its products to Industry 4.0. The EDIP platform comprises numerous functions, compatible HMI devices and other services that facilitate the system integration of new devices. Bürkert also offers a free software program, the Communicator, which features diagnostic functions for monitoring of operating data as well as alarm messages for customised parameters.



With the launch of the electromotive seat valves Bürkert now offers a complete process valve that sets new standards with respect to performance, reliability and cost-effectiveness.

Bürkert Fluid Control Systems
D 74653 Ingelfingen

Dry Fog Z demonstration video available to view online

Cherwell highlights new cleanroom decontamination system at Pharmig

Cherwell Laboratories, specialists in cleanroom microbiology solutions for the pharmaceutical and related industries, has once again supported Pharmig's Annual Conference. This conference allowed individuals within pharmaceutical, healthcare and NHS Industries, to keep up to date with current topics and developments in microbiology.

The Cherwell Laboratories' stand featured a variety of its microbiology solutions portfolio, including a video displaying the newest addition to the range, the Dry Fog 2 cleanroom decontamination system. The video, now available to view online, demonstrated the key advantages of this stainless steel, portable, cleanroom decontamination system in action; displaying how rapid decontamination within small rooms and whole suites can be achieved with its use.

Cherwell also displayed a selection of its

products suitable to meet the environmental monitoring and process validation requirements of the pharmaceutical, healthcare and other related industries. Examples of the Redipor® range of prepared media agar plates, in various combinations of packaging, showed the flexibility of the offering from Cherwell, which allows them to provide specialist prepared media solutions to meet specific requirements.

Maintaining strong customer and industry links is very important to Cherwell; therefore the Company was well represented at the event, with Managing Director, Andy Whittard; Sales Manager, Andrew Barrow and Sales Specialist, Sandra Hulme available on the stand to discuss customer requirements. Quality Manager, Harshad Joshi and new Microbiology Product Specialist, Andrew Ramage also attended as delegates in

order to keep abreast of the latest developments and further expand their knowledge.

Disseminating some of his key learnings from Pharmig, Andrew Ramage has recently posted a Pharmig 23rd Annual Conference blog on Cherwell's website reviewing some of the 'hot topics' and current regulatory requirements discussed. These include the importance of a robust environmental monitoring programme when operating aging manufacturing facilities, as well as updates to Annex 1 of the EU GMP guide.

Andrew Barrow, Cherwell Laboratories' Sales Manager, commented, "Attending and supporting key events such as Pharmig's annual conference enables us to keep informed of the very latest matters in pharmaceutical microbiology and regulatory information, as well as meeting customers to discuss their specific needs. Staying up to date with the industry and our customer's specific requirements allows us to continue to supply high quality products, supported by excellent customer service."

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ENGEL at Interplastica 2016

Maximum safety at lower cost



ENGEL system solutions enable the optimum interaction of injection moulding machine, mould, process technology, automation and support. This improves overall efficiency while helping to develop secure yet cost-effective solutions for strictly regulated clean room operations. ENGEL will show how this is done at the Interplastica 2016 fair in Moscow, which takes place from January 26th to 29th.

**26th - 29th January 2016:
interplastica 2016,
Moskau (Russland)**

For ENGEL, Interplastica 2016 will be all about medical technology. "For quite some time the market has been dominated by imported products. The quality of some of these can be low," reveals Olaf Kassek, Managing Director of OOO ENGEL in Moscow. "Despite relatively high administrative barriers to certification, more and more medical technology and lab technology products are being produced in the country. At the same time, demands on the quality of products as well as manufacturing equipment are rising." Thanks to its expertise in system solutions, ENGEL ranks as a preferred partner to the plastics processing industry on this market as well. In fact, ENGEL can already point to numerous references in Russia. "Where the injection moulding machine, process technology, mould and automation are coordinated around each other from the start, we can exploit efficiency potential to the full while optimising the manufacturing cell and minimising particulate emissions for use in a clean room," says Kassek. As a systems supplier, ENGEL is continually expanding its range of products that meet the requirements of good manufacturing practice (GMP); conveyor belts with a clean room design are also offered. The latest GMP-compliant peripherals from ENGEL include a gripper housing that facilitates the deployment of standard handling systems in a clean room. Around the world, ENGEL is supplying highly integrated and automated manufacturing cells for medical technology from a single source; on request, the company will also undertake full GMP documentation on behalf of customers.

Large moulds on small machines

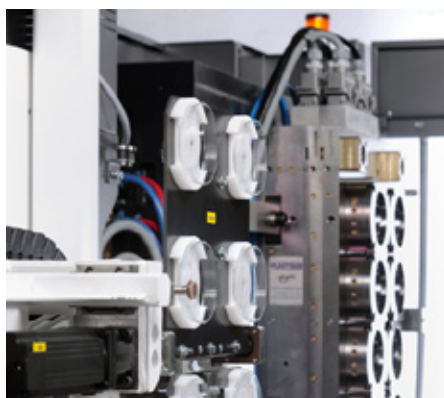
In the medical technology sector, maximum safety is the most important criterion; maximum performance and minimal unit costs are also long-established requirements in this sector. To achieve the shortest possible cycle times and low investment costs while ensuring the best possible safety levels,



Short cycle times and maximum safety for the lowest possible investment cost are requirements in the manufacture of consumables for medical technology and lab technology – including the petri dishes that ENGEL will produce at its stand during Interplastica. (Picture: ENGEL)



