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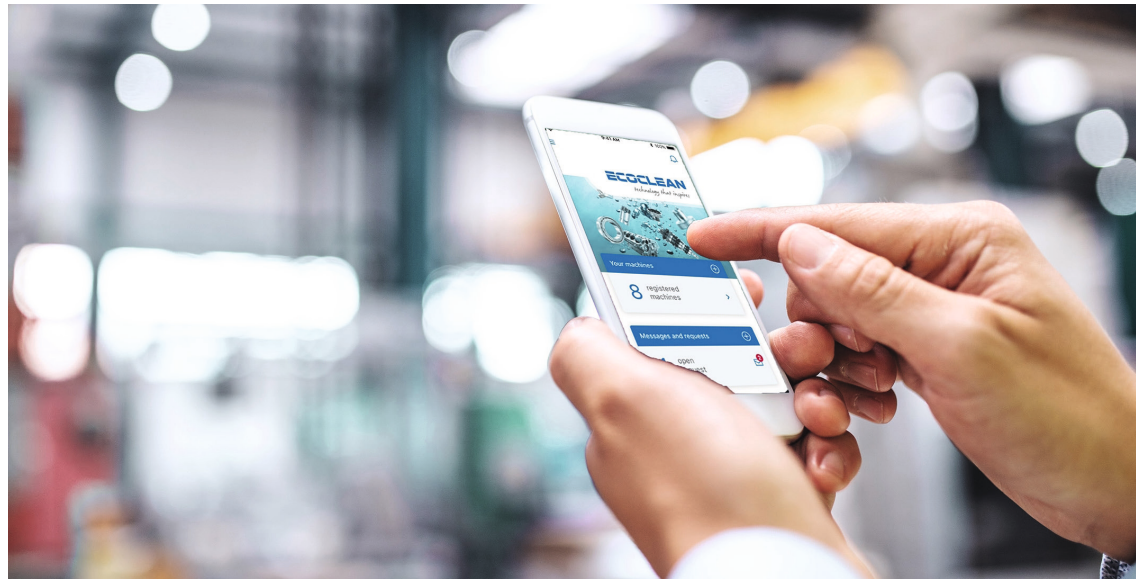
ECOLAB®

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Simply register and contact the responsible service team directly. The new service app with chat, photo and video functions allows you to reach the helpdesk quickly and easily. (Source of photo: Ecoclean GmbH)

Simple, fast and direct way to customer services

Ecoclean: new service app optimizes communication

Whether it's a question about a maintenance job, a technical problem or a spare part that's needed - the new service app for IOS and Android makes it easy to contact the Service team directly at the relevant Ecoclean branch. The two-way real-time connection via chat function and video telephony with live image transmission allows problems to be solved both quickly and efficiently.

A system reports an error, a problem arises during maintenance work, a spare part is not in stock or there's a technical query about a machine or process: these are only some of the reasons why the equipment manufacturer's service team needs to be contacted in order to get a cleaning system operational again as quickly as possible.

Fast and straight to the right service employee

To give plant users even faster and more effective support in such cases, Ecoclean also offers a range of digital services. These include the new service app for IOS and Android that is designed for smartphones as well as for the web interfaces of desktops and tablets. The application software, which is currently available in seven different languages, automatically forwards service requests directly to the service staff at the responsible Ecoclean branch.

The app has various menu options for contacting the service team, such as 'Report malfunction', 'Spare parts inquiry' and 'Technical support'. This pre-selection helps to ensure that the request is routed to the appropriate member of the relevant service team. If a company has more than one Ecoclean cleaning system in operation, the machine in question can be selected from the 'My Machines' menu. This way, service employee know exactly which system is concerned as soon as they are contacted, and have the necessary documentation at hand.

Easy to use and reliable: real-time connection via chat and video

During the service request, a two-way real-time connection with chat, photo and video functions simplifies communication between the machine operator and the Ecoclean service team. For example, the photo of a de-



The two-way real-time connection simplifies communication between customer's staff and Ecoclean's service team. Work can be followed live and Ecoclean service staff can intervene immediately if necessary. (Source of photo: Ecoclean GmbH)

fective component can be sent live, enabling it to be quickly identified by the service employee and an order or quote initiated. The information and instructions required to remedy a problem or for system maintenance can be transmitted directly to customer's staff by smartphone. The video chat function allows helpdesk employees to follow the work being carried out in real time and intervene immediately if something goes 'wrong'. With the telephone or chat function, queries can be answered straightaway or more detailed instructions given.

his helps make sure that malfunctions or maintenance tasks are not only rectified or performed more quickly by the plant user's staff but also more reliably. Consequently, the digitized service support minimizes unscheduled machine downtimes and associated production losses. This also reduces the number of necessary trips by support staff as well as CO₂ emissions.

The service app can be downloaded for Android devices from Google Play and for IOS devices from the App Store.

Ecoclean GmbH
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February 2020


Dear subscribers,
three days of lounging in Karlsruhe were very strenuous - but also very enjoyable: many interesting conversations, met many familiar and friendly people again, got to know many new and interested people.
Thank you for the informative, pleasant and cordial discussions.

I was particularly pleased with the consistently positive response to our new **YEARBOOK**. And to learn that this „book“ is now part of the basic literature of new employees in some companies makes me a little proud.

I think we are on the right track.
Also with the new Internet site: **www.reinraum.de**
Even clearer, even faster, even better in search. Optimized for mobile, tablet and computer. The display adapts easily. Take a look.
Although this is only the beginning. There's more to come. Stay tuned.

But now to the current newsletter.
There is also an **innovation** here:
On the following five pages you will get an overview of the newsletter content and can easily and directly forward to the article by mouse click: **>more**.
And in the top left corner you can click on **<i** to return to the table of contents.

I wish you interesting reading
With kind regards


Reinhold Schuster



now available:
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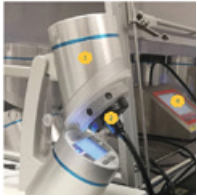
TABLE OF CONTENTS Cleanroom Newsletter 02-2020



Simple, fast and direct way to customer services

Ecoclean GmbH

A system reports an error, a problem arises during maintenance work, a spare part is not in stock or there's a technical query about a machine or process: these are only some of the reasons why the equipment manufacturer's service team needs to be contacted in order to get a cleaning system operational again as quickly as possible. [>more](#)

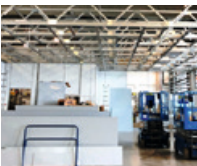


Air Outlet Particle Filter

For Viable Air Sampler MAS-100 NT®

MBV AG

Viable Air Samplers are used for quantitative determination of airborne contamination in cleanrooms and isolators. To maintain the cleanliness of the environment, the air flow should neither disturb the unidirectional air flow nor pose a contamination risk to the environment. [>more](#)



Clean air at Plansee

Schilling Engineering GmbH

With more than 14,000 employees at 50 production sites worldwide, the private company Plansee Group generated sales of EUR 1.5 billion in the 2018/2019 financial year, making it one of the world market leaders in powder metallurgical processing of tungsten and molybdenum. [>more](#)



Call for a global disinfectant standard

Ecolab Contamination Control

Maintaining environmental control in a pharmaceutical manufacturing environment is dependent on the facility's cleaning and disinfection programme, which requires the selection of the appropriate disinfectants, their proper application, and an assessment of their capability to inactivate or kill bacteria and fungi. [>more](#)



Optimized equipment availability and process reliability improve efficiency

Ecoclean GmbH

In all industrial sectors, component cleaning plays a major role when it comes to product quality and added value. If equipment does not function according to plan or if a cleaning system suffers unscheduled downtime, this usually has negative consequences, such as the return of faulty goods or disruptions to production [>more](#)



CWS Cleanrooms plans takeover of profi-con

CWS-boco Deutschland GmbH

profi-con is headquartered in Leipzig. The company specialises in the cleaning of dust-free and sterile rooms, such as those used in the microelectronics or pharmaceutical industry. The CWS Group will take over the approximately 200 employees as well as the management and initially continue operating the „profi-con“ brand on [>more](#)



Gerresheimer increases production capacity for plastic containers and opens new plant in India

Gerresheimer AG

“Today marks the start of a new chapter in the success story of Gerresheimer and Triveni. We acquired a majority stake in the company on December 18, 2012 and now, seven years later, we are opening a new production site to boost our capacity”: this is what Niels Düring, Global Executive Vice President at Gerresheimer Plastic Packaging, [>more](#)



Bosch Packaging Technology is now Syntegon

Bosch Packaging Technology

Syntegon Technology is the new name among the market leaders in the processing and packaging industry. Known as Bosch Packaging Technology until late 2019, the former Bosch division today presented itself as an independent enterprise at the company headquarters in Waiblingen (Germany). [>more](#)



Scale-up for increased reliability

Harro Höfliger Verpackungsmaschinen GmbH

When almost 20 years ago, the pharmacist Dr. Karlheinz Seyfang founded the Pharma Services department at Harro Höfliger and set up the first cleanrooms, he made the company a pioneer among machine manufacturers. Since then, this area has seen continuous growth and has become an integral part of the ALL YOU NEED service idea. [>more](#)

TABLE OF CONTENTS Cleanroom Newsletter 02-2020



Pfeiffer Vacuum supplies leak detectors for the world's largest and most powerful particle accelerator

Pfeiffer Vacuum GmbH

Pfeiffer Vacuum has received yet another major order for leak detectors from CERN. CERN is seated in Geneva on the Franco-Swiss border and is the largest center for particle physics research in the world. Its main business is fundamental physics – finding out what the universe is made of and researching the basic constituents of matter. [>more](#)



Type II glass injection and infusion bottles for parenteral applications

Gerresheimer AG

“Our customers want safe, flawless products from us. So, we need to make sure that we have the best possible production process, even before hardening and tempering the inside of the type II glass, by monitoring the situation constantly and intervening where required,” says Silvio Carriço, Senior Product Manager [>more](#)



Arburg: New Managing Director Technology & Engineering

ARBURG GmbH + Co KG

Guido Frohnhaus brings the ideal qualities to his role as Managing Director Technology & Engineering at Arburg. For many years, he was employed at the Turck Group, one of the leading groups of companies in the industrial automation sector. [>more](#)



Röchling Strengthens Medical Division

Röchling SE & Co. KG

Mannheim-based plastics expert Röchling restructures its Medical division: On 1 January 2020, Dr. Boris Fröhlich will take over the position of CEO in the Medical division from Prof. Hanns-Peter Knaebel, who will in the future be responsible for the Automotive and Medical divisions on the Group Executive Board in addition to his role [>more](#)



New instruments for battery research

Messe München GmbH

Lithium-ion batteries are used in electric cars, smartphones and many other mobile devices. Nevertheless, they have various disadvantages – from questionable ingredients such as cobalt to flammability and self-discharge. Researchers around the world are therefore working to optimize lithium-ion batteries, or to develop alternatives [>more](#)



Focus on automation and digitalisation

ARBURG GmbH + Co KG

„Our customers in the U.S. are very interested in electric machines and automation solutions. And our digital products and services are also becoming more and more important,” says Friedrich Kanz, Managing Director of Arburg Inc. „With fully automated production of pump heads, we will be able to demonstrate our expertise in turnkey [>more](#)



Innovative micro-infusion pump from Gerresheimer subsidiary Sensile Medical for EVER Pharma

Gerresheimer AG

The D-mine® pump is used to administer apomorphine in the advanced stages of Parkinson's treatment. Simple handling, safety, and ease of use were the main aims behind the development. The compact design is down to Sensile Medical's special micro-rotation pump technology and is straightforward to use thanks to an intuitive [>more](#)



Schreiner MediPharm to Showcase New Robust RFID Pharma-Label and Secure Supply Chain Solutions

Schreiner MediPharm

Interaction between the user and the pharmaceutical manufacturer, and communication between the product and a medical device: Equipping pharmaceutical products and medical devices with RFID-Labels results in smart devices that help optimize processes and enhance ease and safety of use. [>more](#)



Packaging and administering biologicals safely and securely

Gerresheimer AG

The pharmaceutical industry is focusing on new therapies. Personalized treatment such as cell therapies, new biomolecules, and drugs for rare diseases are playing a key role in new approaches. This is why smaller batch sizes are often requested for filling. In addition, bottled products are sensitive to their storage environment, the container. [>more](#)

TABLE OF CONTENTS Cleanroom Newsletter 02-2020



Toward Autonomous Production

Messe München GmbH

Visitors to automatica 2020 will find answers to the questions about how the topics of digital transformation, man and machine as well artificial intelligence (AI) will affect the manufacturing world of tomorrow. Falk Senger, Managing Director of Messe München, emphasized: "automatica is aimed at companies from all sectors of industry. [>more](#)



Microfluidics and bio chips are the centre of attention at COMPAMED 2019

Messe Düsseldorf GmbH

"Companies showed up at COMPAMED to prove that they are innovative forces to be reckoned with and to demonstrate that they are strong partners for the medical technology industry in this market environment, which is becoming increasingly demanding," observes Wolfram Diener, Operative Managing Director of Messe [>more](#)



Electric, efficient, eSy – valves with new motorized eSy actuators

GEMÜ Gebr. Müller Apparatebau GmbH & Co. KG

For several years now, the processing industry has been increasingly looking for alternatives to pneumatic actuators. Electric valves are an option. These have particular appeal on account of their cost efficiency and performance. The reduced risk of contamination and the application in a wide variety of plants are also positives in favour of [>more](#)



Air Outlet Particle Filter For Viable Air Sampler MAS-100 NT®



Author: **Roland Durner, MBV, Switzerland, Tony Ancrum, Anne-Grit Klees, Merck KGaA Darmstadt, Germany**

Introduction

Viable Air Samplers are used for quantitative determination of airborne contamination in cleanrooms and isolators. To maintain the cleanliness of the environment, the air flow should neither disturb the unidirectional air flow nor pose a contamination risk to the environment.

