



### WHITEPAPER MOQLERO GENERATION 9

#### SYSTEM ENVIRONMENT

#### **SERVER**

Cloud-based solution

Microsoft SQL Server

Python report generation

PHP 8.4

#### **NOTEBOOKS**

Windows 11

#### **SECURITY**

#### LOGIN OPTIONS WEB PORTAL

LDAP

Company-internal SSO

#### **ROLE-BASED ACCESS TO WEB PORTAL**

Permissions checked via group memberships for each action/page

#### **ENCRYPTION**

End-to-end communication via SSL/TLS

#### SAP INTERFACE

Authentication and Authorization via x509 certificate and secret

#### SAP INTERFACE

#### **AUTOMATIC DATA TRANSFER**

Automatic order reception and creation from SAP

Automatic transfer of completed orders and results to SAP

#### **SECURITY**

Fully SSL/TLS-encrypted communication

Authentication and authorization via x509 certificate and secret





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#### **WEB PORTAL**

#### **GENERAL**

Measurement protocols/reports

Workorder management

Master data management \*)

Maintenance breaks

Trend analysis

Audit trail

#### **DEVIATION MANAGEMENT**

Automatic notifications

Digital workflows for issue resolution

Electronic signature required for non-conformities

Repeat measurements can be triggered after repairs

Integrated, automatic, and complete documentation

#### **CHANGE MANAGEMENT**

Automatic notifications

Changes must go through a digital workflow

Electronic release of changes only by authorized personnel

Integrated, automatic, and complete documentation

# NOTIFICATIONS / ALARMS

#### **NOTIFICATIONS / ALARMS**

Deviations/Discrepancies, Maintenance Breaks

Pending/started/completed/deleted Workflows or Management Procedures,

Required/pending Signatures

# INTERNATIONAL FEATURES

#### **MULTILANGUAGE**

English, German, Mandarin

#### **TIME ZONES**

All supported, time format local datetimeoffset





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#### **NOTEBOOKS**

## 14 SUPPORTED MEASUREMENT METHODS

#### **AUTOMATED CONTROL OF PARTICLE COUNTERS** \*\*)

Automatic configuration of measurement parameters (e.g., duration)

Automatic start and stop of measurements

Simultaneous control of up to 6 devices

#### **AUTOMATIC READING AND EVALUATION**

Measurement results automatically and error-free transferred to notebook

Automatic evaluation of the results against configured limits

#### SPONTANEOUS / AD-HOC MEASUREMENTS

Measurements can be performed without a work order

Also fully automated (configuration, control, evaluation, etc.)

#### **OVERVIEW, ACTIVITIES, AND N-FINDINGS**

Complete overview of open and measured orders

Guidance, execution, and confirmation of typical activities

N-Findings can be set

# PARTICLE MEASUREMENTS

#### **MEASUREMENT METHODS**

Classification/Monitoring in Operation

Classification/Monitoring at Rest

Zero measurements

Particle measurement in gases

Recovery test (2 options available)

Clean-up Test (EU GMP Annex 1 2022)

#### **ADDITIONAL OPTIONS**

Parallel measurements: Conducting multiple measurements simultaneously

Block measurements: Multiple samples of a measuring point are measured in a block and jointly evaluated as valid/invalid



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#### **TYPES**

Integral filter test

Filter scan test (sequential)

Filter scan test per ISO 14644

Filter scan test per customer SOP

Filter scan test by separation efficiency criteria

#### STATIC RETESTING / LEAK TESTING

Following leak detection in the measurement results

Following failed visual inspection

# LAMINAR FLOW BOXES, EQUIPMENTS

#### **MEASUREMENT METHODS**

Qualification and maintenance measurements

Air velocity measurements

### PHYSICAL ENVIRONMENT MONITORING

#### PHYSICAL PARAMETERS OPTION

Pressure, humidity, temperature

#### **ACTIVITIES**

#### **DOCUMENTED MANUAL INTERVENTIONS**

Covers typical tasks during monitoring or classification (e.g., CG-distributor change)

#### **AIR MEASUREMENTS**

#### **MEASUREMENT METHODS**

Air exchange rate

Airflow volume

**MASTER DATA IMPORT VIA CSV** 





#### **APPENDIX**

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# SUPPORTED PARTICLE COUNTERS

Abakus (Markus Klotz GmbH)

Apex R5p (Lighthouse Worldwide Solutions)

CAS CI-1053 (Climet Instruments Company)

CAS CI500 (Climet Instruments Company)

Lasair II (Particle Measuring Systems)

Lasair III 5100 (Particle Measuring Systems)

Lasair III 310B (Particle Measuring Systems)

Met One 2400 (Beckman Coulter)

Met One 3400 (Beckman Coulter)

PZG 31 (RR Reinraum Elektronik)

Solair 3100 (Lighthouse Worldwide Solutions)

... Any particle counter you use

\*)

# MASTER DATA MANAGEMENT

#### SAP ORDERS

#### **DEVICES**

Particle counters Probes

Pressure sensors Diffusers

Differential pressure sensors Dilution stages

Temperature sensors Vane anemometers

Humidity sensors Hot-wire anemometers

Airflow sensors Balometers

Measurement notebooks Flow measuring devices

#### **MEASUREMENT POINTS**

Particle Activities

Filter Air exchange rate

Physical environment Airflow volume

LF Maintenance

**LOCATIONS** 

Buildings Facilities / Equipment

Rooms Room parts

**ORGANIZATION** 

Departments Standard comments

Users (Maintenance breaks)

**ACCEPTANCE CRITERIA** 

Hygiene zones / Cleanliness classes

Warning limits

Filter classes

Physical environment limits

Clean-up



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