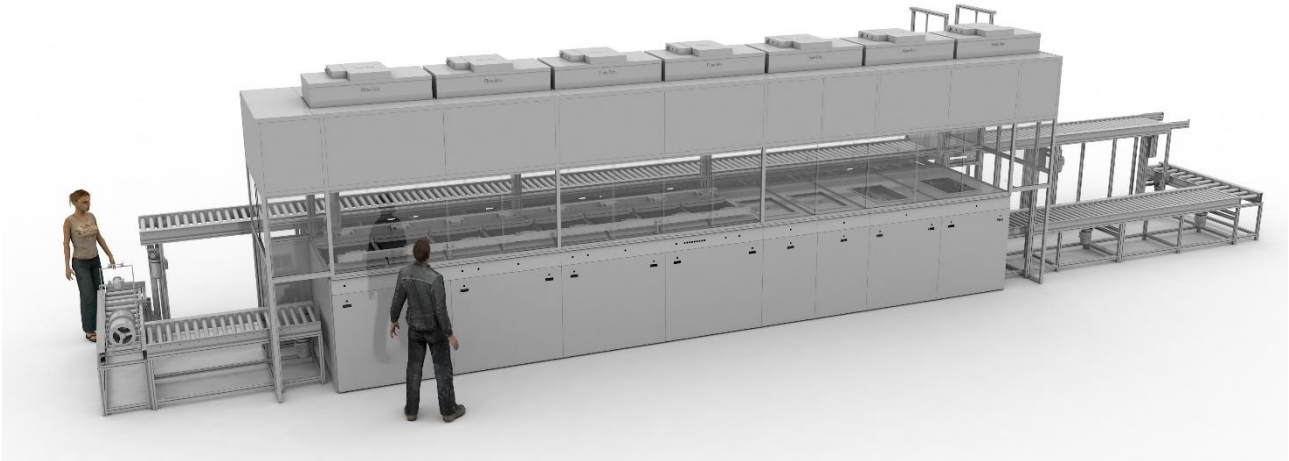
# Cleaning more than a Million Parts per Day to Cleanroom Standards

## Ultrasonic Cleaning System for Medical Equipment Parts

A cleaning process causing no damage to the product while meeting stringent specifications on the removal of particulate, film-type and microbiological contaminants – such was the requirement defined by Lake Region Medical. Addressing these objectives, UCM AG of Switzerland designed an ultrasonic fine-cleaning system providing reliable cleaning of more than a million stainless steel turned parts and tubes per day, six days a week, with products being discharged directly into a GMP Class D cleanroom.



The enclosure comprises integral filter systems to support cleaning under cleanroom conditions.

Lake Region Medical GmbH evolved from the tube making operations of Süddeutsche Feinmechanik GmbH, a company founded in 1953, and emerged in its current form following the amalgamation of Accellent and Lake Region Medical in 2014. Headquartered in Aura/Bavaria, the company has about 270 employees developing and producing high-precision tubes, tube fittings and machined parts made of high-grade steels and special alloys. Around 85% of this output is destined for use in med-tech and pharmaceutical industry products. Other customer groups include the foodstuffs, aerospace and automotive industries.

### Cleaning outsourced by the customer

In 2013, one of the company's customers from the pharmaceutical / med-tech sector identified a need to expand their cleaning capacity for stainless-steel turned parts and tubes. The company resolved to farm out this operation to Lake Region Medical. Under the contract specification, the equipment to be procured for this purpose had to achieve given levels of cleanliness – with limits on particulate, film-type and antimicrobial contaminants – while also ensuring that the parts would emerge from the cleaning process undamaged. A further challenge resided in the product geometry. The turned parts,

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…measuring up to 10 mm in diameter, have very fine drilled holes. The tube parts are up to 60 mm long, with internal diameters of only 0.4 mm, and must be reliably cleaned on the inside as well.

## Cleaning performance, process documentation and validation

Lake Region Medical opted to invest in an ultrasonic fine cleaning system made by Swiss UCM AG, a member of the SBS Ecoclean Group. Its choice was prompted by this supplier's competence and know-how in the design of cleaning systems for medical technology applications. Moreover, this cleaning system ensures that the exacting cleanliness and throughput specifications, as well as the customer's expectations regarding process stability and batch documentation, are reliably fulfilled. 'In generating the extensive and detailed documents needed to qualify and validate the system, UCM gave us much valuable support. Compatibility with existing installations was also achieved, as desired by the customer', notes Klaus Wisnewski, Development Engineer at Lake Region Medical.

The cleaning system comprises a total of 13 stations. All process sequences and parameters as well as equipment functions are automatically monitored, logged and documented on a continuous basis.

## Tailored to ensure high process reliability

The cleaning system comprises 13 stations in total. These are designed for the individual process steps, i.e., loading, cleaning and rinsing with ultrasound, hot air and vacuum drying with infrared support, and unloading. Cleaning and rinsing steps are carried out with fully demineralized water. A demin. water

The cleaned parts exit into a cleanroom through an airlock.

treatment system adapted for this purpose is included in the scope of delivery. In order to accommodate cleaning under cleanroom conditions, the system is fully enclosed and its enclosure is equipped with appropriate filtration systems and pressure monitoring.
The parts are cleaned in bulk or arranged in part carriers, depending on type. The product is manually placed in special drums or baskets which are then automatically fed to the system. 'For part-specific cleaning, we defined various cleaning processes and stored them in the system's controller", Klaus Wisnewski explains. The programs, as well as the part and batch information, are entered via a bar code. The part container type and number are likewise recorded at this stage. All program sequences, process parameters and equipment functions – e.g., condition of cleaning and rinsing fluids, automatic input of cleaning agent, individual timer settings, temperatures, ultrasound frequencies and power – are automatically monitored. Upon completion of each batch the process is analyzed, with assessment of the cleaned parts, via the process data tracking function. Moreover, the data for each batch are recorded and archived as a document to ensure proper traceability of the products. Upon selection of the program the cleaning process is executed fully automatically.

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… The cleaning and rinsing fluids enter the tanks from below, move upwards and then exit by overflow on all sides. Thanks to this four-sided overflow feature developed by UCM, foreign matter removed from the product is discharged from each tank straight away. This avoids re-contamination during unloading of parts while also preventing the formation of dirt deposits in the tanks. In addition, this fluid management ensures a very uniform treatment of bulk products. A further detail enhancing the reliability and safety of the cleaning process are the so-called medicinal tanks and the system's special piping. Both are specially designed to combat germ formation. Moreover, all process areas are automatically sanitized (i.e., disinfected) in their entirety at regular intervals by a program developed specifically for this purpose.

After drying, the parts are conveyed into a GMP Class D cleanroom via an automatic airlock. Inside the cleanroom they are unloaded and packed. A return conveyor system takes the empty part containers and conveying racks back to the loading end.
'The equipment is in operation around the clock, six days a week. We clean more than a million parts per day, and the result meets our exacting demands", Klaus Wisnewski adds in closing. Lake Region Medical's satisfaction is further attested by the fact that the company has already ordered a second system of identical design from UCM.

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