As portable air samplers are sometimes moved and used in various environments with different levels of microbial contamination, there might be a risk of cross-contamination from higher to low contaminated environments.

The MAS-100 NT® is equipped with a brushless motor which generates a minimal amount of particles, so that no filter is required even for GMP Grade A usage. A H13 particle filter can be mounted at the exhaust air, when needed (see Figure 1).

Merck provides results on the cleanliness of MAS®100 NT with and without in-built filters under several scenarios.

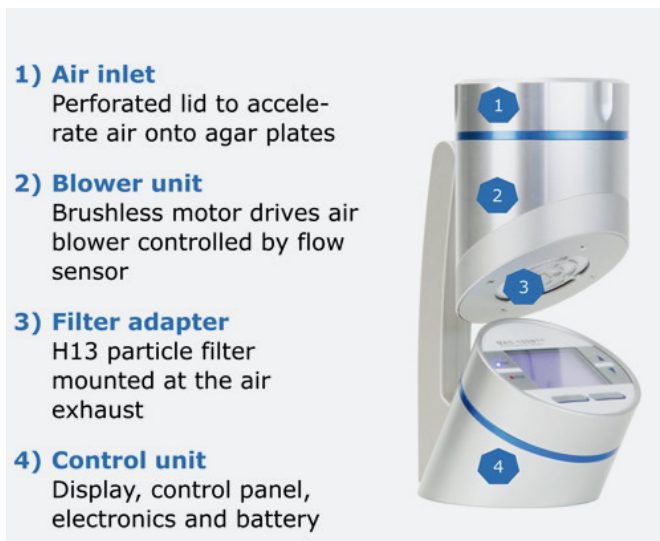


Figure 1 – MAS®100 NT equipped with a H13 particle filter.

Test Setup

The standard MAS-100 NT® air sampler is compared to a MAS-100 NT® equipped with a H13 filter. The particle emission under different environmental conditions is measured using an ACS Plus particle counter, which is directly mounted to the air outlet of the air sampler.

In figure 2 the MAS-100 NT® is positioned in a non-controlled reference environment, whereas in other configurations the instrument is placed beside the ACS Plus particle counter (KM Optoelektronik GmbH, Germany) in the cleanbench.

Results and Discussion

1. CROSS-CONTAMINATION OF CLEANROOMS

Once the test system was established the basic assumption was to be tested: Is there really a need for a filter to prevent the transfer of particle contamination between different environments?

A 1000 l air sample was collected with a MAS-100 NT® in the reference environment with or without filter. Thereafter the instrument was transferred into the clean environment and started again. Particle counts were taken from the exhaust air at the outlet every 5 s. The test was repeated 5 times for both setups. In tests without filter we found a total of 126 – 296 particles in the first 5 seconds after starting the blower and between 0 and 3 particles for the second 5 seconds and no particles thereafter (Figure 3). A total of 1042 particles were detected

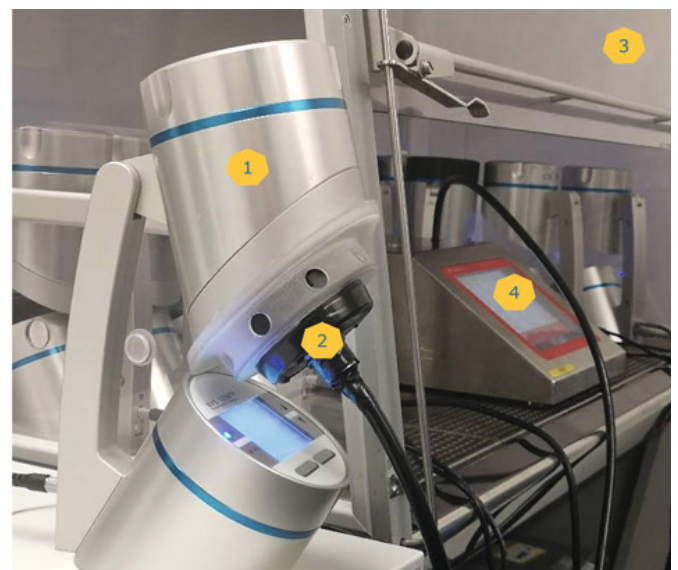


Figure 2 – Experimental set-up of particle measurements: 1) MAS®100 NT in reference environment; 2) Sampling adapter collects exhaust air and directs it to the particle counter; 3) Biosafety workbench with low particle count environment; 4) Particle counter ACS Plus in biosafety workbench.

Air Outlet Particle Filter For Viable Air Sampler MAS-100 NT®

between all 5 repetitions, about 12% of them larger than 1 µm. The data demonstrate that there is a minimal transfer of particles between different environments. The fact that there were no particles detected after 10 seconds proves that the particles were not generated by the blower motor or other instrument components.

If the MAS-100 NT® was equipped with a HEPA air outlet filter 0–6 particles were counted in the first 5 seconds and 0 thereafter (Figure 3), all of them smaller than 1 µm. The filter dramatically reduced the transfer of particles and virtually eliminated the risk of them being CFU as those tend to be larger than 1 µm.

2. FILTRATION EFFICIENCY OF THE COMPLETE ASSEMBLY

10 filters on two different units of MAS-100 NT® (5 filters each) were tested for filtration efficiency of the complete assembly of air sampler, filter adapter and HEPA filter. The filter it-self is rated H13 and we expected therefore a filtration efficiency of 99.95% or better for particle sizes of 0.3 µm or larger. For every test we took a reference sample by measuring the particle count of the exhaust air of a MAS-100 NT® running in the reference environment. As the particle load was very high, we took 10 samples of 10 s each and extrapolated the particle count to 1000 l. This reference count was compared to a 1000 l sample taken from the identical MAS-100 NT® with particle filter running in the same environment. Every 3 minutes the particle count was recorded to assess if there was a trend. In all cases the filter assembly passed,

and even exceeded, the required performance threshold (Table 1) for H13 filters. Throughout the 36 minutes (approx. 1 m³) sampling interval there was no trend for any filter (data not shown). The filter assembly therefore meets the need to protect an environment from carry-over of particles from another environment with lower particle rating.

3. LONG-TERM FILTRATION EFFICIENCY

It is recommended to recalibrate a MAS-100 NT® annually. Therefore, under normal usage a filter should be able to be used for a complete calibration interval. We assumed that 10 samples of 1000 l per day would be taken under intense usage for 300 days per year. This amounts to about 21 days permanent operation. Two MAS-100 NT® with filter were run continuously for 21 days in the uncontrolled reference environment. From time to time 1 m³ of the exhausted air were sampled for particles from both devices and compared to the reference sample taken immediately before or after without filter. There was no detectable deterioration of filtration efficiency during this time. All filters were meeting or exceeding H13 filter specification. Also, there was no detectable filter clogging and airflow calibration remained within specification.

Summary

The MAS-100 NT® is a portable instrument, which is designed for quantitative analysis of microbial contamination in air. The brushless motor does not generate particles, which exceed the limits of a cleanroom ISO 5. This study investigates the need for filtration of the exhaust air, especially when air sampling with the same instrument is performed in environments with various contamination rates.

- There is a risk of minimal transfer of particle carry-over between different environments from air trapped inside a microbial air sampler.
- Particle carry-over is essentially eliminated by the insertion of a HEPA filter at the air outlet of the MAS-100 NT® viable air sampler.
- The filter has no significant influence on the airflow calibration and therefore on the microbial sampling efficiency.
- Stressing the filter for a simulated year of heavy usage in an uncontrolled environment does not reduce the filtration efficiency and does not clog the filter.



Figure 3: Transfer of particles from low to high contaminated to low contaminated environments

	0.3 µm	0.5 µm	1.0 µm	3.0 µm	>5.0 µm	Total Particles
ISO 5 particle limit	10200	3520	832	N/A	N/A	N/A
ACS Plus: Clean air in workbench (mean, n=2)	15	8	5	2	7	37
ACS Plus particle Counter: Non-controlled air (mean, n=2)	762'314	186'569	45'432	4'462	5'923	1'004'700
Reference: MAS-100 NT® without filter (mean, n=10)	701'746	163'906	42'185	4'109	4'956	916'901
MAS-100 NT® w. Filter (mean, n=10)	69	6	1	0	0	76
Filter Retention Efficiency	99,99%	100%	100%	100%	100%	99,99%
Max particle count with filter	119	14	6	0	1	140
Min particle count with filter	6	1	0	0	0	0

Table 1: Filtration efficiency of the HEPA H13 filter assembly for the MAS-100 NT®

For reference also the permissible particle concentrations of ISO Class 5 are given.



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Since no suspension was possible on the on-site ceiling, the cleanroom was designed to be self-supporting using a truss made of aluminum profiles.

Clean air at Plansee



Plansee invests in 400 square meters of cleanroom with the latest technology

The Plansee Group, based in Reutte, Austria, specializes in the powder metallurgical processing of the high-tech metals molybdenum and tungsten. Ongoing investments in the development of new products and process improvements secure the site and the employment of the approximately 2400 employees. Now an almost 400 sqm cleanroom of ISO cleanroom class 6 has been put into operation, which meets the high safety standards of the semiconductor industry.

Clean metal processing

With more than 14,000 employees at 50 production sites worldwide, the private company Plansee Group generated sales of EUR 1.5 billion in the 2018/2019 financial year, making it one of the world market leaders in powder metallurgical processing of tungsten and molybdenum. The headquarters and the largest production site are located in Austria, where the company originated in 1921 as the Plansee metal works.

If a metal processing operation first brings to mind production with chips, dust and dirt, exactly the opposite is true in case of Plansee. The company focuses on high-melting metals such as tungsten and molybdenum, which have special properties such as high resistance and good conductivity. The metals are first processed into high-purity powder and then pressed and sintered. The semi-finished products and components are required in the electronics industry, in semiconductor manufacturing and in medical technology. Absolute cleanliness in production therefore has top priority.

For the current production of components for semiconductors, the process even takes place within an ISO class 6 cleanroom. In the state-of-the-art cleanroom CleanCell4.0® parts made of molybdenum

and other materials are assembled, which could be impaired in their function by the smallest impurities. Contamination of the sensitive components by particles must be absolutely ruled out. That is why over half of the 400 sqm production area meets the strict cleanliness requirements of ISO cleanroom class 6.

Cleanroom technology with energy-efficient air circulation

Clean air is introduced into the cleanroom with the help of laminar flow units integrated in the ceiling, which are equipped with ULPA15 high-performance filter. The particle-free air flows displace airborne particles downwards and are then discharged from the cleanroom into the air circulation system. This air exchange process is carried out up to 60 times an hour. Recirculation and return air are routed within the cleanroom walls. The already cooled and filtered air is circulated, which contributes to the very efficient operation of the cleanroom. In addition, the air flow within the walls ensures optimal use of space. Plansee opted for a cleanroom system from Schilling Engineering. Mario Kuisle, project engineer at Plansee explains the advantages of the system: "The air circulation of the CleanCell4.0 cleanroom system convinced us from the start. This will enable us to save high energy

Clean air at Plansee



Special cleanroom furniture and roller shutters with non-contact control ensure safe processes.

