# Press release

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**As the general contractor, Weiss Klimatechnik provides turn-key clean room technology to modernise HumanOptics AG’s production.**

**Manufacturing implants for eyes is an extremely sensitive sector. The smallest contamination could cause major damage. Therefore implants are produced in clean room conditions. In order to modernise the existing clean room technology and to create more production capacity, HumanOptics commissioned Weiss Klimatechnik to plan, construct and qualify a new clean room complex. All construction work had to be carried out during ongoing production while strictly observing the EU GMP guideline.**

**Quality requirements in the growth market**

Based in Erlangen, HumanOptics is a leading innovator and premium provider in the intraocular implant sector and serves a fast-growing market. The product range includes high-quality and series-produced standard intraocular lenses as well as products customised to individual requirements in ophthalmic surgery. All solutions are developed and produced at the sites in Erlangen and Sankt Augustin. To avoid damage to products and to protect patients, particularly strict quality requirements apply at HumanOptics for every stage of work. These requirements include production in GMP-compliant clean room conditions.

**Modernisation and expansion during ongoing production**

In view of the positive market development, HumanOptics wanted to comprehensively modernise the production area at the Sankt Augustin site and expand to a total of 700 m² GMP-compliant clean room area in accordance with guidelines C and D. HumanOptics site manager, Mario Sündermann explained, “We want to continue to grow and tap into new markets. At the same time, we are striving for a new level of quality in our production process.” At the same time, a declared aim was also to gain the FDA certification for the American market. A particular challenge was that all construction work had to be planned and implemented in such a way that ongoing production was not impeded.

**Experienced partner for production conditions in the medical technology sector**

The specialist, Weiss Klimatechnik, was commissioned to plan, construct and qualify the clean room. It had to ensure that production could continue without interruption. Furthermore, it had to take into consideration two system areas that operate differently. A customised solution with its own chiller in split design, coordinated filter fan units and a special building automisation was developed to make this possible. The air-conditioning systems were designed as mixed air systems with outdoor air and recirculating air content and they ensure the air supply for the new production areas. In doing so, the room air conditions, such as temperature, relative humidity, room pressure and clean room classification, are observed while considering the heat loads.

**Monitoring system monitors and documents critical parameters**

The order also included a monitoring system so that statutory requirements, common industry standards and customer-specific parameters are always observed. A GMP-compliant monitoring system based on the **weiss**technik S!MPATI® software was installed. This guarantees that purity class, temperature, humidity and room pressure always correspond to the statutory quality requirements for production.

**Implementation, results and outlook**

On the basis of the detailed plan, the implementation was carried out in four stages within 10 months. After dismantling the old areas, the new production areas were constructed. Then the air-conditioning system was installed and also qualified by Weiss Klimatechnik. The ongoing production remained undisturbed throughout the whole procedure. The new clean rooms are in operation 24 hours a day, 365 days a year. The air-conditioning system was designed so that an area currently used for storage can easily be converted to a class D clean room at a later date if required. That makes the new site particularly flexible and future-proof.

Site manager Mario Sündermann summarised the project, “Our intention was to work with a competent partner that could provide us with a turn-key solution from a single source and that could also guarantee us after sales service. Weiss Klimatechnik has implemented this excellently.”

**Features of the project:**

- Floor area of 700 m²

- Dismantling old premises in production

- Ongoing production during the construction phase

- Walk-in clean room cabin class: EU GMP – guidelines: C

and D

- Room conditioning 22 °C ± 2K

- Relative humidity 40 – 60 %

- Compact chiller in split design

- Special filter fan units

- Outdoor dehumidification via a second installed refrigerant circuit

in the cabinet-type air-conditioning unit

- Monitoring system S!MPATI® monitor

- GMP qualification (DQ/IQ/OQ)

- Microbiological bacterial count

- Complete EI&C and software development

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Weiss Klimatechnik provides reliable air-conditioning solutions wherever optimal climatic conditions for man and machine are required: in industrial production processes, clean rooms and measuring rooms, hospitals, mobile operation tents or in the information and telecommunication technology fields. As one of the leading providers of professional clean room and air-conditioning systems, we provide you with effective and energy saving solutions, and support you with our expertise from the planning to the implementation of your projects. The Weiss Technik companies are part of the Schunk Group, which is based in Heuchelheim, close to Giessen. www.weiss-technik.com

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