



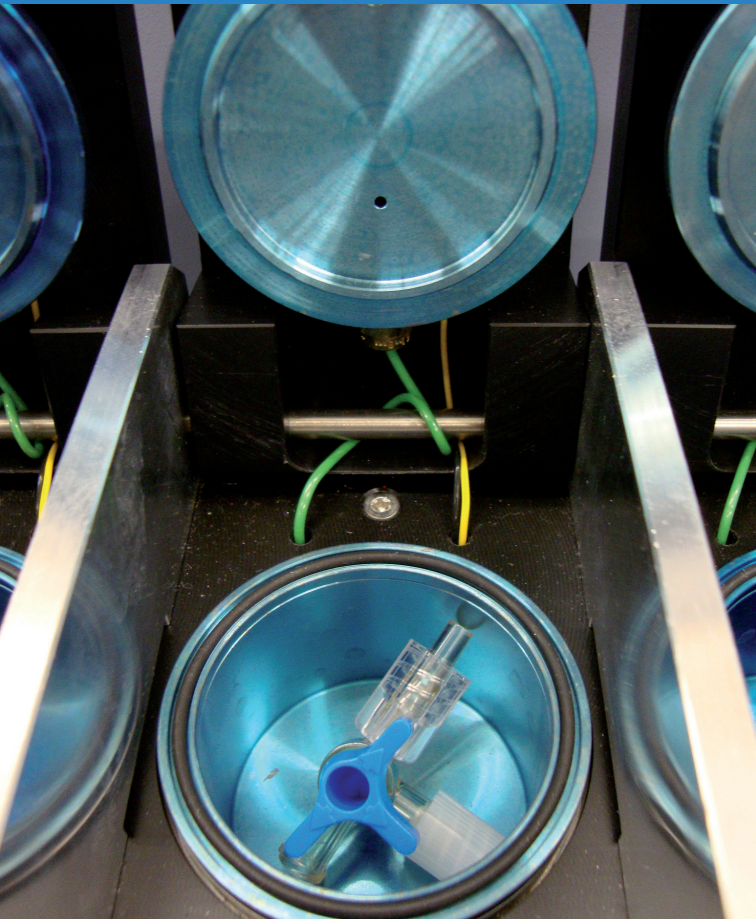
**Fraunhofer**

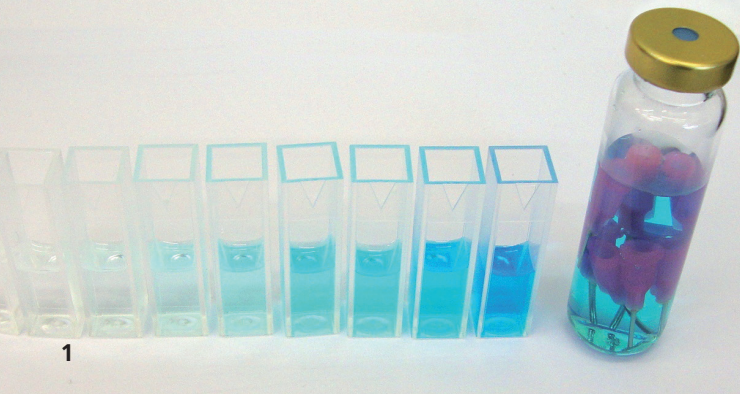
**IPA**

**FRAUNHOFER INSTITUTE FOR**

**MANUFACTURING ENGINEERING AND AUTOMATION IPA**

# **CONTAMINATION CONTROL IN MEDICAL TECHNOLOGY**





In order to reliably exclude as best as possible any risks associated with their usage, numerous medical products have to fulfill strict requirements concerning the absence of critical residues. To characterize processes and products, usually tiny amounts of biotic and/or chemical residues have to be detected using analysis methods when cleanliness is validated. Hardly any discipline in medical technology other than contamination control demands such high levels of knowledge and experience in order to implement optimum testing methods and analysis techniques for a given task.

### **Contamination control / range of tests**

All the cleanliness tests performed here in one of Europe's most renowned laboratories for contamination control are carried out by skilled technicians, biologists and engineers. We test products on the basis of recognized standards using the wide range of state-of-the-art analysis instruments we have at our disposal.