Material locks and doors contain an intelligent lighting concept that takes flushing times into account and indicates when a door can be opened.

costs in the long run. Another important factor was the fact that the air flow inside the walls ensured optimal use of space. The cleanroom was adapted precisely to our conditions."

The particular conditions of the on-site location required in many respects a cleanroom, which was tailored to customer requirements. The project engineer remembers some of the challenges that the planning cleanroom company faced: "The on-site ceiling of the Plansee hall is structurally unsuitable for suspension, among other things due to the expected snow loads. Subsequently, the cleanroom ceiling was constructed using a self-supporting framework made of aluminum profiles. The ceiling is accessible and has been marked with stable walking paths. A huge advantage of the construction is that the cleanroom was built without supports and columns."

Modular design

Another challenge was the required height of the cleanroom, which was designed to be four meters higher than normal cleanrooms. The height required by the installation of measuring machines could be achieved with removable wall elements. The ceiling, which is equipped with 67 clean air units, has a modular structure and can be flexibly redesigned. The modular system of the CleanCell4.0® cleanroom enables flexible planning of future utilisation, as Mario Kuisle explains: "The modular design of the cleanroom system helped us significantly in our investment decision. We wanted to be able to quickly and flexibly convert the cleanroom to other production processes.

Components for semiconductor production are manufactured in the 400 sqm CleanCell4.0® cleanroom of ISO cleanroom class 6.

We are currently producing for semiconductor production and have integrated the production machines into the cleanroom walls. Thanks to the modular wall and ceiling elements, we can convert to changing allocation concepts in the future."

Intelligent control

Dimmable LED light strips are integrated homogeneously into the aluminum strips of the ceiling which with 1000 lux achieve uniform lighting with little shade and contribute to energy savings. Doors and material locks are also illuminated with LEDs and using various colours visualise whether a door can be opened or must remain closed for pressure compensation and active flushing. The connected control and monitoring system CR-Control® offers intelligent control, using which individual filter units, production-relevant room data such as temperature and humidity and the air conditioning technology are controlled and monitored. The air conditioning is characterised by an extremely energy-efficient treatment of the air. The high-precision air-conditioning technology temperates the room with a very slight deviation of $\pm 1^\circ\text{C}$ and is also characterized by extremely energy-efficient air conditioning. Mario Kuisle is very satisfied with the first months the cleanroom has been in use: "The cleanroom runs flawlessly. The technology is very complex, but perfectly coordinated and well thought out. The energy optimisation of the cleanroom was very important to us. Using a heat pump, we can save high additional costs in the long term. We also have the option of programming a night-time reduction. The quiet filters and good lighting are also very positive, which facilitates the daily work in the cleanroom."



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Call for a global disinfectant standard

The time has come for industry and disinfectant manufacturers to set out guidelines for evaluating products appropriate for pharmaceutical cleanrooms, says Tim Sandle in conjunction with Ecolab Life Sciences.

Maintaining environmental control in a pharmaceutical manufacturing environment is dependent on the facility's cleaning and disinfection programme, which requires the selection of the appropriate disinfectants, their proper application, and an assessment of their capability to inactivate or kill bacteria and fungi.

Disinfectants have a variety of properties that include spectrum of activity, mode of action, and effectiveness. Equally, the chemicals are often categorised into groups based on their chemical nature, spectrum of activity, or mode of action. Effectiveness is assessed through disinfectant efficacy testing.

A problem faced by users, is the array of different (and often contradictory) standards together with differing and often unrealistic, acceptance criteria. For those working in pharmaceuticals and healthcare, a global approach applicable to these sectors is required.

The Life Sciences division of Ecolab has developed a new ap-

proach to meet this need, and the key aspects of this useful approach are discussed in this article.

Why disinfectant efficacy testing matters

Qualification of a disinfectant is demonstrated through performance testing to show that the disinfectant is capable of reducing the microbial bioburden found in a pharmaceutical manufacturing area. The primary tests are divided into suspension tests, surface tests and field trials.

The field trial is the final piece of the qualification jigsaw and it is essentially an assessment of environmental monitoring data; the suspension and surface tests are generally taken to be the core disinfectant efficacy tests.

Of these two, the surface test is the most robust. While supplier data can be taken for suspension tests, undertaking some form of surface test is normally expected of the user. The surface test is the one required by regulatory agencies, as set out by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) in document P1007.

There are differences in the approaches between North America and Europe, and with the guidance issued by professional bodies. This array of approaches creates confusion.

With the surface test, representative manufacturing surface samples are inoculated with a selection of microbial challenge organisms. A disinfectant is applied to the inoculated surfaces and exposed for a predetermined contact time, after which the surviving organisms are recovered.

The number of challenge organisms recovered from the test samples (exposed to a disinfectant) is compared to the number of challenge organisms recovered from the corresponding control sample (not exposed to a disinfectant). Successful completion of the validation



Call for a global disinfectant standard

qualifies the disinfectant evaluated for use.

In setting out to perform surface testing, it stands that there is no 'universal' approach to disinfectant efficacy testing. There are differences in the approaches between North America and Europe, and with the guidance issued by professional bodies. This array of approaches creates confusion for the user and also leads to inappropriate levels of testing. Some of these differences are drawn out below.

Global differences in efficacy tests

Both the EU GMP and the US FDA regulations mention the importance of the pharmaceutical manufacturer evaluating the efficacy of the disinfectants used, and various standards are available to guide the microbiologist through this process.

The user can choose from CEN (European Committee for Standardization); AOAC (Association of Official Analytical Chemists International) or ASTM (American Society for Testing Materials) standards (North America); or draw on guidance from a professional body or non-mandatory compendia, such as USP 40-NF35 Chapter . These standards and guidelines are contradictory and not totally suitable for the pharmaceutical cleanroom.

Differences include recommended organisms (often different types of organisms); the surface coupon sizes; permitted inoculum volumes; test recovery method; whether interfering substances are present; whether physical action is permitted (wiping); starting microbial challenge levels; and log reductions (4 to 3 logs). In addition to the standard panel of prepared cultures, organisms isolated from the facility should also be tested as per regulatory expectations.

It is important to note these standards are multi-industrial (including industries where high levels of microbial contamination would be expected). The lack of a universal approach leads to user and regulatory confusion, and often the consequential outcome of over-specifying the acceptance criteria.

The time has come for industry and disinfectant manufacturers to set out a new solution to this regulatory issue that is appropriate to pharmaceuticals. One such approach has been proposed by Ecolab Life Sciences through the Validex Programme.

Validex: The Ecolab approach

In drawing a framework for what such a global standard will look like, Ecolab reviewed the essential factors that need to be captured within a disinfectant efficacy test targeted for classified cleanrooms and associated controlled-but-not-classified (CNC) areas. Here the most important factors are:

- The microorganisms used should reflect those commonly recovered from pharmaceutical facilities
- The target reductions should reflect the levels of contamination typically seen within pharmaceutical facilities
- The surfaces challenged with microorganisms should be representative of the surface finishes found in pharmaceutical cleanrooms

- Contact times should reflect operational conditions
- Application of mechanical action
- Soling (surface cleanliness)

Representative microorganisms

The test panel of organisms should be populated with microorganisms commonly found in pharmaceutical facilities. Examples of representative organisms, highlighted by Ecolab for the pharmaceutical context are:

- Staphylococcus aureus
- Staphylococcus epidermidis
- Micrococcus luteus
- Escherichia coli
- Pseudomonas aeruginosa
- Burkholderia cepacia
- Bacillus subtilis
- Candida albicans
- Penicillium chrysogenum
- Aspergillus brasiliensis

These organisms are reflective of what is carried on operators, associated with water systems, linked to equipment transfer, or representative of common fungi. Plus, efficacy studies need to be supported from organisms isolated from the manufacturing environment, especially where such organisms are different to the above list. Factors to consider when selecting such organisms include:

- Ensuring that all process cleanrooms are reviewed (from Grade A to Grade D).
- Review data from water systems used to dilute disinfectants.
- Ensure that the review covers a sufficiently long period of time to account for variables such as seasonal variation.

Such reviews should be conducted periodically, for example, annually.

Appropriate microbial challenges

With target populations, the criteria should be reflective of the regulatory recommended permitted maximum levels of microorganisms while also being sufficiently high to show a logarithmic reduction. The highest microbial surface level permitted in an EU GMP Grade D cleanroom, for instance, is 100 CFU. Under this requirement, there is little value using a starting challenge inoculum of one million cells or more and seeking a 6-log reduction.

A further reason for setting realistic challenges is because test organisms will be grown as healthy laboratory cultures and challenged while in the logarithmic phase of growth. Such organisms are typically more resistant than organisms within the cleanroom environment, which are often not growing and subject to external stress factors. Hence, it is important to set appropriate and realistic acceptance criteria so that products are not being unnecessarily or overly challenged. On this basis, recommended challenges under the Ecolab proposal are shown in Table 1.

The above acceptance criteria are equivalent to those recommended in USP .

When preparing microbial cultures, starting inocula should be sufficiently high in order to compensate for in-test dilutions and to account for some loss of viability during drying. Ecolab recommends 1.5 x10⁷ to 5.0 x 10⁷ for bacteria; 1.5 x10⁶ to 5.0 x 10⁶ for fungi and bacterial spores.

Table 1: Recommended challenges by Ecolab proposal

Disinfectant	Acceptance Criteria (log ₁₀)
Vegetative cells	>Log 3
Bacterial and fungal spores	>Log 2

Call for a global disinfectant standard

Representative surfaces

Prior to initiating disinfectant efficacy validation, a comprehensive survey of the materials comprising the room surfaces (floors, walls, windows) and equipment (stainless steel, acrylic, polyvinyl chloride, and so on) present in the facility which could potentially be exposed to the disinfectant should be conducted.

In terms of selecting common surfaces, the Ecolab approach is to draw up a matrix where users are advised to assess the following factors in order to select 'worst case' surfaces:

- Hydrophobicity
- Surface roughness
- Potential for chemical interaction at surface
- Prevalence
- Contamination risk (such as with horizontal surfaces are a greater risk than vertical; plus, those surfaces that are frequently touched)
- Proximity to product, areas where critical activities are performed

From this, common surface types may include:

- Vinyl
- Aluminium
- Epoxy coated flooring
- Glass
- Stainless steel
- PVC
- Polyurethane coated walls
- Plexiglass
- Acrylic
- Polycarbonate
- Gloves

The size of the test coupon should be standardised (you can get better recovery from a smaller coupon).



Contact times

There is little value in evaluating disinfectants targeted to kill vegetative microorganisms with contact times for longer than 5 or 10 minutes. One reason is practical; a busy pharmaceutical facility will not be wanting to wait for 60 minutes every time a disinfectant is applied.

Another reason is scientific; given the rapid air changes found in many cleanrooms and clean air devices treated surfaces will dry quickly and no surface will remain 'wet' for a prolonged period, triggering the need for repeated application. Therefore, relatively short contact times should be targeted.

Mechanical action

The method of application for the most disinfectants to a surface is either by spraying and wiping or mopping (commonly described as involving 'mechanical action').

There are clear advantages with this since wiping can increase the efficacy of disinfection and physically removes particulates, soiling materials (and residues), and microorganisms (microorganisms that are detached from surfaces are easier to kill). The activity of wiping also ensures a controlled delivery of the disinfectant onto the surface. Therefore, the inclusion of mechanical action is an important part of the disinfectant efficacy evaluation.

Soiling

Disinfectant standards outline challenges with soiling. The application of additional soil (to create 'dirty' conditions) should not be necessary when evaluating disinfectants in a pharmaceutical facility since disinfectants should be being applied to clean surfaces.

Making sure a global disinfectant efficacy standard happens

With Ecolab having set out some clear, sensible and reproducible criteria for the evaluation of disinfectants for use in pharmaceutical facility cleanrooms, it is now time for industry and manufacturers of disinfectants to come together to ensure that such an approach becomes the de facto approach for the industry.

This can happen through users developing protocols along the lines recommended; having supplier recommending the revised criteria; and, most importantly, engaging with regulators to present the scientific arguments behind the approach and seeking universal acceptance of what needs to become a global standard for disinfectant efficacy testing as applied to pharmaceuticals.



