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# Case Study

## weisstechnik implements GMP clean room complex for manufacturer of ocular implants

| WHY | HOW | WHAT |
|---|---|---|
| Clean room new build with production continued<br>Two plant areas | Turnkey solution<br>Air-conditioning technology with particle monitoring and qualification | 700 m² clean room area<br>GMP class C and D<br>FDA certification |

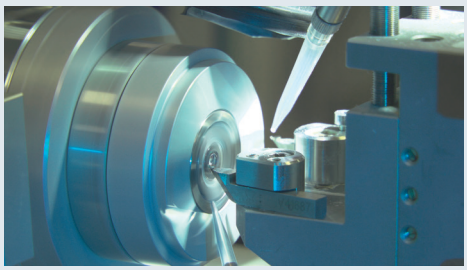
### WHY – The challenge.

The company HumanOptics AG based in Erlangen/Germany is a leading supplier of high-quality, series-produced standard ocular lenses as well as individual customised products. The ocular lenses and implants are produced under GMP-compliant clean room conditions.

In order to increase production capacity, the production space at the Sankt Augustin site is to be completely modernised and extended to 700 sqm. The new clean room complex had to meet the requirements of GMP Classes C and D as well as the FDA directives for the American market.

One special challenge was that production was to continue without interruption during the entire conversion phase. In addition, the plant was to be designed in such a way that two plant areas can be operated independently of each other in terms of climate.

### HOW – The idea.



To ensure trouble-free realisation, a four-stage conversion plan was developed and implemented in only ten months with production running and in close cooperation with the on-site architect's office. During stage 1, the old clean rooms were dismantled, in stage 2 the new production rooms built. Then the air-conditioning technology was installed and qualification carried out (DQ/IQ/OQ).

In order to create two plant areas that can be controlled separately, a customised solution with separate split-design chiller, matching filter fan units and special building automation was developed.

A GMP- and FDA-compliant monitoring system was installed to monitor and document all production parameters.



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### WHAT – The solution.

The air-conditioning system is designed as a mixed air system using both outside and recirculated air. It is centred around reliable Vindur® Compact air-conditioning units.
These condition the clean rooms to 22 °C with a deviation of +/- 2 K.
The relative humidity is 40 – 60 %. The outside air is dehumidified by a second refrigerating circuit installed in the air-conditioning unit.

In order to integrate two differently operating plant areas, a chiller in split design, matching filter fan units, various personnel and material airlocks and a customer-specific building automation system are used.

**Products selected:** Air-conditioning units Vindur® Compact 90.3 CWD and Vindur® Compact 160.3 CWD

The measuring and control technology as well as the software were designed to customer specifications. To secure all climate parameters in a GMP- and FDA-compliant way, a monitoring system was integrated on the basis of the S!MPATI@ monitor software from **weiss**technik. After installation, the clean room complex was qualified by **weiss**technik (DQ/IQ/OQ) and put into service.

### Special technical features

- Dismantling of old rooms in production
- Continuous production during the construction phase
- Compact chiller in split version
- Special filter fan units
- Outside air dehumidification via second chiller installed in the climate chamber unit
- Monitoring system S!MPATI® monitor
- GMP-qualification (DQ/IQ/OQ)
- Complete EMC and software development




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