The tie-bar-less ENGEL victory injection moulding machine facilitates highly efficient manufacturing concepts. (Picture: ENGEL)



With no obstacles to circumvent thanks to a barrier-free clamping unit, direct access from the side to the mould is possible. (Picture: Hekuma)

ENGEL uses tie-bar-less injection moulding machines to mass-produce consumables for medical technology and lab technology. At the ENGEL stand in hall 3 at the Interplastica fair, a tie-bar-less ENGEL victory 300 tech injection moulding machine will be used to produce petri dishes (four pieces per shot, each comprising an upper and lower section). The 4+4-cavity mould – produced by Plasticsud of Castelnaudary in France – is very large in relation to the required clamping

force, yet can still be installed on a 3,000 kN injection moulding machine thanks to the barrier-free mould area. "Because there are no tie bars in the way, the mould mounting platens on ENGEL victory machines can be fully used up to their very edges," explains Kassek. "In many applications, then, a smaller injection moulding machine than the mould size would normally dictate can be used. This cuts investment costs as well as operating costs substantially."

There are also benefits in terms of automation. As regards handling, it is possible to access cavities directly from the side without having to circumvent any obstacles, which helps to reduce cycle times. To manufacture the petri dishes, ENGEL has integrated a high-speed automation supplied by system partner Hekuma (Eching, Germany) into the overall concept. The manufacturing cell only needs 4.8 seconds to produce four petri dishes.

The ENGEL victory injection moulding machine presented in Moscow is fitted with a servohydraulic ecodrive – another factor in achieving efficiency. Thanks to ecodrive, the drives are idle and consume no energy during cooling phases, for example. Depending on the type of machine and the application, this cuts the energy requirement of hydraulic drives by 30 to 70 percent.

Close to its customers – anywhere in the world

With its systems expertise and focus on applications, ENGEL offers individual customers around the world a competitive edge by addressing their specific needs. The more complex the application, the more important is the company's proximity to clients, even at the project planning stage. ENGEL established a subsidiary in Moscow in 2006. Further service and training facilities are located in St. Petersburg and Nizhny Novgorod. Fifteen service technicians provide support to customers in Russia, both on site at client premises and through the ENGEL e-connect.24 service package. By means of a remote connection, the ENGEL technicians are able to view actual screen images on machine control units and even access remote systems. In this way, all manner of problems can be conveniently diagnosed and rectified via the Internet, which means the plastics

Maximum safety at lower cost

processing firm does not need to engage in costly and time-consuming service on site. At the same time, a special spare parts warehouse and service hotline guarantee short distances and fast responses.

“We believe there is still great potential in Russia,” emphasises Olaf Kassek. “At the present time, local production of high quality medical products, packaging and automobile components is being ramped up significantly for some 140 million inhabitants. To achieve this, the country will continue to have a need for high performance injection moulding machines and efficient technologies developed and produced in western Europe.”

ENGEL AUSTRIA GmbH A 4311 Schwertberg



Together with its system partner Hekuma, ENGEL has created a high-speed automation to produce the petri dishes. (Picture: Hekuma)

Company boosts industrial microbiology expertise to enhance customer support

Cherwell strengthens team with Microbiology Product Specialist appointment



Andrew Ramage, Microbiology Product Specialist, Cherwell Laboratories

Cherwell Laboratories, specialists in cleanroom microbiology solutions for the pharmaceutical and related industries, are pleased to announce the appointment of Andrew Ramage as Microbiology Product Specialist. As an industrial microbiologist, Andrew's appointment demonstrates Cherwell's ongoing commitment to providing customers with excellent customer service and the highest quality of products.

Andy Whittard, Managing Director of Cherwell, commented, “With the focus on

excellence in customer services remaining a core principle within the company, Andrew will be a valuable addition to the team. Andrew's background within industrial microbiology provides a thorough understanding of the applications for which our products are used. Along with his first-hand experience of the challenges of interpreting and implementing regulations within the pharmaceutical and associated industries, Andrew's knowledge and expertise will further strengthen the expert support we provide to our customers.”

Andrew's role as Microbiology Product Specialist will involve providing direct technical and applications support to customers and distributors of Redipor® Prepared Media. As well as working with customers to ensure Cherwell offers the specific products required for their specialist applications, Andrew will also be maintaining, developing and sharing Cherwell's understanding of regulatory requirements and scientific advances. For example, he has recently posted some of his key learnings from Pharmig in his 'Pharmig 2015 Annual Conference blog' on Cherwell's website.

Prior to joining Cherwell Laboratories, Andrew has had over 15 years' valuable experience working as both a Quality Control Microbiologist and within an aseptic manufacturing facility. Most recently, Andrew worked at the National Institute for Biological Standards and Control, managing the QC microbiology laboratory, where Cherwell's Redipor® prepared media products are regularly used.

Commenting on his new role, Andrew said, “Having been a long-time customer of Cherwell Laboratories and having appreciated the quality of the customer service received, it is great to get the chance to further enhance that service by sharing my knowledge and experiences. I look forward to helping customers make the best use of our products and helping to solve their problems.”

During Andrew's career, he has gained extensive experience of the Environmental Monitoring of cleanrooms, the testing of sterile and non-sterile products, and the fumigation of both cleanrooms and high containment level laboratories. This knowledge and expertise and experience of using Cherwell's products, will help Cherwell strive to provide the right product and service to meet customer's needs.

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