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Optimized equipment availability and process reliability improve efficiency

Reducing cleaning costs with individually adapted services

To guarantee continuous and consistent cleaning results, it is essential that cleaning can be planned. For this, a system has to function in an optimal way and fluctuations in the process or unscheduled downtimes must be avoided. A service concept that is tailored to the requirements of the equipment user and implemented in close cooperation with the manufacturer helps to achieve this. Therefore, Ecoclean has developed a wide range of services that can be individually combined.

In all industrial sectors, component cleaning plays a major role when it comes to product quality and added value. If equipment does not function according to plan or if a cleaning system suffers unscheduled downtime, this usually has negative consequences, such as the return of faulty goods or disruptions to production or delivery processes. The result is increased unit costs, which are detrimental to profitability and competitiveness.

Optimized process quality and equipment availability

If process quality and the availability of the cleaning system are always kept at an optimal level, related costs and image damage can largely be avoided. Ecoclean has developed a comprehensive portfolio of services and products for this purpose. The services offered range from advice during the planning of a new system to ensuring the availability of the system throughout its entire service life, as well as assistance in optimizing cleaning processes, adapting the system to new requirements and improving energy efficiency. In the global service network of the equipment manufacturer with its locations and agencies, more than 125 customer service employees take care of around 5,000 installed systems.

Individually combinable services

Regular maintenance is key to ensuring consistently high process quality and system availability. To meet the wide-ranging requirements and wishes of equipment users, regular service agreements can be tailored to respective needs. In this way, maintenance can be

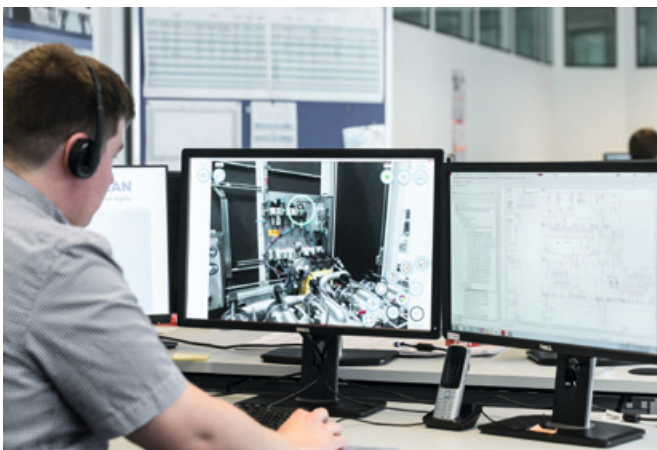
carried out during a 'controlled production downtime' when it suits and at minimized cost.

If a malfunction needs to be rectified quickly, Ecoclean customer service is available 24 hours a day, seven days a week. Remote service enables experts with in-depth process and system knowledge to access equipment remotely, analyse the cause and help solve the problem at a time arranged with the user. Of course, faults can only be rectified fast if the equipment user has the necessary spare and wear parts in stock. For this reason, the customer service staff also recommend which spare parts should be procured for the respective system. If worst comes to worst, they make sure that the required spare and wear parts are shipped quickly anywhere in the world.

New service app for fast and efficient communication

The new service app for IOS and Android will be available from January 2020 and permit two-way exchange between equipment users and Ecoclean customer service employees via video call and chat functions. The information and instructions required for troubleshooting or system maintenance can be transmitted directly by smartphone. Using the phone's camera, helpdesk employees can follow the work closely and intervene immediately if something goes 'wrong'. The normal phone and chat function can be used to answer questions immediately or to clarify instructions. This state-of-the-art form of service support minimizes the need for long and costly trips. It not only reduces equipment downtimes but also CO₂ emissions.

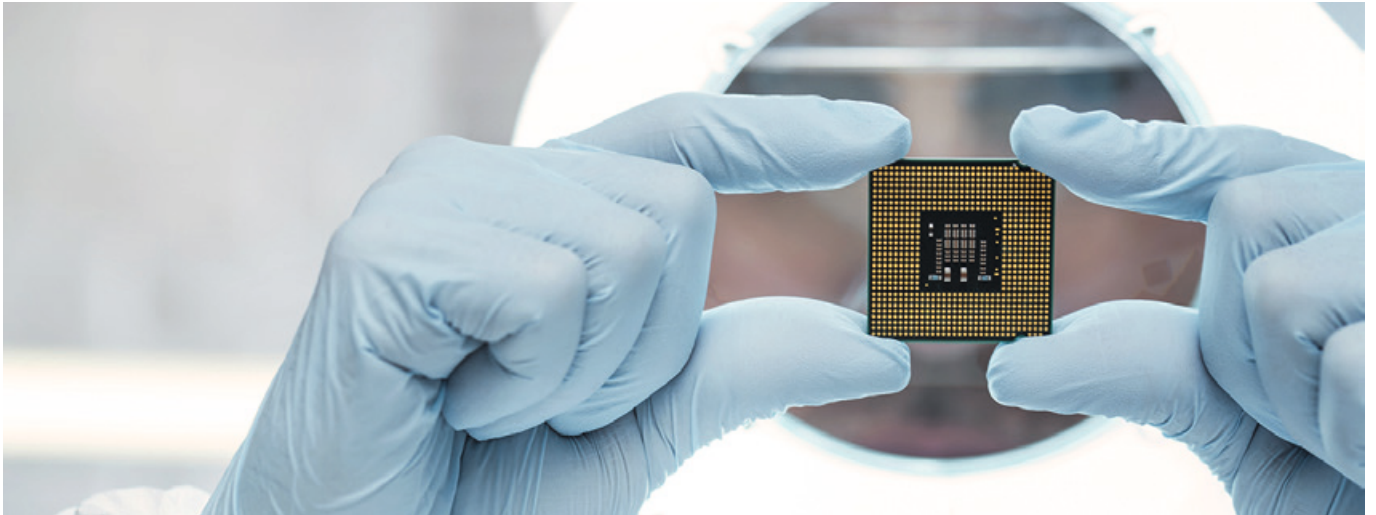
Ecoclean GmbH D 70794 Filderstadt



Remote service provides fast and efficient remote assistance in the event of malfunctions. The new service app enables two-way exchanges via video calls with transmission of live imagery.



Regular maintenance is key to high process stability and equipment availability, as well as preservation of a system's value. Regular service agreements tailored to the individual situation and requirements of the equipment user ensure optimal reliability at affordable costs.



CWS Cleanrooms plans takeover of profi-con



The CWS Group, a complete system provider in the solution areas Hygiene, Workwear and Fire Safety, plans to take over cleanroom cleaning service provider profi-con via its CWS Cleanroom business unit. Subject to the approval of the antitrust authorities, CWS will thus be expanding its range of cleanroom products and services through the complete acquisition of the company. This will make CWS the first full-solution provider in this field in the market. The acquisition also includes profi-con's "ReinraumAkademie", a training facility for the professional cleaning of cleanrooms.

Employees and management to be retained

profi-con is headquartered in Leipzig. The company specialises in the cleaning of dust-free and sterile rooms, such as those used in the microelectronics or pharmaceutical industry. The CWS Group will take over the approximately 200 employees as well as the management and initially continue operating the „profi-con“ brand on an independent basis. All of the profi-con locations – in particular Leipzig and Aschaffenburg – are to be retained.

„The acquisition of the profi-con Group constitutes the continuation of our full service & solution strategy,“ emphasises Markus Schad, head of the CWS Cleanroom business unit. „The addition of profi-con's cleaning operations, on-site services and training activities expands our portfolio and enables us to open up new growth potential for the CWS Group's Cleanroom segment. The acquisition complements our existing range of offerings with the focus on services for cleanroom textiles and makes for a bundle of services not available on the market up to now. This will give our customers even more choice in the contamination control segment.“

CWS will strengthen profi-con nationally and internationally

profi-con's Managing Director Wolfgang Tolzin too sees the sale as a strategic opportunity for his company: „The takeover by the CWS Group means we can expand our joint market position at both the national as well as international levels. This growth potential is highly attractive for us and was one of the main reasons behind the sale to CWS Cleanrooms. Together, we can continue progressing the development in the market and offer our customers even more solutions from a single source in the future.“

About CWS

With innovative, sustainable and digital rental solutions, CWS contributes to a healthier and safer tomorrow. The CWS range is di-

vided into products and services in the areas of Hygiene, Floor Care, Workwear, Fire Safety, Cleanrooms and Healthcare. Since April 2019, all service areas of the company have been operating as an integrated system provider under the name of CWS.

CWS is a brand of CWS-boco International GmbH and its subsidiaries. The group currently employs around 10,600 people in 16 countries. In 2018, the company generated a turnover of €1,141 million. CWS-boco International GmbH and its subsidiaries are wholly owned by Franz Haniel & Cie. GmbH.

About profi-con GmbH

Founded in 1985, profi-con is an established service provider in the cleanroom sector, looking after sterile rooms in the pharmaceutical, genetic engineering, biotechnology and medical technology industries. The company also provides professional cleaning services for dust-free cleanrooms in the microelectronics, semiconductor, optoelectronics, automotive and plastics technology industries. In cooperation with the CleanroomAcademy, profi-con provides training courses, coaching, workshops and seminars covering all aspects of cleanroom technology and operation.

CWS

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Gerresheimer increases production capacity for plastic containers and opens new plant in India

Gerresheimer has had a strong foothold in India for some years through Triveni Polymers Pvt. Ltd. in Kundli. A second production site is now being opened in the city of Kosamba to help bolster production capacity to cope with the high demand for Triveni round containers. The official opening ceremony will take place on December 16 on the site's premises in Kosamba, in the district of Surat, with international guests invited to attend.

"Today marks the start of a new chapter in the success story of Gerresheimer and Triveni. We acquired a majority stake in the company on December 18, 2012 and now, seven years



The modern production hall in Kosamba.

later, we are opening a new production site to boost our capacity": this is what Niels Düring, Global Executive Vice President at Gerresheimer Plastic Packaging, will be saying at the official opening of the new plant in Kosamba on December 16, 2019. He will add that, with the second site up and running and the warehouses available in Hyderabad, it will be possible to significantly reduce the time it takes to deliver products to customers, enhance supply performance, cover a wider area, and ensure business continuity.

His welcoming speech will follow a presentation of the plant by Jari Tevajarvi, Vice President Asia Plastic Packaging, and Plant Manager Prakash Dhameja. The ceremony

is set to attract numerous guests from both India and abroad, including official representatives from the local region.

Production of Triveni round containers is due to begin in class-8 and class-9 clean rooms at the end of the year. At the same plant, Gerresheimer Pharmaceutical Packaging Mumbai Pvt. Ltd. will be making vials out of tubular glass for pharmaceutical and diagnostic applications, as well as ampoules. Next in the pipeline is a new production facility that is being built as a greenfield project on the same industrial park.

Gerresheimer AG
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Bosch Packaging Technology is now Syntegon



- Transaction wrapped up on schedule, business development remains stable
- Into the future with new brand and a new mission: Processing and packaging technology for a better life
- Newfound independence allows for greater flexibility
- Business to focus on intelligent and sustainable technologies
- Service offering will be expanded

Syntegon Technology is the new name among the market leaders in the processing and packaging industry. Known as Bosch Packaging Technology until late 2019, the former Bosch division today presented itself as an independent enterprise at the company headquarters in Waiblingen (Germany). Syntegon Technology's business focus is on intelligent and sustainable technologies for the pharmaceutical and food industries. Extending the service range is a priority for the company. Syntegon Technology employs 6,100 people at more than 30 locations worldwide. It posted 1.3 billion euros in sales in 2019. Bosch disclosed its plans to sell the packaging machinery division to a newly incorporated entity managed by CVC Capital Partners, a leading private equity and investment advisory firm, in July 2019. The transaction was completed according to plan, with the company gaining full independence at the turn of the year.

Transaction wrapped up on schedule as business development remains stable

The sale of Bosch Packaging Technology was completed on January 2, 2020, as envisioned. Bosch had announced in June 2018 that it intended to sell its packaging division, finding a buyer a year later in CVC Capital Partners (CVC). Bosch Packaging Technology then expanded its headquarters in Waiblingen, Germany, augmenting it with new departments required for the switch. Business developments remained stable in the interim, bucking the trend in the sluggish machine engineering sector. Sales in 2019 came to 1.3 billion euros, matching the previous year's figure.

The new owner, CVC, aims to vigorously develop the company as a whole and expand intra-group synergies. Commenting on the closing

Bosch Packaging Technology is now Syntegon

of the sale, Marc Strobel, a partner at CVC Capital Partners said, "CVC is delighted to see the transaction completed on schedule. Syntegon Technology has a strong presence in many market segments, great technological know-how, and innovative power. We want to build on these strengths jointly with management and the entire workforce."