#### *Our services:*

- Fast, reliable cleanliness analyses based on recognized standards
- Characterization of highly-clean components
- Comprehensive particle analysis
- Investigation of organic and ionic residues



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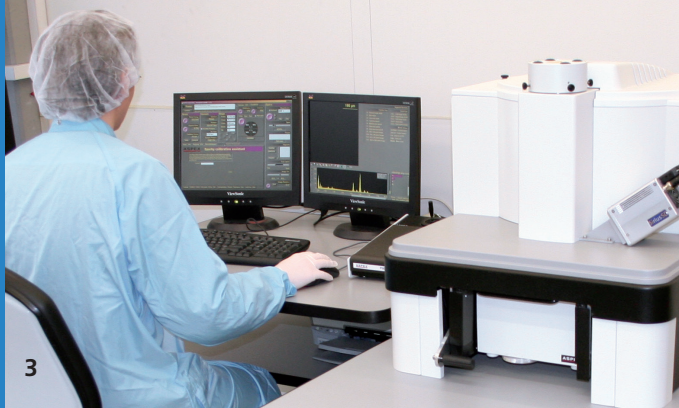
- Evaluation of outgassing behavior and of the ability of materials to resist metabolism
- Sterility tests and determination of microbial contamination in cleaning processes

### Test laboratory / testing technology

Our modern cleanroom and microbiology laboratories and corresponding testing facilities have numerous functions.

*Equipment / analysis technology (extract):*

- Diverse laboratory microscopes measuring 2  $\mu\text{m}$  and upwards
- Measurement technology for particles in liquids down to the submicron range
- Material and particle analysis using SEM/EDX
- Chemical analysis of organic particles with the aid of RAMAN spectroscopy and FTIR spectroscopy
- Gas chromatography-mass spectroscopy GC/MS
- Thermodesorption measurements with TD-GC/MS
- Diverse emission chambers for organic residues
- Chemical oxygen demand (COD) or total organic carbon (TOC) to assess the total amount of organic contamination
- Determination of conductivity to assess the total amount of ionic contamination
- Ion chromatography IC-HPLC



## Our references

To date, in collaboration with leading life science and medical technology companies, numerous contamination control tests have been carried out on medical products. For 30 years, Fraunhofer IPA has concerned itself with cleanliness issues in the semiconductor, automotive, life science, aerospace and medical technology sectors. In diverse committees, Fraunhofer has been primarily responsible for the development of internationally recognized guidelines and standards, such as SEMI, VDI 2083, VDA 19, ISO 14644 and ISO 16232. Hundreds of specialists have since visited our basic seminars, which we hold on our premises in Stuttgart or directly on site at your company if required.

- 1** *Photometric determination of cleaning efficacy using test contamination.*
- 2** *Assessing increases in conductivity as a measure of the cleanliness of a test object.*
- 3** *Particle analysis with SEM/EDX.*



## Further range of services

The department of Ultraclean Technology and Micromanufacturing is a skilled and efficient research and development partner regarding contamination control in the field of medical technology.

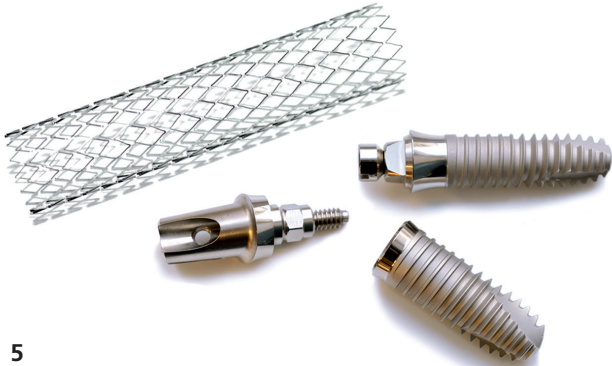
*Some of our services are listed below:*

- Developing, qualifying and monitoring cleaning processes
- Qualifying components, operating utilities and cleanrooms
- Developing production-related testing techniques
- Standardizing testing and qualification methods for products and processes
- Providing advice on the design and optimization of cleanliness-suitable manufacturing processes
- Planning and realizing cleanrooms and clean zones
- Training cleanroom staff

**TITLE** *Sampling organic contamination in an emission chamber.*

**4** *TD-GC/MS for analyzing organic contamination.*

**5** *Medical implants.*



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**Fraunhofer Institute for  
Manufacturing Engineering and Automation IPA**

Nobelstrasse 12

70569 Stuttgart | Germany

**Director**

Prof. Dr.-Ing. Thomas Bauernhansl

**[www.ipa.fraunhofer.de](http://www.ipa.fraunhofer.de)**

If you require more information about our range of services or specific advice, please get in touch with our contact partners.

**Department**

Ultraclean Technology and Micromanufacturing

**Contact**

Dipl.-Biol. (t. o.) Markus Keller

Phone +49 711 970-1560

[markus.keller@ipa.fraunhofer.de](mailto:markus.keller@ipa.fraunhofer.de)

Dipl.-Ing. Christian Ernst

Phone +49 711 970-1248

[christian.ernst@ipa.fraunhofer.de](mailto:christian.ernst@ipa.fraunhofer.de)

**[www.ipa.fraunhofer.de/cleanroom](http://www.ipa.fraunhofer.de/cleanroom)**