NEW BRIGHT SPOTS IN MEDICAL TECHNOLOGY

The new MDR: What you need to know.

An innovative all-rounder for microscopy and endoscopy.

A successful trade fair appearance with WiN network partners.
BRIGHT PROSPECTS

The number of applications for optical processes and technologies in medical technology has been on the rise for years. This trend is expected to intensify in the future since the unique properties of light, combined with other future technologies, will enable a boost in innovation hard to imagine today.

At WILD, we are looking forward to actively participating in this development. Since modern photonic devices are mostly a complex combination of optics, electronics, surface processing, precision mechanics and software, they are perfectly suited for the WILD Group’s core competencies. The group has been a sought-after partner for the development and production of diagnostic devices for ophthalmology, lasers for surgical applications, laboratory equipment for chemical analysis, IVD equipment, lighting sources for surgery microscopes or surgery lights. This issue of PRISMA describes how we support our customers in the entire diversity of these innovative areas.

We also glimpse into the future of photonic applications with the new multi-colour light source for microscopy and endoscopy that is currently being developed by Photonic.

One of the most pressing issues for medical technology manufacturers that cannot be left waiting any longer is the new MDR. Business Developer Wolfgang Stieglmayer explains in an interview how you can make your products fit for the new regulation and why WILD can support you in the process.

Yours Manfred Gallé
Together with three of its WIN network partners, WILD is presenting bundled expertise for photonic applications in medical technology to visitors at COMPAMED 2018.

Medical technology customers are finding it increasingly difficult to keep track of developments and to build up functioning interfaces while, at the same time, maintaining a fast pace. WILD therefore used this year’s COMPAMED as an opportunity to demonstrate how projects can be advanced quickly and safely despite the ever-increasing requirements with the help of well-coordinated partnerships. The systems partner has developed such partnerships within its WILD Integrated Networks, in short WIN, which is comprised of companies such as velixX, INSION and CDE Communications Data Engineering. At COMPAMED, the network partners are also exhibiting together this year. “This makes it easier for interested parties to comprehensively address their tasks in the areas of medical & life sciences and in-vitro diagnostics & analytics person to person and to gain insight into the latest developments in these areas. For every aspect, you can immediately find the right expert”, WILD Group’s CTO Wolfgang Warum explains.

More specifically, velixX can provide advice in connection with the development of device modules or complete systems for in-vitro diagnostics, thereby also contributing a lot of experience in cooperation management and planning. INSION specialises in micro-optics, measurement equipment and spectrometers. Software developer CDE provides information on application software, big data, data mining and predictive analytics. As the central knowledge hub of this network, WILD pools all of these individual skills and guarantees efficient serial production thanks to its extensive production expertise and secure processes. “In addition, in such joint venture projects, we contribute the necessary documents and certificates required for registration and we support the project partners in their communication with the relevant agencies. For our customers, this means that they have a main contact partner to support them in every project phase. There are no interface problems and customers are certain to accomplish the desired project success”, emphasises Manfred Gallé, Head of the Medical Technology Division.

WILD’s main focus at this year’s COMPAMED 2018 (Hall 8a | J19) is “Photonics in Medical Technology”. The company will be focussing on this booming field of application by presenting assemblies and other exhibits and staging several expert talks. In an expert lecture to be delivered at the Suppliers Forum (13 November 2018, from 2.30 to 3.00 pm, Hall 8b | G40), WILD Business Developer Wolfgang Stiegmaier and Dominic Konrad from WIN network partner IQC will be explaining how to implement the MDR most efficiently.

At this year’s MEDICA 2018 (Hall 17 | D20), Photonic will be presenting various light sources and modules for medical technology and surgery lights, as well as its 2-in-1 combolight for the examination and treatment of infant jaundice.
In medical technology, photonics is considered to be a driving force behind innovations and solid growth. The WILD Group demonstrates everything that is possible in fields such as diagnosis, treatment, lighting or analysis and scanning.

After being treated as a niche market for a long time, photonics has developed into a key technology for many industries and an enabler for comprehensive system solutions in recent years. Medical technology, in particular, is benefiting from the unique properties of light. In combination with other future technologies, photonics can bring about a real boost in innovations.

The WILD Group, too, is convinced that light is a true all-rounder. With more than 50 years of experience, the contract developer and manufacturer is a frontrunner in the area of photonic applications and a long-standing partner of several medical technology pioneers. "Photonic and optical technologies have seen an unprecedented pace of development. Metrology components, light sources and optics are becoming ever more compact, cost-effective, as well as smaller and quicker. Their list of applications is growing ever longer. More and more optical measurement methods and treatments in medical technology are contactless and thus significantly more comfortable. Ever more powerful microcontrollers can perform complex measurements using sophisticated algorithms", stresses WILD Group’s CTO Wolfgang Warum.