SYNTEGON

PROCESSING & PACKAGING

Into the future with a new brand

"Processing and packaging technology for a better life!" This is Syntegon's mission statement. The company is determined to improve the lives of consumers and patients with intelligent and sustainable processing and packaging solutions. A new corporate brand was developed over the past few months. The name Syntegon stands for synergy, technology, and focus on the future. The new corporate color green underscores the importance of sustainability and health. The square in the newly designed logo symbolizes a package as well as packaging technology's ability to protect products.

The entire workforce will celebrate the independent company's launch with management on January 16, 2020. The ceremony at the Waiblingen headquarters, broadcasted live around the world, will be followed by events held at the individual locations. Syntegon Technology will share the news with its business partners today. Chairman of the Executive Board Dr. Stefan König takes this opportunity to send an emphatic message: "We are building on 150 years of experience and the 64,000 machines deployed by our customers, and pursuing new avenues of business. Now, more than ever before, we are working on intelligent and sustainable technologies and embracing the collaboration with our business partners in the true spirit of partnership."

Greater flexibility and focus on caring partnerships

This newly gained independence enables Syntegon Technology to be even more flexible. And newly added departments at the head-



Die neuen Syntegon-Flaggen wehen nun vor der Firmenzentrale in Waiblingen.

quarters such as Purchasing and IT shorten the distances between in-house units and facilitating interaction with customers and suppliers. Whereas the company had been part of a large corporation with diverse divisions, it can now create a business framework that is an even better fit for the industry. This new setup will enable the company to enhance its profile as a leading processing and packaging company.

Syntegon Technology aims to set new priorities for services. Impelled by the spirit of partnership with its customers, the company is striving to improve its processes. One goal is to reduce response times to customer enquiries; another is to further increase the availability of service technicians. Syntegon Technology is also investing in a customer and technology center at its Waiblingen headquarters. The processing and packaging technology company collaborates with global corporations and regional market leaders, and is determined to offer even more attractive services for medium-sized enterprises and startups.

Intelligent and sustainable technologies

Syntegon Technology has intensified its efforts to develop intelligent and sustainable technologies. Drawing on a deep well of experience in developing and integrating software solutions, the company uses connected components as well as components enhanced with artificial intelligence to this end. It puts a premium on ensuring sophisticated technologies are simple to use. The greater goal is to collect and evaluate data to avoid machine downtime, maximize product quality, and optimize overall plant efficiency.

The enterprise is pursuing two approaches to produce sustainable packaging – one is to use mono materials rather than conventional multilayer films, and the other is to use paper packaging as an alternative to plastic. Syntegon Technology supports its customers on the path to a sustainable future with material testing, machine applications, and innovative packaging designed to meet the requirements of products, transport modes, and regional circumstances. The company has also significantly reduced its machines' energy consumption.

The numbers speak for themselves

A campaign to train the spotlight on Syntegon Technology's new brand is underway. The company is letting the numbers tell the story. Featuring prominently on the website at www.syntegon.com/numbers, these persuasive figures show what Syntegon is all about. The next highlight on the agenda is the Düsseldorf interpack trade fair, where the company will present its fresh, new brand identity to customers in May 2020.



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(Photo: Helmar Lünig, shutterstock.com/Haywiremedia, Harro Höfliger, Andreas Dalferth, Jan Seidl)

Scale-up for increased reliability

With the expansion of cleanroom facilities and a state-of-the-art laboratory, Harro Höfliger is further increasing its testing capabilities for customers. New possibilities for product analysis and safety precautions help to minimize risks for customers, but also for employees. Four employees talk about the possibilities, benefits and opportunities this expansion offers.

When almost 20 years ago, the pharmacist Dr. Karlheinz Seyfang founded the Pharma Services department at Harro Höfliger and set up the first cleanrooms, he made the company a pioneer among machine manufacturers. Since then, this area has seen continuous growth and has become an integral part of the ALL YOU NEED service idea. When purchasing machines and developing processes, risk minimization is a top priority. With the range of services offered by the Process Services Division, Harro Höfliger guides customers every step of the way from the initial idea to production. The expansion of the cleanrooms and the new laboratory were imperative in order to further increase this service portfolio. The expansion is part of the ongoing commitment to improvements that motivates Harro Höfliger: Providing more service to our customers, the best possible protection for our employees and the environment, plus the opportunity to continuously optimize our machines.

We started to plan the expansion of our four cleanrooms three years ago. It was already clear at that time that we were reaching our limits with the available capacities. During factory acceptance tests (FAT), for example, a room may be occupied by a machine for up to several weeks. In addition, many of our customers wish to outsource trials because they do not have the necessary facilities in-house. Therefore, the decision to expand our capacities was made quickly. We now have a total of ten cleanrooms with a total area of more than 500 square meters, and an additional 60 square meters of laboratory

space available. The largest room measures about 10 x 5 meters. Three of the cleanrooms are defined as High Potent areas. An additional air lock with an air shower makes it possible to work safely with highly potent active substances up to OEB 5. Four of the ten cleanrooms can be operated at a relative humidity of ten percent using additional dryers. A ring line supplies all cleanrooms with demineralized water. The air humidity, the air flow and the temperature can be controlled in every room as required. The measured values are shown on a display and saved for monitoring. In order to protect the environment, we not only filter the exhaust air, but also separate the wastewater: Contaminated water is channeled into a special tank for incineration by a disposal company. However, protecting our employees and customers was also very important to us: The air shower, lowerable door seals and a slight negative pressure in all rooms prevent contamination of the surrounding areas when processing active substances in the cleanrooms. Special air extraction systems at the laboratory workstations also ensure a more comfortable work environment.

Most employees in Pharma Services come from the pharmaceutical industry. We know our customers, speak their language and understand what they need. These are important prerequisites for exchanging ideas in a true spirit of partnership. Our customers already benefit from the fact that we work with a wide range of products and formulations every day. Based on the experience of each individual employee, we have an eye for what will work and what could cause

Scale-up for increased reliability

problems. This enables us to provide customers with concrete solutions, such as a specific dosing system for their products, while always keeping in mind a possible scale-up. The dialogue between Pharma Services, the Design Department and the customer is the recipe for success when it comes to machines that are optimally tailored to the product. Thanks to the increased opportunities offered by the new cleanrooms and laboratory space, we can develop and verify filling processes in close cooperation with our colleagues in machine development. At a very early stage we can ensure a reliable reproducible product quality across all scale-up steps and thus, every now and then, we can contribute to accelerating product approval together with the customer. By using the Design of Experiment (DoE) methodology, we perform experiments, for example, with different machine speeds and variable filter inserts, and create a process window with parameters that work reliably.

Just two years ago, we restricted our approach to purely physical measurement methods. Now we can perform a much wider range of analytical tests. With the new particle measuring systems, ultra-fine particles can be measured, which could influence the later processing of a product. New are our capabilities in the wet-chemical field: By using high-performance liquid chromatography (HPLC), we can determine if and to what extent active agent particles accumulate on machine surfaces. We aim to ensure, for example, that no uncontrolled loss of active ingredients occurs during filling processes. By measuring the uniformity of the mixture content, we test how a product



The air shower provides a safe working environment when handling highly potent substances. (Photo: Helmar Lünig, shutterstock.com/Haywiremedia, Harro Höfliger, Andreas Dalferth, Jan Seidl)



Extensive analytical tests can be carried out with the aid of modern measuring systems. (Photo: Helmar Lünig, shutterstock.com/Haywiremedia, Harro Höfliger, Andreas Dalferth, Jan Seidl)

behaves under different manufacturing conditions and whether this might influence the filling properties. For inhalation, we now have the New Generation Impactor (NGI), a kind of lung filtration simulation. The NGI gives us the possibility to determine the fine particle fraction (FPF) or the fine particle dose (FPD). This analytical option is one of the most complex I know of. Now we have much better overall control of the filling process. We can analyze the CPP (Critical Process Parameters), the CMA (Critical Material Attributes) and other similar relevant information for our customers, or perform data queries directly via our already extensive product database. All this offers the best prerequisites for providing our machine designers and developers with the solid data they need for the targeted, rapid and successful design of a machine or for improving existing ones.

Our customers usually have certain ideas about the type of dosing system they want their product to be processed or filled with. With the help of the analytical facilities in our laboratory, we can determine at a very early stage whether these ideas indeed can be implemented or if we need to influence machine development with insights gained from previous research. Due to the regulatory requirements in the pharmaceutical industry, modifications to the machine or the product after approval are very costly and time-consuming. Therefore, certainty about the functionality of the process at an early stage is particularly valuable. As process managers, we work hand in hand with our laboratory team and the design department to meet the customer's specific product requirements. We never cease to welcome these insights as a part of our ongoing internal development. With the help of our new cleanrooms, we have the unique opportunity to recreate the product conditions found on the customer's premises, to better understand potential issues and to find suitable process solutions. By simulating the real conditions, the complex test program for qualification and validation of new machines can be scaled back, or tests for parameter setups or for special solutions can be transferred to HH, for which the customer preferably provides active pharmaceutical ingredients (API) or a placebo. Training and production support at the customer's site can also reduce the costly and time-consuming start-up phase of the machine.

This article was first published in the HARRO magazine 08-2019.

Harro Höfliger Verpackungsmaschinen GmbH
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The largest cleanroom measures 10 x 5 meters and offers space for entire machines (Photo: Helmar Lünig, shutterstock.com/Haywiremedia, Harro Höfliger, Andreas Dalferth, Jan Seidl)

Pfeiffer Vacuum supplies leak detectors for the world's largest and most powerful particle accelerator

- Long-standing relationship between CERN and Pfeiffer Vacuum
- Vacuum technology for probing the fundamental structure of the universe
- Helium leak detector ASM 340 for the Large Hadron Collider

Pfeiffer Vacuum has received yet another major order for leak detectors from CERN. CERN is seated in Geneva on the Franco-Swiss border and is the largest center for particle physics research in the world. Its main business is fundamental physics – finding out what the universe is made of and researching the basic constituents of matter. The particle accelerator LHC (Large Hadron Collider) has a circumference of some 27 kilometers and collides proton or ion beams at nearly the speed of light. The LHC is the largest vacuum installation on Earth with thousands of welds, flanges, feedthroughs and complex internal circuits.

For the accelerated particles to travel in beam lines, ultra-high vacuum (UHV) is essential.

To maintain such a very low pressure it is crucial to keep the leak rates as low as possible. The most advanced leak detector technology from Pfeiffer Vacuum has been chosen by CERN. Andreas Schopphoff, Head of R&D Market Segment: "The cooperation between CERN and Pfeiffer Vacuum is based on many years of working together in a spirit of trust. We are very proud that our advanced leak detection technology has been chosen once again for its future projects."

The leak detector ASM 340 is an easy to operate device that can detect leaks down to $< 5 \times 10^{-13}$ Pa m³/s. With a built in backing pump of 15 m³/h small as well as big volumes can be leak tested. The patent pending functionality makes it possible to start at 100 hPa which can be very convenient for such a big installation like the LHC.

Furthermore, the leak detector is so compact that it can be easily maneuvered underneath the cryostats and beam lines of the LHC. Nowadays helium leak detectors are based on a patented design from Dr. Becker at Pfeiffer Vacuum who proposed to use a turbopump as a kind of filter and safety element in front of a mass spectrometer. At the time, CERN was one of the first customers to buy this innovative technology and has continued to be a major user of Pfeiffer Vacuum products to this day. Generating the vacuum inside the LHC, measuring it and analyzing the partial pressure requires comprehensive vacuum technology, a major part of which is being supplied by Pfeiffer Vacuum.

CERN was founded in 1954 and now employs around 2500 staff and hosts more than 10,000 visiting scientists from all over the world.





You can now walk straight from the type II glass production line into the cleanroom.

Type II glass injection and infusion bottles for parenteral applications

Gerresheimer Essen: new Center of Excellence for making type II glass

As a leading provider of specialty pharmaceutical packaging, Gerresheimer also specializes in manufacturing pharmaceutical containers made from type II glass. Two hardening and tempering methods allow extremely small injection bottles as well as typical infusion bottles with larger volumes to be produced. Guaranteeing the quality and hydrolytic resistance of the type II glass is the top priority here. The company is defending its leading position by introducing innovative furnace technology, expanding its cleanroom, and introducing automation and digitalization to its testing and packing lines.

