A series of micro-objectives, specifically designed for the OmniVision CMOS image sensor OV6946, offers new high-precision solutions in the miniaturisation of imaging. The smallest dimensions, paired with brilliant imaging quality, are the prominent features of these objectives. The main fields of application spread from industrial inspection probes and technical imaging sensors, to a wide variety of medical instrument solutions. Typical specifications are:

- 400×400 imaging dots at just 1.75µm pixel size
- FOV up to 140 degrees barrel diameter of 1.5mm by 7mm length
- high resolution over full image size.

The objectives can easily be adjusted to customer specifications in terms of mechanical and optical imaging parameters, such as:

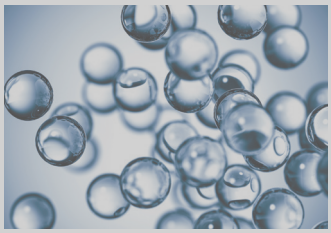
- field of view
- working distance
- direction of view
- depth of field.

Mikrop will support customers with optic design using its in-depth experience and manufacturing know-how, in order to achieve the best possible technology and business solutions.

Further information
Mikrop
www.mikrop.com

Medical-grade custom glass manufacturing

Mo-Sci specialises in manufacturing technical glass materials such as glass powders, microspheres, and ingots specifically designed and manufactured for the medical industry. Mo-Sci materials, like bioactive glass and precision glass microspheres, can be found in numerous medical devices on the market today The company has melting



Mo-Sci produces technical glass materials for medical devices.

capabilities for temperatures up to 1,600°C and quantities from a few kilograms up to several thousand kilograms annually. Its unique in-house capabilities allow it to melt larger quantities in a variety of crucible types. Customers look to Mo-Sci when they need high-purity implant or medica-grade glass materials or custom glass compositions specific to their applications needs. Other service capabilities offered include glass analytics, coatings, spheroidisation and glass development.

Mo-Sci also serves the aerospace, energy, automotive and defence industries among others. MO-SCI is ISO 9001 and AS9100-certified.

Further information
Mo-Sci
www.mo-sci.com

World's smallest linear ball bearing for precise positioning

MPS develops micromechanical systems of the highest quality.

With more than 80 years of experience in the field of high-precision microsystems, MPS Microsystem, based in Switzerland, can offer complete customised solutions, including innovative technologies for micropositioning applications in the medical, optics and research markets.

MPS Microsystems has extended its product range of miniature ball screws, linear ball bearings and electromechanical microsystems with the smallest linear ball bearing in the world.

With an inner diameter of 1.5mm and outer diameter of 3mm, it is fitted with four rows of 20 balls each (0.3mm in diameter) for a total length of 4mm. The Grade 3 balls (the highest quality defined by the ISO 3290/DIN 5401 standard), and high-precision execution of the cage and housing reduce friction and eliminate the stick-slip effect. Special executions with biocompatible materials can also be developed upon request.

Further information
MPS Microsystems
www.mps-microsystems.com

Prepare for the changing European regulatory landscape

The NSAI is helping companies to prepare for the regulatory changes.

In April 2017, the European Commission published two new regulations: Medical Device Regulation 745/2017 (MDR) and In Vitro Diagnostic Regulation 746/2017 (IVDR), which will replace the existing Medical Device Directive, Active Implantable Medical Device Directive and In Vitro Diagnostic Directive. One of the driving factors behind the revision was the need for increased supervision of notified bodies by competent authorities.

It is important that manufacturers of medical devices give appropriate attention to the requirements that are being placed on notified bodies. The additional competency and organisational requirements are having an impact on the resource capacity of notified bodies. This, in turn, will affect manufacturers in terms of audit scheduling and lead times for product submissions with their respective notified bodies.

The National Standards Authority of Ireland (NSAI), and the wider notified body community, is responding by increasing resources and communication with clients regarding the potential for extended lead times. Manufacturers should maintain clear and frequent communication with their notified body.

Aside from the effect on notified bodies, other key impacts of the new regulations include technical documentation updates; increased post-market surveillance requirements, including a more formal system for reporting and reviewing post-market data; and the potential for increased clinical data requirements to support the performance and safety claims made by the manufacturer.

The above changes are certainly posing a challenge to the industry; however, there are several positive aspects to the new regulations. There will be more consistency in the approach of notified bodies to conformity assessments; also, the clearer and more prescriptive requirements of the MDR and IVDR should result in an improved quality of technical documentation. It is our hope that these changes will continue to improve the safety of medical devices in Europe and, therefore, continue to improve the quality of life of those receiving them.

Overall, it cannot be underestimated how important it will be for industry and notified bodies to communicate clearly, this will, along with significant hard work from all parties, ensure a smooth