Scanning and analysing
For instance, WILD is currently manufacturing a tabletop device for chemical analysis using NIR spectroscopy. It is used, among others, in the pharmaceutical industry and can determine the ingredients of both solid and liquid samples within a few seconds. The device stands out through its robustness, precision, high usability and extremely quick measurement times. "The requirements for us are accordingly high. The manufacturing process of various complex components must be very stable.

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Because of the model diversity, a flexible supply chain that allows for quick reaction is necessary”, project manager Josef Kraker explains.

**Diagnosis and treatment**

Photonic GmbH, the lighting specialist within the WILD Group, is currently working on expanding the potential of its “ATO–Light for Life” examination lamps into phototherapy. The result is a two-in-one combination device for the diagnosis and treatment of newborn jaundice. It translates into less stress for the babies, optimises the personnel workflow and saves costs.

A complex system for the control of the ocular fundus, which WILD has been manufacturing for several years on behalf of a renowned producer, delivers proof that examinations using light are quick, contactless and less invasive, while at the same time being highly effective. The device contains lasers with different wavelengths. One of the biggest challenges is to adjust these in relation to each other so as to rule out any mutual interference. “We support our customers in the constant improvement of their serial systems by providing various services such as co-engineering, reengineering and value engineering”, project manager Wolfgang Pischounig explains. “Our FDA-compliant change management system is a significant support in this regard.”

Be it in dermatology, ophthalmology, surgery, endoscopy, laser ENT treatment or photodynamic therapy, the sheer range of applications and particular properties render laser an ideal treatment tool. WILD has extensive experience in all of the aforementioned areas and, among others, manufactures assemblies and devices for ultrashort pulse lasers, femto-second lasers, excimer lasers, Nd:YAG lasers, diode lasers, fibre lasers and CO2 lasers. The assembly and adjustment of such modules requires specialised skills, which WILD combines under one roof. They range from the alignment turning of optics with arcsecond precision to beam shaping and precision mechanics to bespoke cleaning processes. In addition, the systems partner masters all processes which are essential for these products, from fine cleaning and cleanroom assembly to an extremely sophisticated logistics concept, which ensures that no contamination can take place after cleaning. All of the aforementioned applications are also available with LED, a field Photonic GmbH is particularly focused on.

**Lighting**

Photonics is also capable of replacing conventional technologies. Lighting specialist Photonic, for instance, is currently developing a novel multicolour light source for medical and laboratory fluorescence microscopy and endoscopy. To find out more, go to page 7 of this issue.

WILD has also already completed the development of an innovative high-performance xenon light source for surgical microscopes which can be used, for instance, in neurosurgery. Experts from WILD, Photonic and the WIN Partner Network were responsible for the software development and electronics and for thermal and structural simulation and design.

Thanks to the cooperation with the WIN participants, WILD was able to manufacture the first prototype in just 13 months. Production of the high-performance light source began at the WILD factory in Völkermarkt in October 2018.

“Metrology components, light sources and optics are becoming ever more compact, cost-effective, as well as smaller and quicker.”

Wolfgang Warum, CTO WILD Group
The clock is ticking. The objective is to make rational use of the transitional period and develop an efficient implementation strategy. WILD Business Developer Wolfgang Stiegmaier knows a thing or two about how you can manage your MDR.

The short transition period from the MDD to the new MDR is causing a headache for many medical technology companies. What do you believe are the decisive first steps to successfully tackle this challenge?

Wolfgang Stiegmaier, WILD Business Developer: „The new MDR is more extensive and considerably more precise than the MDD was. For many companies, this means they have to react quickly, as they would otherwise be forced to withdraw products currently on the market. This is, for instance, because the requirements for documentation are no longer met or the product falls into a higher class, whereby software especially is affected. Therefore, in order to manage the transition to the MDR, it will be necessary to analyse where the specific discrepancies are for the respective company. An essential first measure would, for example, be certification according to ISO 13485:2016. Those who meet these high requirements are mostly capable of complying with several of the provisions of the MDR.“

How does WILD support its customers in this process?

Stiegmaier: “We are currently developing a comprehensive service package designed to help our customers make their products fit for the MDR. Among others, we prepare the document requirements in accordance with Annex II of the MDR. As a contract manufacturer for medical technology, we also provide support in the risk assessment of production processes and their validation.”