“Our customers want safe, flawless products from us. So, we need to make sure that we have the best possible production process, even before hardening and tempering the inside of the type II glass, by monitoring the situation constantly and intervening where required,” says Silvio Carriço, Senior Product Manager Pharma, Food, & Beverage.

Center of Excellence specializing in making type II glass

For many years now, Gerresheimer has produced pharmaceutical bottles made from type II glass for drugs administered parenterally by injection or infusion. After overhauling and upgrading its clear-glass furnace in Essen, two new production lines were opened that will mainly be used to make type II glass and link directly to the newly expanded cleanroom. As a Center of Excellence for type II glass for the whole of the Gerresheimer Group, the site will focus on further increasing its capacity and expertise, supplemented by sizable investment in state-of-the-art self-learning testing lines, among other things. Gerresheimer is thus reinforcing its position as an innovative provider of parenteral solutions.

Type II glass – perfect for parenteral applications

Type II glass is a form of soda-lime glass, also called soda-lime-silica glass, by far the most common kind produced industrially. As the name suggests, its main ingredients besides sand are soda (sodium carbonate) and lime (calcium oxide). Type II glass is subject to a special

surface treatment process known as interior hardening and tempering that makes its surface less prone to leaching caused by alkaline solutions. It is the best option for most parenteral drugs.

Interior hardening and tempering as a finishing process

Primary packaging made from moulded glass has always been the go-to container for liquid and solid drugs. Type II glass is soda-lime glass that has been subject to a special finishing method known as interior hardening and tempering, which significantly increases its hydrolytic resistance. Primary packaging for applications of this kind thus has to fulfill especially tough requirements in terms of the glass and how it is hardened and tempered.

Prevention is better than cure

At Gerresheimer, the emphasis is on preventing errors – rather than picking up on them later. The specific requirements are taken into account at an early stage, right when the glass is melted. Special materials are used for this process, such as fused-cast alumina blocks. Among other things, these ensure that the stringent quality requirements made of the glass can be met reliably. The automated monitoring of drop formation and insertion into the tool close the loop, ensuring end-to-end control of the glassmaking process.

Arburg: New Managing Director Technology & Engineering

- Guido Frohnhaus to take over as Managing Director Technology & Engineering at Arburg from January 2020
- Mechanical engineer with many years of experience in industrial automation
- Family-owned company with strong senior management team

At the start of the year, Guido Frohnhaus has taken over as Managing Director Technology & Engineering at Arburg GmbH + Co KG in Lossburg. The 50-year-old engineer's remit includes the Production, Research & Development, Materials Administration and Technical Administration departments.

Guido Frohnhaus brings the ideal qualities to his role as Managing Director Techno-



Guido Frohnhaus is the new Managing Director Technology & Engineering at Arburg. (Photo: ARBURG)

logy & Engineering at Arburg. For many years, he was employed at the Turck Group, one of the leading groups of companies in the industrial automation sector.

As a Managing Director at Werner Turck GmbH & Co. KG in Halver, Mr Frohnhaus was responsible for the Development and Production departments. Prior to this, he spent around five years as Vice President of Technology at the Turck national subsidiary in the USA as well as several years working in management roles at an automotive supplier.

Technology and management expertise

Guido Frohnhaus began his career by completing an apprenticeship as a toolmaker. He then went on to study mechanical engineering, specialising in manufacturing engineering, at the University of Wuppertal. While working in the USA, he also obtained a Master of Business Administration (MBA) from Capella University in Minneapolis, Minnesota, USA.

ARBURG GmbH + Co KG
D 72290 Loßburg

Röchling Strengthens Medical Division

Mannheim-based plastics expert Röchling restructures its Medical division: On 1 January 2020, Dr. Boris Fröhlich will take over the position of CEO in the Medical division from Prof. Hanns-Peter Knaebel, who will in the future be responsible for the Automotive and Medical divisions on the Group Executive Board in addition to his role as CEO of the Röchling Group. Boris Fröhlich will also be responsible for marketing and sales in Röchling's smallest division as Chief Sales Officer.

He will be supported by Evelyn Thome, who will take on the role of CFO of Röchling Medical alongside her position as CFO of the



Boris Fröhlich

Röchling Group. Knaebel will take over as Chairman of Röchling Medical's Supervisory Board: "Boris Fröhlich and Evelyn Thome are an excellent choice for Röchling Medical's Executive Board. I will continue to strongly support the Board in my new role," he said.

Boris Fröhlich moved to Röchling from the pharmaceutical and medical technology company B. Braun Melsungen AG, where he was Managing Director of B. Braun Deutschland GmbH & Co. KG and Senior Vice President of Marketing and Sales Germany. He also worked as a project manager for the spin-off of B. Braun Deutschland GmbH & Co. KG.

The 51-year-old studied medicine in Heidelberg. Fröhlich then worked in the Salem hospital in Heidelberg and, from 2001 to 2008, in the hospital for general, gastro-intestinal and transplant surgery at the Heidelberg University Hospital. As well as being chief physician, he was also awarded his doctorate there in 2007.

In 2009, he joined the medical technology company Aesculap in Tuttlingen where Fröhlich worked in various roles until 2016, the last of which were that of Vice President of Global Marketing Indication Management Neuro and Cardiothoracic Surgery and Head

of Marketing Expert Management. He switched to the Aesculap parent company B. Braun Melsungen AG in 2016. Boris Fröhlich graduated with a Master's degree in business administration medical devices and health-care management from Furtwangen University in 2013.

"Boris Fröhlich joined our team as an exceptionally experienced manager from the medical technology industry. I have known him personally for over 20 years and have worked with him for many years. His expertise, personality and creativity will help keep us on the path to success," said Knaebel.

Following the restructuring of Röchling Medical, Knaebel will officially be appointed CEO of Röchling Automotive on 1 January 2020, a position that he has already held on a temporary basis for the last few months. "We have introduced many changes at Röchling Automotive in the last six months, which we have pooled in part in the structural project DRIVING FUTURE. It is important to me that we support this process with the Executive Board of Röchling Automotive SE," said Knaebel.

Röchling SE & Co. KG D 68165 Mannheim

analytica 2020

New instruments for battery research



- The world's leading trade fair as a driving force for global cooperation
- Modern analysis indispensable for battery research
- All leading instrument manufacturers represented at analytica

Researchers all over the world are working on powerful batteries for the energy revolution. Modern analysis technology is indispensable for this. Analytica therefore focuses on new devices and methods for battery re-search. The world's leading trade fair for laboratory technology, analysis and biotechnology with accompanying analytica conference will take place from March 31 to April 03, 2020, on the fairgrounds of Messe München.

31st March - 03rd April 2020: analytica 2020, Munich (D)

Lithium-ion batteries are used in electric cars, smartphones and many other mobile devices. Nevertheless, they have various disadvantages – from questionable ingredients such as cobalt to flammability and self-discharge. Researchers around the world are therefore working to optimize lithium-ion batteries, or to develop alternatives such as sodium ion batteries. For this, they need the latest analytical methods.

"Many equipment manufacturers have recognized the urgency in battery and power research and specified their systems accordingly," explains Susanne Grödl, Exhibition Director analytica at Messe München. analytica presents the entire gamut of analysis systems that contribute to further development of storage technology for electric energy. The recently published "Trend Report Battery and E-Mobility" also provides information on highlights from battery research.

Technologies for better batteries

Anyone who wants to develop better batteries must understand the processes inside the cell. For example, the ageing of the electrolyte, that conductive medium between the two electrodes, is crucial for the safety, service life and performance of a battery. In particular, spectroscopic methods and the coupling of chromatography and mass

spectrometry are being used by researchers to investigate which undesirable substances are produced during electrolyte ageing. Based on this knowledge, more stable electrolytes and new electrolyte additives are developed.

The electrodes likewise change over time. In lithium-ion batteries, for example, branch-like lithium protrusions, so-called dendrites, can form on the negative electrode. They are considered to be a causative factor of internal short circuits and battery fires. Microscopy methods – from light microscopy to extremely high-resolution atomic force microscopy – make dendrites visible and provide information for the development of safe batteries. Surface-sensitive techniques such as ATR-FTIR spectroscopy and Raman imaging also identify alterations and deposits on the electrodes.

In addition, battery research needs devices for determination of physical parameters. Surface measuring instruments, for example, support electrode design, because large electrode surfaces increase battery capacity and allow rapid charging. Calorimeters, in turn, can be used to investigate the heat emission of batteries, which is related to self-discharge.

Instruments for battery research at analytica

At analytica, interested parties can find out which analysis method is best suited to a specific problem. Instruments for battery research are offered by Bruker, Metrohm, Thermo Fisher Scientific, Shimadzu and many other exhibitors.

"Battery research is innovative cutting-edge research that requires cutting-edge analysis systems," emphasizes analytica's Exhibition Director Grödl. In order to ensure that new instruments meet the high requirements, in the development of many instruments manufacturers and users collaborate closely. Grödl emphasizes: "Analytica sees itself as a driving force behind such cooperations. We are therefore delighted that all leading suppliers of analysis systems will be presenting their innovations at analytica."



Arburg at Plastec West 2020

Focus on automation and digitalisation



- Turnkey: Electric Allrounder turnkey system 470 A manufactures medical technology product
- arburgXworld: New customer portal available internationally
- LSR processing: Complex partner applications

Electric high-end technology, automation and digitalisation: These will be the key topics presented by Arburg at Plastec West 2020 in Anaheim, California/USA, from 11 to 13 February 2020. At the Arburg booth 3928, an electric Allrounder 470 A with a Multilift Select Cartesian robot will demonstrate efficient production of precision parts for medical technology. Visitors will also be able to experience the new „arburgXworld“ customer portal. Another two electrical Alldrive machines with LSR applications will be on show at partner booths.

11th - 13th February 2020: PLASTEK WEST, Anaheim, CA (USA)



Friedrich Kanz, Managing Director of Arburg Inc., sees great demand in the U.S. for electric Allrounder and turnkey systems. (Photo: ARBURG)

„Our customers in the U.S. are very interested in electric machines and automation solutions. And our digital products and services are also becoming more and more important,“ says Friedrich Kanz, Managing Director of Arburg Inc. „With fully automated production of pump heads, we will be able to demonstrate our expertise in turnkey solutions at Plastec West. Visitors will also have the option to experience the ‚arburgXworld‘ customer portal live at the trade fair. Anybody interested in LSR processing with Allrounder machines will be able to view complex applications at the booths of our partners Elkem and M.R. Mold & Engineering.“

Alldrive Allrounders manufacture precision parts

An Allrounder 470 A impressively demonstrates the performance of its high-end electric Alldrive series. The exhibit has a clamping force of 1000 kN (110 US-tons) and is equipped with an 8-cavity mould. With a cycle time of around 25 seconds, the machine produces pump heads with a weight of 1.0 grams, which are used in medical technology, for example. Demoulding of the inner core of the complex component occurs via an ejector system with stripper plate, while the side cores are demoulded when opening the mould. The Multilift Select robotic sys-



At Plastec West, an electric Allrounder 470 A produces pump heads for medical technology fully automatically. (Photo: ARBURG)

tem removes the moulded parts and transfers them to a tube system that provides them separately for each cavity.

The electric Allrounder 370 A at the booth of M.R. Mold & Engineering also features an automated system. A Multilift Select robotic system inserts thermoplastic discs in the mould, which are extrusion coated with LSR in a cycle time of around 60 seconds. The Multilift then removes the finished multi-component discs and sets them down onto a conveyor belt.

Elkem also presents another LSR application: An electric Allrounder 370 A with 4-cavity mould produces baby comforters made of LSR in various Shore hardnesses in a cycle time of around 30 seconds.

Customer portal, „arburgXworld“

The new customer portal „arburgXworld“ is available internationally in 18 languages since October 2019. At Plastec West 2020, experts from Arburg will present the portal to interested visitors and show numerous functions that make everyday digital injection moulding easier. The basic version of the portal includes four free apps – Machine Center, Service Center, Shop and Calendar. In addition, there are paid apps that offer considerable added value to users. These include, for example, Self Service for interactive support in the event of a machine malfunction or standstill, Virtual Control for simulating machine control, and the Configuration app that customers can use to configure

and order the new 270 S compact Allrounder online. Arburg summarizes the entire spectrum of digital products and services, which also includes numerous assistance functions, in its „arburgXworld“ program.

