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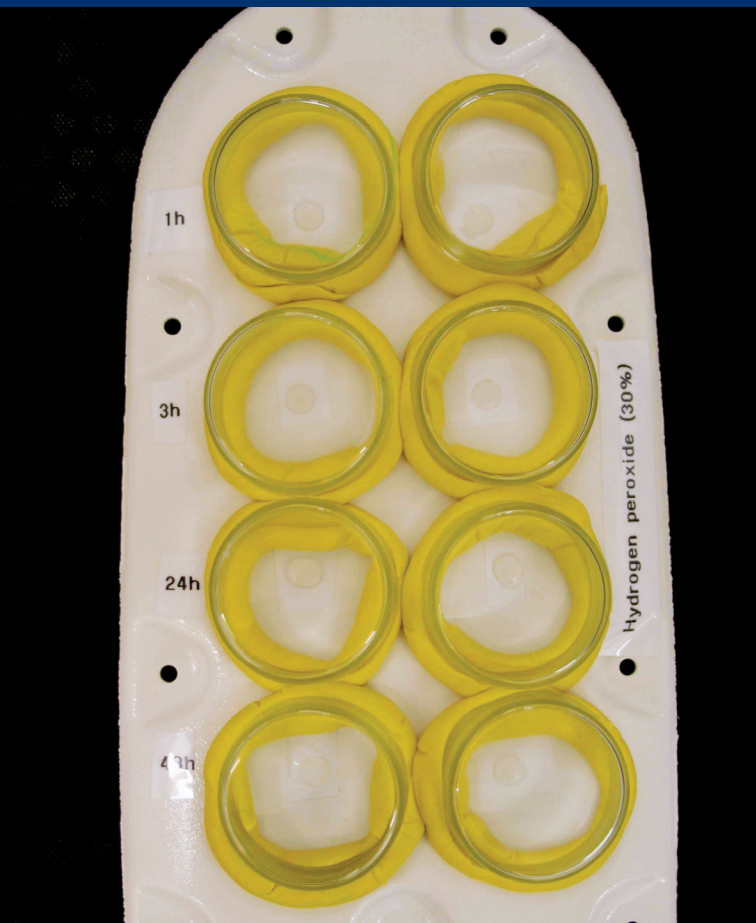
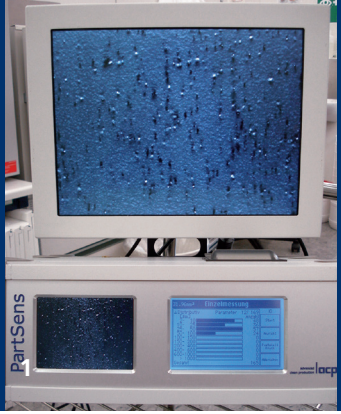
CLEANABILITY AND CHEMICAL RESISTANCE OF OPERATING UTILITY SURFACES





Starting point

When integrating operating utilities into cleanrooms, a whole range of requirements has to be fulfilled. On top of low particle emission and outgassing properties, operating utilities also have to be easy to clean as well as resistant to the cleaning and disinfection reagents used. Especially in clean manufacturing environments where products sensitive to microorganisms are produced, the ability to effectively clean and disinfect the surfaces of all operating utilities is a core GMP requirement.

Cleanability

The aim of this test is to assess how effectively defined concentrations of contamination can be reduced using ultra-pure water or a different user-specific cleaning technique. In the test, the surface of an operating utility is contaminated with a test substance in a defined way and subsequently wiped clean. The relative success of the cleaning method in relation to the initial level of contamination is then ascertained. The reduction in particle concentrations of specific sizes is then correlated with the surface cleanliness classes (SPC) stated in ISO/FDIS 14644-9 and the results documented accordingly.

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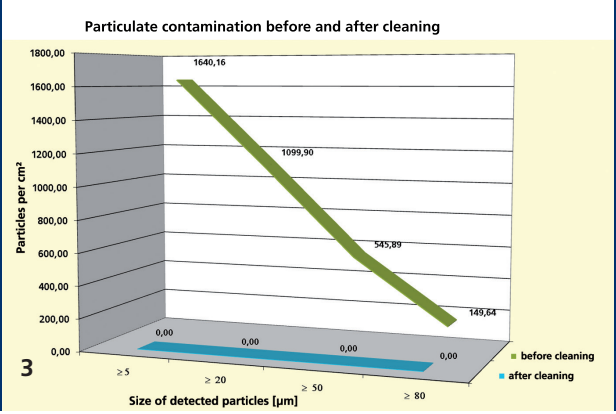
Chemical resistance

Assessing chemical resistance shows to what extent a tested material is suitable for use in a clean manufacturing environment. All materials have to be resistant to cleaning, process and disinfection media. The tests are carried out in compliance with ISO 2812. In the tests, the surfaces under investigation are treated with the respective test reagent and then inspected visually, macroscopically and microscopically at defined points in time in order to detect any possible modifications.

Chemical resistance is assessed conform to ISO 4628-1 on the basis of the surface changes identified. Either the immersion test according to ISO 2812-1 or the spot test according to ISO 2812-4 is performed.



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Areas of application

All operating utilities used in cleanrooms or clean manufacturing areas that regular cleaning and disinfection can be tested, e. g.:

- Cleanroom furniture
- Switching cabinets
- Machines and robots
- Lighting systems
- Wall coverings
- Floor coverings

Additionally, materials used in the manufacture of such operating utilities can also be tested in advance in order to assess their cleanability and resistance to chemicals.

1 *Particle measuring device PartSens.*
2 *Measuring head.*
3 *Cleaning success.*

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Our references

- AMF-Mineralplatten GmbH Betriebs KG
- Geiger Handling AG
- Gerflor Mipolam GmbH
- Odenwald Faserplattenwerk GmbH
- Tyco Electronics idento® GmbH
- Freudenberg Bausysteme KG
- Weiss Klimatechnik
- Glamento GmbH
- edding International GmbH

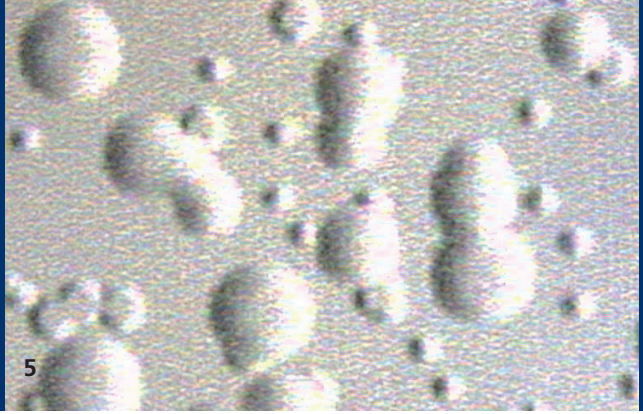
Our range of services

- Assessing cleanability in accordance with the surface cleanliness classes stated in ISO/FDIS 14644-9
- Performing liquid chemical resistance tests according to ISO 2812 and VDA 621
- Determining and classifying chemical resistance in compliance with ISO 4628

TITLE *Spot test according to ISO 2812-4.*

4 *Immersion test according to ISO 2812-1.*

5 *Visible surface changes: blistering.*



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