WILD collaborates with the consultancy firm IQC and has recently even expanded cooperation with them. Why did you take this step?

Stiegmaier: “As a partner in the WILD Integrated Networks, IQC AG’s CEO Dominic Konrad has been assisting us in connection with regulatory issues for quite some time, especially with regard to our quality management system. Thanks to the cooperation with IQC, in our new service package we can now offer our customers assistance also in the areas of product development and production.”

INTERNATIONAL QUALITY CONSULTING (IQC)
IQC AG is a globally operating independent consultancy firm offering advice to medical product manufacturers and pharmaceutical companies, as well as to medical technology suppliers and biotechnology companies.

Its highly qualified consultants contribute their years of professional experience from working in leading positions in medical technology and pharmaceutical companies to these projects. This ensures that companies like WILD and their customers can immediately implement the imparted knowledge without discrepancies between theory and practice.
A NEW ALL-ROUNDER.

Photonic is currently developing a novel multi-colour light source for microscopy and endoscopy which promises lower costs and a longer service life. It also delivers more energy in the desired excitation spectrum for fluorescence applications.

In its quest into ever smaller worlds, medicine needs increasingly more efficient tools. As a result, the significance of fluorescence imaging for medical and laboratory diagnostics is growing, especially in the early detection and treatment of tumours. This is due to the fact that, despite the widespread use of imaging technologies such as sonography or MR, surgeons ultimately rely on their trained eye, e.g. when they have to remove cancer foci. Finding the dividing line between a tumour and healthy tissue is a difficult task. This is where fluorescence microscopy and endoscopy can be of great service.

Having a powerful light source is particularly important. The current trend is moving in the direction of LED solutions which allow for a much more economical operation. They require less power and have a significantly longer service life than xenon lamps, which have to be replaced after around 1,000 hours. Photonic is working on a completely new solution in this field, a multi-colour light source. It is based on the F6000-M, currently the brightest endoscopy light source on the market and expands the spectrum beyond the visible range (VIS) and into NIR and UV. To achieve this, the new light optically mixes several LEDs and couples them together again in a light guide. “It uses high-power LEDs, some of which are not yet available on the free market and have been specially developed for our requirements.” Photonic product manager Christoph Csekö emphasises. The optics design required for the mixing of the beam comes from WILD. “Of course, if a customer or an application requires laser instead of LED, we can also offer a solution.”

Multicolour light sources are already available on the market, but they are fitted with expensive xenon lamps or several colour LEDs. Their disadvantage is that there are gaps in the spectrum between these LEDs. Photonic’s new development, however, offers a solution with a continuous white spectrum and additional fluorescence ranges in the UV and NIR spectrum. Its advantage over individual colour LEDs is the continuous Visible Spectrum (VIS) and the extensions beyond VIS, allowing for a more universal use of the module. Compared to xenon light sources, the new light delivers clear economic (no lamp replacement) and ecological (no lamp disposal) advantages. WILD develops the multi-colour light source primarily according to specific customer requirements and integrates it in microscopes or endoscopes as a module.

VISIT US AT MEDICA
For more information on our multi-colour light source, visit our Medica Booth (Hall 17 | D20)
The experts agree: Only those companies that transform their supply chain management now will remain competitive in the future as logistics concepts, combined with new technologies, have an impact on both the speed of processes as well as on their quality and absence of defects. Yet no two companies are the same. Who are, therefore, innovations interesting for? What impact do they have on companies in Carinthia? Erik Wirsing | Schenker AG, Sven Kaulbach | Linde Material Handling, Rene Rossmann and Heinz Brumnik | MAHLE Filtersysteme, as well as Daniel Valtiner | Infineon Technologies gave their answers to these questions and their take on future topics from four different industries at this year’s Logistik-Forum Kärnten.

The lectures were followed by a panel debate on possible applications in practice. The participants discussed how to establish a multi-stage supply chain and effectively procure materials based on consumption.

CEO of the WILD Group, Josef Hackl, contributed his thoughts on the topic of "SCM of complex technological products in small and medium series". „Practice has shown that customer needs are becoming more and more volatile. The information flow between supply chain companies is mostly delayed and is subjectively interpreted. This is precisely where the classical origin of the bullwhip effect lies. To counter this phenomenon, WILD has developed a communication chain based on the principle of vendor-managed inventory (VMI). This principle builds on new SCM processes and digitalisation. The system has been tested and optimised and is now available." The participants in the subsequent workshop dealt with the benefits of such a system and the best ways to apply it.