Arburg USA – turnkey expertise and comprehensive consulting

The Arburg USA team currently has about 100 employees at three Technology Center: Rocky Hill (Connecticut), Elgin (Illinois) and Irvine (California). Half of them are active in after sales, including field service, customer hotline and spare parts business. Around 15 employees advise customers in the fields of application technology, automation and turnkey solutions. The rest of the team are responsible for sales, additionally supported by external sales representatives.

The showrooms at the three locations are equipped with numerous Allrounder machines used for training and for trials with customer moulds. In addition, at the headquarters in Rocky Hill, the company configures Allrounder machines according to customer specifications, as well as turnkey systems. For these tasks and to meet high demand, the area of the US headquarters is currently being almost doubled.

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Innovative micro-infusion pump from Gerresheimer subsidiary Sensile Medical for EVER Pharma

Developed specially by Sensile Medical for EVER Pharma under the brand name D-mine®, this wear-able micro-infusion pump has already been launched in several European countries. The compact, patient-friendly infusion pump is used for the continuous subcutaneous administration of drugs to treat Parkinson's disease. The first micro pump from Gerresheimer subsidiary Sensile Medical to be available on the market, it gives Parkinson's patients greater independence in their day-to-day lives.

The D-mine® pump is used to administer apomorphine in the advanced stages of Parkinson's treatment. Simple handling, safety, and ease of use were the main aims behind the development. The compact design is down to Sensile Medical's special micro-rotation pump technology and is straightforward to use thanks to an intuitive menu interface.

Parkinson's patients often have difficulty moving and appreciate the pump's ease of use, such as the automatic dosing function, the lack of complicated flow rate calculations, and the intuitive menu system. Its integ-

rated choice of languages and the full-text display on its color screen make it easier to learn the ropes, while modern technologies such as data storage and individually adjustable basal rates support better treatment management. The D-mine® pump comes with a specially designed charging station and does not need any conventional batteries.

With its brand of the Parkinson's drug apomorphine and its own medical product, EVER Pharma now offers a comprehensive treatment package.



Gerresheimer AG
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Schreiner MediPharm to Showcase New Robust RFID Pharma-Label and Secure Supply Chain Solutions



“Connectivity” and “Integrity of the Supply Chain” are two hot topics of the pharmaceutical industry to be addressed by Schreiner MediPharm at this year’s Pharmapack in Paris. On February 5 and 6, in Hall 7.2 at Booth D46, the pharma label specialist will present a special product innovation: a Robust RFID-Label delivering reliable end-to-end functionality from production to final use. Two other innovative products to be showcased ensure the integrity of primary containers: Cap-Lock for sealing prefilled syringes and Flexi-Cap Prime that irreversibly indicates any tampering attempt on a vial.

05th - 06th February 2020: Pharmapack 2020, Paris (F)

Robust RFID-Label Ensures Reliable Connectivity

Interaction between the user and the pharmaceutical manufacturer, and communication between the product and a medical device: Equipping pharmaceutical products and medical devices with RFID-Labels results in smart devices that help optimize processes and enhance ease and safety of use. Extreme robustness and perfect performance of the RFID-Labels throughout the various processing stages and across the entire supply chain are prerequisites for achieving these objectives. Particularly critical to ensuring robustness is the label’s design.

The new Robust RFID-Label from Schreiner MediPharm consists of a label-integrated RFID tag that is secured by the label’s special construction. Thus, potential damage to the

RFID chip, for instance due to mechanical impact during the manufacturing and handling processes, can be avoided. This guarantees perfect end-to-end performance of the RFID chip from production to final use – especially on round containers with narrow radii. Schreiner MediPharm customizes the label’s design to suit the respective application and pharmaceutical manufacturing process. Thus, pharmaceutical manufacturers are provided with an effective and reliable solution supporting product and patient safety.

Cap-Lock and Flexi-Cap Prime Support Integrity of the Supply Chain

Ever since the EU Falsified Medicines Directive came into effect, tampering with secondary packaging of prescription medicines has been more difficult. However, legislation has not yet resolved the issue of ensuring the integrity of primary containers. With Cap-Lock and Flexi-Cap Prime, Schreiner MediPharm is presenting two security concepts that prevent undetected opening of a primary container and thus ensure its integrity: The

Cap-Lock cap adapter seals prefilled luer-lock syringes and reliably indicates if a syringe has been opened before. The innovative Flexi-Cap Prime cap label makes any attempt of tampering with a vial irreversibly visible.

[Schreiner MediPharm will also take part in the Pharmapack conference program and present the following topics together with its partners:](#)

- A Novel Container Integrity Concept for Vials – Use Cases and Concepts for Machine Processability
Workshop session with Bausch + Ströbel Maschinenfabrik Ilshofen, February 5, 10.00 – 10.40 a.m.
- Pharmaceutical Labeling for Prefilled Syringes – Providing More than just Information
Learning lab with Schott AG, February 6, 3.10 – 3.40 p.m.

Schreiner MediPharm
D 85764 Oberschleissheim



Cap-Lock from Schreiner MediPharm easily, intuitively and safely protects syringes against undetected tampering attempts.



Due to its combined tear strip for the label and cap, the new Flexi-Cap Prime offers even higher safety.



The new Robust RFID-Label from Schreiner MediPharm ensures reliable end-to-end functionality of the RFID chip.

Workshop at Pharmapack

Packaging and administering biologicals safely and securely



Which glass and plastic primary packaging and which administration systems are suitable for newly developed drugs, such as biologicals, and therapies? What do chronically ill patients need to be able to take care of themselves reliably on an ongoing basis? These and many related questions will be answered by Amir Tahric and Dr. Wenzel Novak in their workshop at Pharmapack on February 6 at 10 a.m.

05th - 06th February 2020: Pharmapack 2020, Paris (F)

The pharmaceutical industry is focusing on new therapies. Personalized treatment such as cell therapies, new biomolecules, and drugs for rare diseases are playing a key role in new approaches. This is why smaller batch sizes are often requested for filling. In addition, bottled products are sensitive to their storage environment, the container. Containers therefore need to be individually adapted to the application. The ongoing shift of treatment away from hospital and toward the patient's home relies on user-friendly administration systems like injection pumps.

The aim of the presentation is to provide participants with more up-to-date knowledge about the current state of development

for new drugs and therapies. In the practical part of the workshop, the advantages and disadvantages of existing and new delivery strategies will be evaluated. They will then be aware of the new requirements that can be used to find the best possible solution for new developments in future.

The topics

- Wearables – pumps worn on the body to deliver higher volumes and doses
- Polymer syringes to reduce drug-container interaction
- Silicone-free glass and polymer syringes for sensitive drugs
- Ready-to-fill vials for greater flexibility
- Syringes: integrated safety device for the simple and inexpensive implementation of statutory safety requirements

The speakers

As Senior Global Director Business De-

velopment MDS at Gerresheimer in Bünde, Dr. Wenzel Novak is responsible for business development for glass and plastic packaging such as syringes, bottles, inhalers, and other application systems. He studied biology and gained his doctorate in physics at the Max Planck Institute for Neurochemistry in Munich.

As Vice President Business Development at Sensile Medical AG, a Gerresheimer Group company, Amir Tahric is responsible for communications with the pharmaceutical industry aimed at combining the drug with the device and providing patients with an injection pump that is straightforward to use. He has many years of professional experience in developing and producing sophisticated products for the medical and pharmaceutical sector.

Gerresheimer AG
D 40468 Düsseldorf



automatica 2020

Toward Autonomous Production



automatica is continuing on its growth course. The upcoming trade fair will occupy a record area of 76,000 square meters. There will be an additional hall, more than 900 exhibitors and new highlights. Munich will be the meeting place for the international automation industry from June 16 to 19, 2020.

16th - 19th June 2020: automatica 2020, Munich (D)

Visitors to automatica 2020 will find answers to the questions about how the topics of digital transformation, man and machine as well as artificial intelligence (AI) will affect the manufacturing world of tomorrow. Falk Senger, Managing Director of Messe München, emphasized: "automatica is aimed at companies from all sectors of industry. The range of topics goes far beyond a traditional exhibition. The supporting program provides a unique platform for dialog as well as access to innovations, knowledge and trends with high business relevance." To cover the enormous range, automatica will also occupy Hall C6, which will be called „Future Robotics Hall“ starting from 2020.

Robotics and automation will always be in great demand

The topic of automation plays an important role in the economy as a whole. Patrick Schwarzkopf, Managing Director of VDMA Robotics + Automation, explained: "Robotics and automation is the key technology for increased competitiveness, quality and sustainability. If you want to make the best use of intelligent automation and robotics as well as find out about all new trends, you will find answers at automatica in Munich. It is clearly the leader in this topic area."

Key players and new exhibitors

The continued strong participation of exhibitors shows that automation solutions are in demand more than ever. The presence of important key players, in particular industry leaders in robotics such as ABB, FANUC, KUKA and YASKAWA, confirms the leading trade fair character of automatica. Many new exhibitors are also present, including Basler, Baumer, Hanwah, Nokia Solutions & Networks, Schaeffler Technologies and ZF Friedrichshafen. Demand is particularly strong in



the field of collaborative mobile robotics, to which the "Future Robot Hall" C6 is dedicated. Seven months before the start of the trade fair, the growth in exhibition area from abroad is already 12 percent higher compared to the final result in 2018.

The vision of autonomous production

Topics such as digitalization, big data and artificial intelligence provide enormous opportunities for manufacturing companies. But how can they benefit? To what extent can the factory of the future be automated? Are further steps toward autonomous production possible and sensible? What role will people play in the future? There is no doubt that today's reality is still far from the vision of autonomous production. But the rapid pace of technological progress makes an open dialog on opportunities and prospects urgently necessary, because tomorrow's production is moving away from sequential to matrix production. This requires driverless transport systems to become more flexible, machines to solve complex tasks increasingly autonomously, and software to become even more networked and intelligent. automatica, a meeting place for pioneers, visionaries, entrepreneurs and technology experts, provides the ideal platform for professional exchange and further development of creative ideas for production of the future.

Further expansion: automation & IT

Digital transformation encompasses all areas of the economy and requires new thinking, new alliances, new processes and structures. With the IT2Industry exhibition area with approx. 80 expected exhibitors, the IIoT Forum and the Smart Maintenance Pavilion, automatica spans the spectrum from robotics and automation to information technology and all the way to cloud computing and big data.

VDMA Robotics + Automation will demonstrate a sustainable approach for standardized and vendor-independent data exchange with the OPC UA demonstrator. At the same time, the OPC Day Europe 2020 will again take place within the context of automatica.

NEW: IIoT Conference – powered by automatica and Heise

To bring the production and IT worlds closer to each other, automatica is developing a new format in cooperation with Heise Verlag, one of the leading media houses in the ICT environment. As part of the IIoT Conference, the classic automatica topics will be addressed with IT-related lectures. The goal is to bridge the gap between automation engineers and software developers as well as IT professionals.

Toward Autonomous Production

The offer is aimed at a technical audience from the IT industry and consists of a conference day and a half-day workshop.

NEW: automatica expands the sensor technology area

Relevant data form the basis of technologies such as big data and artificial intelligence. Sensors are becoming an important part of the value chain and consequently for automatica. For the first time at automatica 2020: "The Sensor Show", a component-oriented sensor exhibition area with lecture stages and supporting congress. The aim of the expansion of the trade fair offer is to increase the focus on the already established topic of sensor, test and measurement technology to complete the value chain and cover areas for new visitor target groups. Well-known companies such as the BMW Group, Deloitte, Tesla, Hugo Boss, MTC Aero, Dell EMC, General Motors and TATA Technologies have already confirmed their participation in "The Sensor Show Congress" and the network forums of "The Sensor Show".

Orientation knowledge with high business relevance

With expert forums, international congresses, demo shows and use cases, a service robotics exhibition area as well as „hands-on“ formats such as the planned AI-Lab, automatica provides orientation knowledge and consequently concrete added value for visitors and exhibitors. The trend topics of digital transformation, man and machi-

ne interfaces as well as artificial intelligence will be discussed with experts in all their practical scenarios that can be employed in industry.

The automatica forum provides valuable know-how transfer. The top topics of the lectures: Work 4.0, collaborative robotics in actual practice, mobile robotics in logistics, artificial intelligence in production, and data analytics.

The world's leading robotics conference International Symposium on Robotics (ISR) 2020 will take place from June 17 to 18 within the context of automatica. More than 100 talks will provide insights into „state-of-the-art“ robotics technologies.

Automation for the next generation

The shortage of skilled workers is a central issue in the production world. With several initiatives, automatica aims to draw the attention of the young generation to potential in the automation industry. The highlights: the Start-up Arena, the extended Makeathon contest with up to 250 participants, the new format „VDMA Robotics Challenge“ and other attractive offers for university and high school students. automatica is a door opener! Young people from different age groups will find exciting opportunities for participating and trying things out at the fair as well as solid networking possibilities for professional development.

Messe München GmbH D 81823 München

Microfluidics and bio chips are the centre of attention at COMPAMED 2019



Suppliers prove that they are strong partners in a challenging market environment

16th - 19th November 2020: COMPAMED + MEDICA 2020, Duesseldorf (D)

"Companies showed up at COMPAMED to prove that they are innovative forces to be reckoned with and to demonstrate that they are strong partners for the medical technology industry in this market environment, which is becoming increasingly demanding," observes Wolfram Diener, Operative Managing Director of Messe Düsseldorf. This fixed event, which always takes place alongside MEDICA, the world's biggest medical trade fair that just broke its own record by hosting 5,500 exhibitors, this year's COMPAMED also reached new highs by welcoming almost 800 exhibitors from 41 countries (held from 18 – 21 November 2019). Halls 8a and 8b at the Düsseldorf trade fair centre were fully booked out, confirming COMPAMED's position as an internationally leading supplier platform once more. Once again, essential medical technology trends were reflected along with their relevance for upstream development and manufacturing stages and the supplier's role as an important pace setter for medical advancement was highlighted.

Digitalisation remained a clear trend in the medical technology industry. The digital sphere is indispensable for medical technology devices for mobile diagnostics, therapy and laboratory equipment.

"Microtechnology is the key to digitalisation in medical technology" emphasises Dr. Thomas Dietrich, Executive Director of the IVAM Microtechnology Network. "Wearable and networked devices simply wouldn't exist without miniaturised components and procedures that enable ultra-precise manufacturing to be carried out", he continued. As a result, the demand for miniaturisation of medical components continues to experience rapid growth. This is why most of the 55 exhibitors presenting at the biggest joint stand at COMPAMED, "High-tech for Medical Devices" from the IVAM market place, work in this sector. Focal points for the product market include microfluidics, sensor technology, microelectronics and optic technology. Microfluidics is coming up with exciting new application options at the moment.

A revolution in cell culture

IVAM member Micronit has promised no less than a revolution in cell culture, brought about by its new hybrid systems: A multidisciplinary field has been developed under the "Organ on a chip" concept. Here, human cell biology and microfluidics are merged together on

Microfluidics and bio chips are the centre of attention at COMPAMED 2019

lab-on-a-chip architecture. Organ-on-a-chip devices consist of a microfluidic platform that the user manipulates to tailor-make a highly biomimetic system in an artificial environment. The cell culture chips simulate the physiological reactions of organs. These types of applications are the fastest-growing research areas in the life science and pharmaceutical industries. The relevant devices from Micronit have already been used in many research laboratories all over the world and have proven that they are perfect for creating artificial models in the field, including colon and kidney models. "The systems for these are often constructed using different materials such as glass, silicon and polymers; hybrids such as these are part of our core business skill set", stated Remy Wiertz, Key Account Manager at Micronit.

Biochips can replace animal testing

Organ-on-a-chip systems can also be used to investigate active agents in medicines. Due to ethical, economic and scientific reasons, animal testing experiments are being used less and less. This has been brought about by the increasing use of biochips that are colonised with human cells from different organs and supplied with nutrient fluid via small channels. The circulation system and metabolic functions can be simulated using this technology. The active agents of different medicines, cosmetics or chemicals are added, and the subsequent observations enable conclusions to be drawn on the reactions and processes on and in the human body. A high-precision dosage system based on microsystem technology is required to continuously supply the cells with fluid nutrients. It has to be very precise because even tiny fluctuations can affect the test results. These systems are manufactured by HNP Mikrosysteme under the brand name "LiquiDoS". The systems' cores are formed by a micro annular gear pump which is optimally suited to filling the biochips. "Gradual volumetric flows from 1.5 microlitres per minute up to 72 millilitres per minute and dosing volumes from 0.25 microlitres can be administered with our pump", reports Dr. Dorothee M. Runge, who is responsible for Technical Sales Life Science at HNP.

Tools for isolating cells

A diagnosis of cancer is still terrifying to receive, despite decades

of research effort. Even now, only relatively unspecific and aggressive therapies are available for many cases. Scientists now know that every cancer patient requires a treatment that is tailored to the patient. The option of investigating the cells of a tumour individually in detail is an important step towards providing this. To achieve this, doctors need tools in order to isolate a mass of cells, to separate them from each other so that they are available for further analysis. At the Fraunhofer Institute for Microengineering and Microsystems (IMM), scientists are working hard to develop automated methods for isolating and detecting cells. The fact that objects that are a few micrometres in size, such as cells, can be influenced in a targeted manner through microfluidic flows (flows of very small amounts of liquid through very narrow channels, ranging in size from 10 to 100 micrometres) is exploited here. Based on this, a micro dispensing system was developed. This system can detect a few cells in a mass of cells completely automatically and pick them out, placing each individual cell in a separate well on a microtiter plate to make them available for further analysis. To achieve this, the cells are first coloured with a fluorescent dye, transported through a detection zone in a microfluidic flow, illuminated with a laser and determined using the resulting fluorescent radiation. If a cell is detected as cancerous, it is isolated using a targeted pressure pulse. "CTSelect, our fully automated system for circulating tumour cells, will soon be ready to use in research", promises Dr. Sabine Alebrand, who is responsible for the project at the IMM.

Molecular diagnostics for cells, proteins and DNA

The technology platform SYONIS from Jenoptik also offers completely new options for the life sciences sector. "Depending on how it is configured, our modular system can detect cells, proteins or DNA", explains Dr. Ute Hoffman, the Product Manager for Biophotonics at Jenoptik. SYONIS can easily be integrated into existing instruments or new developments thanks to the combination of partially standardised optic, opto-mechanic and electronic modules which are endowed with high-performance image processing and control software. Jenoptik is a system integrator and adapts its imaging processes to the customer's wishes quickly and at a low price. Productivity in scientific and clinical laboratories can be increased significantly using this method. In addition to live cell imaging, SYONIS also supports flow cytometry and molecular diagnostics. "With SYONIS, we're focusing our many years of expertise in digital imaging on the rapidly growing market of biophotonics", states Dr. Stefan Traeger, Chairman of the Executive Board of Jenoptik.

Pharmaceuticals and medicine: huge markets for packaging

COMPAMED 2019 gave a sneak preview of what's due to appear in the world of medical packaging next spring. At the international exhibition for the packaging industry, interpack in Düsseldorf (7 - 13 May) held once every three years, around a third of the 3000 exhibitors will offer solutions for applications in the pharmaceutical sector. The big stakeholders make sure that they get involved at COMPAMED every year. This is true of MULTIVAC, for example. They have stated that they have the broadest portfolio of packaging solutions on the market. The company presented its comprehensive automation and application expertise in packaging small to medium-sized batches of medical products. Their efficient solutions are perfect for packaging a wide variety of products in different packaging formats. The pride of MULTIVAC's exhibition was a packaging line for packaging sterile



Microfluidics and bio chips are the centre of attention at COMPAMED 2019

medical goods. It is equipped with an automated feed system for loading pre-filled glass or plastic syringes. The core of the line is the R 245 thermoforming packaging machine, which can be configured to suit the consumer's needs. "This solution can package 300 syringes per minute, and achieve much more besides", says Verena Vetter, Product Manager for the Medical & Pharmaceutical Division at MULTIVAC.

For the growing market in intelligent plasters fitted with sensors and wireless technology, Harro Höfliger focused on manufacturing and packaging solutions. "We combine different processes and technology to produce and pack these plasters. In addition to a variety of dosing systems, we are also using microfluidics more", states Dieter Haberzettl, Business Unit Leader for Diagnostics at Höfliger. The production of the functional plaster is executed by web processing machines, which laminate special web materials that contain the electronic sensor chip and its peripherals. Then the plasters are cut or stamped out of the web material in the desired size.

COMPAMED- an eternal success story: Components and drives

Other eternal success stories at COMPAMED include components and drives. MeKo Laser Material Processing, for example, has been producing components with narrow tolerance ranges and perfect surfaces for over 25 years. They have just brought out resorbable materials that dissolve completely in the human body. "This means that we have a material alternative for stents that were previously made from steel and nickel titanium", explains Time Fries, Product Manager and Customer Advisor at MeKo.

Nanotec Electronic, on the other hand, is a leading manufacturer of motors and control systems for high-quality drive solutions. Their diverse portfolio of products also targets laboratory automation and medical technology: "For us, this is the biggest field of application, even bigger than machine engineering", confirms Harald Bär, Sales Engineer at Nanotec. Their portfolio extends from small drives for fine-tuned dosage of small amounts, which run at up to only 5 rpm, to dialysis pumps that provide very consistent delivery to high-speed drives that can provide up to 30,000 rpm.

Exact dosage and bacteria-resistant coating

Dosage technology and coating are two enduring and important topics at COMPAMED. The company Vieweg showcased their special dosing systems and a newly developed micro dosing valve for contactless and jet-forming dosage of liquid media. The tiniest and most precise amounts of liquid (from 5 nanolitres per shot) can be handled with their systems. Their main field of application is the production of medical technology, where the smallest amounts of liquid are needed, e.g. a wide variety of adhesives, solvents or silicones.

Meanwhile, LEONI Special Cables has set its sights on preserving hygiene standards and has developed antimicrobial cables and systems for medical technology, e.g. for devices used on, around and inside the body such as ECG machines, endoscopy and ultrasound systems. These products have a bacteria-killing synthetic surface that is effective against both gram-positive and gram-negative bacteria (including multi-resistant pathogens such as MRSA, VRE and ESBL) as well as viruses and fungi. Even when only a small amount of metal oxide is injected into the coating material, a significant bacteria reduction of over 99.99% is achieved for the surface. The antimicrobial effect remains intact at different usage times and different concentrations, even under normal handling (challenged with sweat and protein). This is a stark contrast to the established silver and copper methods currently on the market.

COMPAMED 2019 and MEDICA 2019, held in parallel, took in a total of 121,000 professional visitors between them. Two-thirds came from abroad, representing some 170 countries.

COMPAMED



Messe Düsseldorf GmbH D 40001 Düsseldorf



Electric, efficient, eSy – valves with new motorized eSy actuators

Ingelfingen-based valve specialist GEMÜ is further expanding its product range of motorized diaphragm, globe and diaphragm globe valves.

For several years now, the processing industry has been increasingly looking for alternatives to pneumatic actuators. Electric valves are an option. These have particular appeal on account of their cost efficiency and performance. The reduced risk of contamination and the application in a wide variety of plants are also positives in favour

of electrically operated valves. The valve manufacturer GEMÜ is responding to these customer requirements by further expanding its selection of motorized valves with the launch of the GEMÜ eSyLite, eSyStep and eSyDrive valves.

A low-cost plastic diaphragm valve for simple and cost-sensitive applications is avail-

able in the form of the GEMÜ R629 eSyLite. It constitutes a cost-effective alternative to solenoid valves made of plastic or motorized plastic ball valves.

The GEMÜ eSyStep valves are designed for standard open/close and simple control applications. With regard to the actuator, this is a compact spindle actuator with step motor. Via the interface in the housing cover, the valve can be extended with additional accessories such as diverse electrical position indicators or travel sensors to provide extra functions. GEMÜ eSyStep valves are available in globe valve, angle seat globe valve and diaphragm valve versions made of metal and plastic but adapting to M-block valves is also possible.

The GEMÜ eSyDrive valves are available for variable and complex open/close and control applications in conjunction with high requirements on performance and service life. The actuator is based on the hollow shaft principle. Both the Ethernet-based eSy-web interface, in conjunction with an integrated web server, and the Modbus-TCP communication interface, enable the exchange of parametrization and diagnostics data and the networking of several devices. If necessary, users can also benefit from a range of integrated functions such as stroke limiters and speed settings.

This provides customers with a wide product range of electric valves both for industrial processes and for applications with particularly high purity and hygiene requirements. With the different GEMÜ eSyLite, eSyStep and eSyDrive ranges, valve solutions are available for every price and function segment.



GEMÜ 543 eSyStep



GEMÜ R629 eSyLite



GEMÜ 649 eSyDrive

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Impressum:

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